186

Submitter : Mr. Ron Tisdale

Date: 06/20/2005

Organization : Atoka Memorial Hospital

Category : Critical Access Hospital

CAH-Reloc

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

Critical Access Hospital - Proposed rule Comments SEE ATTACHMENT

CMS-1500-P-428-Attach-1.DOC

RON D. TISDALE
Certified Public Accountant

Member of the American Institute of Certified Public Accountants

P.O. BOX 445 205 S. MISSISSIPPI
ATOKA, OKLAHOMA 74525
PHONE 889-3324

Member of the Oklahoma Society of Certified Public Accountants

June 20, 2005

Attachment to #428

To Whom It May Concern:

Comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

I am the Chairman of the Board of Atoka Memorial Hospital. Our community hospital is a 25 bed Critical Access hospital located in rural southeastern Oklahoma. Atoka Memorial Hospital (AMH) was the first hospital in Oklahoma to be certified as a Critical Access Hospital and was certified as a "necessary provider".

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

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 Our 46 year old facility is outdated, inefficient to operate, lacks space for needed services, and hinders our ability to provided quality services.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

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

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

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

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

This is problematic for the following reasons:

It was not the intent of Congress that CMS would prohibit or hinder communities from replacing facilities that provide quality health care to rural America. Many of the small hospitals in the rural United States were financed under the Hill-Burton act and are now forty to fifty years old. These aging facilities are simply not capable of providing high quality, cost efficient service without the Necessary Provider Designation.

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

The CMS proposed regulations reverse a long standing policy. Designation as a CAH necessary provider is associated with its current Medicare provider agreement which should remain intact unless the CAH fundamentally changes its business or is terminated by Medicare for cause. It is a longstanding policy that the provider agreement describes the legal entity and the services provided – not the physical structure or location. It should also be noted that CMS was required to approve each state's plan for designating necessary providers

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

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

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

Sincerely,

Ron D. Tisdale, CPA
Chairman of Board
Atoka Memorial Hospital

187

Submitter : Dr. Gary Mitchell

Date: 06/18/2005

Organization : Newman Memorial Hopsital

Category : Critical Access Hospital

CAH/Reloc

Hefter.
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

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

Reference: CMS-1500-P

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

To Whom It May Concern:

Comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

I am writing as Chief Executive Officer of the Newman Memorial Hospital in Shattuck, OK and on behalf of rural residents of Oklahoma.

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

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

? It was not the intent of Congress that CMS would prohibit or hinder communities from replacing facilities that provide quality health care to rural America.
? The CMS proposed regulations are an over-reach to a potential problem that can be easily managed without placing a ban on all new construction.
? CMS cost estimates in the proposed rule are simply incorrect.
? The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care.
? The CMS proposed ban on construction is based on a bias against cost based reimbursement rather than on any established fact.
? The CMS proposed regulations reverse a long standing policy that the provider agreement describes the legal entity and the services provided not the physical structure or location. And,
? This proposed rule transfers to CMS control over local rural health care never envisioned by Congress.

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

Specifically, I oppose any and all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. The proposed ?75% threshold? is appropriate and sufficient to assure that a replacement or relocated CAH facility continues to meet the intent of its original Necessary Provider designation.

Respectfully,

Gary W Mitchell, D.Ph, CHE
Chief Executive Officer
Newman Memorial Hospital
905 South Main
Shattuck, OK 73858

188

Submitter :

Organization :

Category : **Hospital**

Date: 06/19/2005

Hefter
Hartstein
D. Romano
Treitel

Issue Areas/Comments

GENERAL

GENERAL

see attachment

SpH
MedPAC

CMS-1500-P-411-Attach-1.DOC

Physician-owned Specialty Hospitals FAQ's

In the public policy debate regarding physician-owned Specialty Hospitals, proponents have advanced a number of options to placate regulators and policy makers and avoid the prohibition of physician ownership. The following FAQs deal with these options as well as general questions. In general, the options consist of half measures cosmetic in nature, treating the symptoms rather than the root cause and designed to change the subject and divert attention. **There is only one cure for a material conflict of interest: end it, prohibit it, and make it clear that it is wrong.** Only then can some of the options described below be effective in deterring bad behavior and exposing and prosecuting subsequent violations.

1. Rather than prohibit physician ownership, can't we (as CMS proposes) refine the Medicare payments to "re-level" the paying field?

Answer: There are plenty of good reasons to encourage CMS to find and cure the imperfections in the Medicare payments. Medicare payments have created financial "winners" and "losers" and you always find scam artists gravitating to the winners (recall Home Health in the late '90s). In outpatient surgery, for example, the advent of APCs in 2000 exposed the embarrassing fact that Medicare was paying freestanding ASCs more than Hospitals for a number of ambulatory surgery procedures. The Medicare Modernization Act (MMA) of 2003 required CMS to fix those imperfections. In May of 2005, Dr. McClellan announced, amid great fanfare, that CMS would have this job completed by 2008! Five years to fix nine categories of well-defined procedures whose resource consumption is quite predictable and with very low variation. And will this dissuade the ASC cherry pickers? Not at all because Medicare only accounts for about 20% of outpatient surgery and ASCs cherry pickers are facile at gravitating toward newly created "winners" and dropping newly created "losers" (the losing specialties will bring those cases back to the full service hospitals).

Refining the 500+ Medicare DRGs into many more strata will be a gargantuan task that will take many years and much more clinical information to determine which strata a given case belongs. The resulting system will be more complicated and coding more difficult. The cherry pickers will game this system so as to make the "up-coding" scams of the past seem minor. **The difference this time is that the doctors themselves will have a material steak in the outcome.** The problem is doctor ownership, not Specialty Hospitals. An important part of CMS' coding discipline is that they count on the patient's doctor to scrutinize and verify the Hospital's coding result. But that relied on the doctor's position as "honest broker", that is the doctor has

no payment riding on the Hospital coding. From the standpoint of Internal Control discipline, it is a "separation of duties" issue.
For some doctor-owned Specialty Hospitals', clinical services are not large Medicare "plays" and will not be materially affected (spine surgery, neurosurgery, bariatric/general surgery). Their cherry picking will work fine for the under-65 (non-Medicare) population. But there are major flaws that make the above points inconsequential.

- Father Knows Best: No amount of Medicare billing data will ever come close to matching what the heart surgeon knows about an elective heart patient when the surgeon makes the hospital decision. Co-morbidities may (or may not) be recorded but how severe are they? How much scar tissue is present from the previous surgery? Is this a compliant patient? Has the patient been compliant with the pre-operative preparation therapies? Does the patient have a supportive home situation for pre and post surgical support? Are there allergies that eliminate the optimal medication regimes? What is the patient's family and social history? How severe are the effects of the patient's prior ethanol abuse, drug abuse, smoking history and eating disorder? Is there an "attitudinal family" in tow that will be litigious and fight over end of life issues, (should they arise)? All of such factors (and many more) paint a composite picture, **known only by the surgeon**, that is highly predictive of a patient's course, outcome, prognosis **and resource consumption**. Refining the DRG payments will have little effect on the surgeon's ability to cherry pick the best cases for his/her Specialty Hospital and take the worst cases to the Full Service Hospital.
- Averaging Still Hurts: To illustrate this flaw, let's use a stylized example. Today, a given heart surgery DRG payment might be based on an average resource consumption that typically varies by plus or minus $10 thousand dollars. Full Service Hospitals have historically experienced an equal number of these high and low resource cases to achieve that DRG's average expense result, with a set relationship to the payment. Obviously, cherry picking heart surgeons can divert the $10 thousand lower expense "winners" to their Specialty Hospital and continue to direct the $10 thousand higher expense "losers" to the Full Service Hospital. Now let's say that CMS, in refining the payments, breaks that DRG into two DRGs, each with a $5 thousand expense swing. The Heart Surgeon still has the intimate knowledge to cherry picks the cases in the same way **and the aggregate result doesn't change**.

  On the payment side, CMS could remove two thousand dollars from this DRG "winner" (to increase the payment on another DRG "loser", in a budget neutral fashion) but that doesn't change the amplitude of the swings in **resource consumption** (real variable costs endured by the

Full Service Hospital and avoided by the Specialty Hospital). If the DRG is broken into two DRGs, the swings will be smaller but still proportional and material. The two thousand dollar pick-up on the non-heart DRG will help the full service hospital but not to the same degree as the harm from the Specialty Hospital's cherry picking.

- How Long will this take? Whatever CMS does, it will take between five to ten years and the gutting of the Full Service Hospitals will be over before it's completed. A six-month administrative extension of the moratorium doesn't come close to comporting with the years that will be necessary to refine the CMS payments.
- The "Wallet Biopsy": No amount of perfecting the DRG payments will ever touch the cherry picking via the results of the wallet biopsy. Uninsured, Charity Care and Medicaid Cases will continue to be directed to the Full Service hospital while the Blue Cross and other well-insured cases are diverted to the Specialty Hospital.

Cherry Picking Inside the Specialty: In choosing a well-paid specialty, the Specialty Hospital avoids providing many other specialty services that don't pay well but are vital to the community. But this iner-specialty cherry picking doesn't stop there; it is also done **within the chosen specialty**. For example, Specialty Heart Hospitals do not provide heart transplant and other end-stage heart services because they have low to no profit margins, are resource intensive and hard work. They also avoid congenital heart services for babies and children for the same reasons. DRG payment changes will not touch cherry picking the children's heart services. If CMS increases the DRG payments on the adult heart "losers", it will result in the Specialty Heart Hospitals cherry picking these new "winners", still to the detriment of the Full Service Hospitals.

189

Submitter : Mr. John Hornbeak

Date: 06/19/2005

Organization : Methodist Healthcare of San Antonio

Category : Health Care Professional or Association

SpH
MedPAC

Hefter
Hartstein
D. Romano
Treitel

Issue Areas/Comments

GENERAL

GENERAL

See Attachment for Specialty Hospitals and MedPAC Recommendations.

CMS-1500-P-412-Attach-1.DOC

Attachment to #412

Physician-owned Specialty Hospitals FAQ's

In the public policy debate regarding physician-owned Specialty Hospitals, proponents have advanced a number of options to placate regulators and policy makers and avoid the prohibition of physician ownership. The following FAQs deal with these options as well as general questions. In general, the options consist of half measures cosmetic in nature, treating the symptoms rather than the root cause and designed to change the subject and divert attention. **There is only one cure for a material conflict of interest: end it, prohibit it, and make it clear that it is wrong.** Only then can some of the options described below be effective in deterring bad behavior and exposing and prosecuting subsequent violations.

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190

Date: 06/20/2005

Submitter : Dr. Richard Guyer

Organization : Texas Back Institute

Category : Physician

NT

Hefter
Hartstein
Walz
Treitel

Issue Areas/Comments

Issues

New Technology Applications

Comments for Charite Artificial Disc - see attachment

CMS-1500-P-416-Attach-1.DOC

Attachment to #416

Friday, June 17, 2005

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

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

I would like to introduce myself as a Spine surgeon of twenty-two years who is one of the original founders of the Texas Back Institute. I have been actively involved in the North American Spine Society and currently serve as its' Second Vice President. More importantly, I have followed the advancement in spine surgery over the last 20 years, and have found that the most important advance in the treatment of spinal disorders has been the development of the artificial disc. My associates and I at the Texas Back Institute became first interested in this in 1990 when we learned of the Charite' artificial disc. As you well know, it took ten years for the disc study to begin and finally was approved by the FDA in October of 2004.

Currently, for our patients with symptomatic degenerative disc disease, the treatment option has been that of fusion. Not only does this entail a longer hospitalization, but also entails a much longer recovery period in which activities are limited and the patients need to be braced until the fusion is healed which can be as early as six months, but can be as long as twelve months or more. The Charite' FDA prospective study showed that the artificial disc patients got out of the hospital a half a day earlier and in the study at the Texas Back Institute we showed that these patients returned to work and normal activities in half the time of the fusion patients. In addition, it is our hope that the theoretical advantage of the artificial disc will be proven out, which is to prevent abnormal stresses on the level above. There is strong 10 and 11 year data from Europe that shows that these artificial discs continue to function after this period of time.

Although it has not been fully delineated, there are preliminary studies that show that the cost of a fusion for degenerative disc disease can range up to twice as much as that for a disc replacement. In fact, I reported this data at the Spinal Arthroplasty Society in May of 2005.

Currently, I do not see a large number of Medicare-aged patients receiving the artificial disc. With the excellent medical care the population is now receiving and the fact people are living longer, I believe that the numbers may increase. Still I would estimate the number of patients in my practice that are Medicare age that are receiving the artificial disc would be somewhat less than 5%. Medicare patients that have received the artificial disc have been as grateful as any other patient, and, in fact, in many ways they benefit more from the accelerated and faster return to activities which is beneficial to general well being.

191

Date: 06/20/2005

Submitter : Dr. John Fisher
Organization : Dr. John Fisher
Category : Physician

DRG/Gen

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-420-Attach-1.DOC

Attachment to #420

MONTEFIORE MEDICAL CENTER

The University Hospital for the Albert Einstein College of Medicine

Department of Medicine
Cardiovascular Division
Arrhythmia Service

111 East 210th Street
Bronx, New York 10467-2490
Tel: 718-920-4291
Fax: 718-547-2111
e-mail: jfisher @ montefiore.org

John D. Fisher, M.D., FACC, FESC
Director, Arrhythmia Services
Program Director CCEP
Professor of Medicine
Albert Einstein College of Medicine

June 20, 2005

Re: File code CMS-1500-P

I understand that in the proposed inpatient rule for FY '06, Medicare is recommending removing hospital procedure 37.26 from the current list of cardiac catheterization procedures leading to DRGs 535 and 536. The removal of code 37.26 results in many more cases going to DRG 515; the impact would be significant given the varying payment levels of the DRGs.

I SUPPORT THE HEART RHYTHM SOCIETY'S (HRS) RECOMMENDATIONS:
A change of this magnitude requires further study and analysis. Inform CMS that the 'bedside EP testing' (CPT codes 93640-93642) the intraoperative EP study (during the implant before closing) no longer maps to 37.26 (as of 2005) and therefore currently is not mapping to DRG 535/536. CMS stated that this issue was still confusing to coders and was a primary reason for this proposal. Additionally, the Heart Rhythm Society recommends the NIPS procedure be removed from 37.26, which will prevent mapping to the higher DRG. However, HRS recommends that the full comprehensive EP study 93620 continue to map to 37.26 and remain in DRG 535/536. The resources and clinical similarity of an EP study and other catheterization procedures, as listed above, are similar.

Sincerely,

John D. Fisher, MD
Former President
HRS (NASPE)

192

Date: 06/20/2005

Submitter : Mr. Dean Verret

Organization : Terrebonne General Medical Center

Category : Hospital

Q Data

Hefter
Hartstein
C. Bodden
M. Krushat

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1500-P-422-Attach-1.DOC

PREMIER

Attachment To #422

Comments on data provisions of FY'06 Medicare Inpatient Prospective Payment System (PPS) Proposed Rule

The ability of hospitals and their vendors to comply with the requirements for timely and accurate data submission has been challenged by miscommunication over data edits, technical ambiguities, and other issues. Therefore, Premier believes that the final rule governing the FY'06 Inpatient PPS should establish a clear documentation and communications process for this purpose. Additionally, Premier believes that hospitals should not be penalized when technical issues specific to the Centers for Medicare and Medicaid Services (CMS) or Quality Improvement Organizations (QIOs) hinder their ability to meet specific data requirements.

Data Submission

- The parameters of the data submission process should be stated explicitly and documented. This includes exact specifications, all edits or audits to be applied, and other related information. Hospitals and their submission agents (vendors) must be privy to such parameters to ensure timely data submission. In addition, CMS should communicate any changes to submission file requirements no less than 120 days prior to the effective/implementation date. No changes should be permitted once a submission quarter has begun, as this puts the integrity of the process at risk.

- For greater reporting accuracy, Premier believes that a test process for validating data file submissions and measuring calculations should be established. Hospitals and submission agents should be provided with a test file in the appropriate file specification format for internal verification *prior* to testing a submission. The process should permit submission of test file(s) to verify file formats, accuracy of data calculations, and other audit criteria related to data submission. An appropriate test process should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Alternately, if hospitals that do *not* sample elect to submit all of their qualifying cases for a given study (i.e., 425 pneumonia cases for a given quarter) and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that *every* one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

Data Validation

- The parameters of the validation process should be stated explicitly and documented. This includes clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well-documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. Premier proposes that any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- Premier believes that the validation process should incorporate *only* data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may earn an *overall* quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably *lower*. In this way, payments risk being based on inconsistent calculations and inaccurate data.

- Further, Premier believes that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data was submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

- Under the proposed rule, CMS only allows ten days for a hospital to appeal its validation; however, the agency fails to specify whether the reference is to "business" or "calendar" days. Premier believes that *neither* case offers sufficient time for hospitals to respond. Therefore, we propose allowing hospitals 30 calendar days to appeal their validation findings.

- Many Premier hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). Premier believes that all communications and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIOs) simultaneously. Such a strategy would simplify and standardize message generation. It would also eliminate the confusing and

often contradictory communications typical of the current process, which requires state QIOs to interpret a given communication before forwarding it to hospitals.

June 8, 2005

193

CAH Reloc

Date: 06/20/2005

Hefter
Hartstein
Collins
Morey
Smith

Submitter :

Organization : St. Luke's Hospital, Inc.

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

St. Luke's Hospital (SLH) in Columbus, N.C. has just filed for CAH status and occupies a facility that is over 30 years old.

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

The relocation language in the proposed IPPS rule is inappropriate and harmful. SLH does not believe that it is the intent of Congress to reduce the number of CAHs that serve the State's volnerable and inaccessible communities simply because a small rural hospital has to move its facility and campus across town. Indeed, SLH believes that Congress intended the Critical Access Hospital designation to support the development and long-term viability of needed and critical healthcare services for small rural hospitals serving rural, inaccessible communities. The IPPS proposed rule for CAHs as written will irreversibly harm the vital and continued development of SLH as a CAH.

SLH suggests that CMS regional offices should review reconstruction and relocation plans on a case-by-case basis as present. If the CAH falls into the relocation criteria, then CMS should determine if the CAH is serving the same population with the same staff and services (the 75% rule that is proposed) in generally the same area (maybe a mileage criteria like "within 5 miles of the previous location" could be developed). If the CAH meets the criteria, then the CAH should be able to receive an expedited favorable decision from CMS approving the CAH's reconstruction or relocation plan, with continued approval to operate as a CAH. Simply determining whether or not a CAH is 'under construction' prior to December, 2003 is not adequate to preserve Congress' intent in establishing the CAH program.

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GHA An Association of Hospitals and Health Systems

1675 Terrell Mill Road • Marietta, Georgia 30067 • (770) 249-4500 • Fax (770) 955-5801

June 24, 2005

Transfers
Impact
MB/H Red.
Hosp Reclas
Geo
CAH Reloc

Hefter
Hartstein
Walz
Hart
Treitel
Kraemer
Seifert
Knight
Kenly
Collins
Morey
Smith

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

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

Critical Access Hospitals

Dear Dr. McClellan:

On behalf of the Georgia Hospital Association (GHA), its 180 member hospitals, health care systems and other health care organizations, we appreciate the opportunity to submit comments on the fiscal year (FY) 2006 inpatient prospective payment system (PPS) proposed rule.

While the GHA is supportive of many of the provisions in the proposed rule, we are particularly concerned about the potential underestimation of the market basket, the proposed expansion of the post-acute care transfer policy and the potential restrictions on the relocation of Critical Access Hospitals (CAHs) with necessary provider status. The proposed rule provides for a market basket update of 3.2%; however, current estimates of the actual market basket increase for FY 2005 is 4.1%. We are concerned that CMS is dramatically underestimating the market basket for FY 2006, and request that CMS review and revise the methodology used to determine the projected FY 2006 market basket, and make the details of the calculation available to the public. GHA is also concerned that the post-acute care transfer policy will have an estimated negative impact of $12.8 million (.5%) on all Georgia hospitals. If implemented as CMS proposes, the effect will be a reduction of the net update factor to 2.7%, which is 1.4% less than the current estimated market basket increase of 4.1%. GHA projections for current total Medicare margins for FY 2006 is –6.4%, or a $238 million dollar loss.

Although GHA is concerned about the negative financial impact of the market basket underestimation and the post-acute care transfer policy on all of our member hospitals, this comment letter focuses primarily on the concerns of our members with respect to the changes proposed for Critical Access Hospitals (CAHs).

A state's authority to grant necessary provider status, and thus waive the distance requirement under the CAH program, expires January 1, 2006. However, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS' proposed rule would essentially bar necessary providers from ever rebuilding more than 250 yards from their current location. Appropriate and necessary relocations to that will undoubtedly result in higher quality care, better patient outcomes, and more efficient service should be allowed. **We urge CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care of and meet the needs of their communities.**

Rural Hospital Redesignated as Urban

One of the requirements for CAH designation is that the hospital must be located in or reclassified to a rural area. As a result of the most recent labor market changes, some counties that were previously considered rural were redesignated as urban. In Georgia, there are six hospitals that are potentially affected by this provision. Per the MMA, a rural county that is adjacent to one or more urban counties is considered to be located in the urban MSA to which the greatest number of workers in the county commutes, if certain conditions are met. These are known as "Lugar Counties." Thus, some CAHs are now located in Lugar counties and are unable to meet the rural location requirement, even though they were in full compliance at the time they were designated as critical access.

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

Necessary Provider Status Relocations

Currently, a governor may certify a hospital as a "necessary provider," which allows a hospital to become a CAH even if it fails to meet the distance requirement of being more than 35 miles (or 15 miles in mountainous areas or by secondary roads) away from a PPS hospital or another CAH. The MMA terminates a state's authority to grant necessary provider status as of January 1, 2006; however, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS proposes that the current designations as "necessary provider" only applies to a hospital's current location. The members of GHA believe that the "necessary provider" designation should be maintained as long as the hospital is serving the same patient population. The date which a hospital starts planning for construction should make no difference.

The GHA believes that CMS is exceeding its authority and independently developing a policy that is in conflict with the law. The MMA clearly established the intent of Congress to exempt current facilities from the expiration of the necessary provider waiver. Yet, for FY 2006 and beyond, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing

site or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area (HPSA) and remains in a HPSA);
- Serves the same community (75 percent of same population, 75 percent of same services, 75 percent of the same staff);
- Complies with the same conditions of participation; and
- Was "under development" as of December 8, 2003 using similar criteria as the specialty hospitals guidelines (architectural plans, financing, zoning, construction bids, etc).

The GHA believes that the date restrictions proposed by CMS are unrealistic and unreasonable. Firstly, December 8, 2003 is simply the date the MMA was signed into law and has no connection to a CAH relocation deadline in law. The ability of governors to newly approve necessary providers expires January 1, 2006, more than 2 years later than the date arbitrarily chosen by CMS for the relocation deadline. Regardless, the law expressly allows those existing providers to maintain their status after that date with no articulated restrictions. **Consequently, we insist that CMS remove the arbitrary date restrictions for relocations that have no basis in law.**

CAHs are often housed in old buildings that are in desperate need of renovations, but prior to converting, these facilities could not gain access to capital due to their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, not because of excessive profits, but because of the stability of Medicare reimbursements covering allowed costs. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or other essential upgrades. **Such improvements will undoubtedly result in higher quality care, better patient outcomes, and more efficient service.**

Many facilities need to, or choose, to rebuild on a new site to be closer to a highway, connect to municipal water and sewer, because of seismic safety concerns, or other reasons that again, will improve patient safety and the quality of care provided. In addition, many CAHs are landlocked with little or no room for expansion, thus they have no choice but to relocate if they must rebuild. As a CAH hospital considering relocation, this rule is unworkable. For many CAHs, any future move is almost prohibited. Many have limited land and no place to construct a new facility. A burdensome requirement is that a hospital's plans to relocate have had to begin before December 2003. For these hospitals to be viable they need to be able to relocate provided that they are still serving the same patient population.

Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.

The GHA believes CMS has gone too far in trying to paint hospitals that are moving a few miles from their current location as having ceased business and reopened as a *new provider*. This shows a general lack of knowledge about rural areas. These CAHs are integral to their communities and often one of the biggest employers. Moving down the road will not demonstrably change the population served. The 250 yards rule is a very restricted number considering that in small towns hospitals might be land locked and they might have to go a mile away, but still be in town. **We further assert that CMS automatically should consider any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.**

If a CAH moves further than five miles, and CMS is concerned about whether the same population is being served, then we would recommend an approach similar to the 75 percent test described earlier. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff, and providing 75 percent of the same services are warranted.

For instance, natural changes in demographics and the practice of medicine will occur over time that may necessitate a change in services when a hospital is rebuilt. Or, a greater reliance on new technology may limit the number or type of staff needed at a newly built facility. **Some flexibility in the measures is needed to allow for such expected changes in the needs of the community.**

Therefore, the GHA recommends that CMS alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show through a needs assessment that the change in services provided would be appropriate, then the test of 75 percent of the services should not need to be met. If a CAH has undertaken a cost comparison that shows that a new facility on another site would be less expensive than rebuilding on the current location, then only two other measures should need to be satisfied. **A combination of criteria suggested would offer CAHs some flexibility and allow for the natural development and maturation of the CAH and the community.**

We also encourage CMS to consider special provisions for hospitals that are merging. Under these circumstances, the two hospitals may not be able to meet the criteria. In these cases, CMS should make determinations on a case-by-case basis. If the merger meets the needs of the communities, then CMS should consider it an appropriate and allowable relocation.

Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when counting the staff, how should the hospital ascertain if the staff would

continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? Is the fact that you plan to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. **CAHs need clear expectations and advanced warning of the standards to which they will be held.**

CAHs are the sole providers of inpatient acute-care services in their communities and often outpatient and long-term care services. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. It is thus, unlikely that they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement there would be other hurdles, such as getting licensed for additional beds in certificate of need states, or hiring additional staff to expand services when there are shortages in many areas, that would need to be surmounted in an effort to build volume to survive under the PPS. For many of these CAHs, loss of their status would force them to close. **Given the role of these facilities in their communities, such closures would have devastating affects on rural healthcare access.**

We urge CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care of and meet the needs of their communities. Instead, CMS should expand and use the criteria recommended above.

Pending Necessary Provider Status Applications

The GHA is concerned about the hospitals that are currently in the process of converting to CAH status under the necessary provider program. We have heard reports from some states that the queue to be surveyed is growing and despite a hospital's best efforts and advanced planning, the survey to obtain the new provider number may not occur by January 1, 2006. It is also possible that the survey will occur, but the plan of correction will not be accepted by the deadline if one is needed. States have an enormous survey workload that is further exacerbated by EMTALA surveys that take priority. **Providers that have gotten to the stage of requesting a survey in advance of the January 1 deadline, but are unable to get the state to complete the survey have clearly demonstrated a good faith effort and should be considered as meeting the deadline.**

The GHA appreciates the opportunity to submit these comments on the proposed inpatient PPS rule for FY 2006. If you have any questions about these comments, please feel free to contact me or Robert Bolden, Director of Fiscal Services, at (770) 249-4505.

Sincerely,

Vi Naylor

Vi Naylor
Executive Vice President

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Date: 06/20/2005

Submitter : Mrs. Tracy Warner
Organization : Iowa Hospital Association
Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1500-P-429-Attach-1.DOC

Q Data
CAH Reloc
WI|BD
WI|OC
Hosp Redes
Geo Reclass
CAH|LUGAR
Transfer
DSH

Hefter
Hartstein
Collins
Morey
M. Smith
V. Miller
N. Kenley
Walz
Hart

IOWA HOSPITAL ASSOCIATION

Attachment #429

June 20, 2005

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

Ref: CMS—1500-P Medicare Program; Changes to Inpatient Prospective Payment System and FY 2006 Rates; Proposed Rule (70 *Federal Register* 23306), May 4, 2005.

Dear Dr. McClellan,

On behalf of Iowa's 116 hospitals, the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the FY 2005 inpatient prospective payment system (PPS) published the May 4, 2005 *Federal Register*.

IHA is supportive of the full market basket update for FY 2006, as mandated by Congress and implemented in this proposal, for hospitals that participate in submitting data on a set of 10 quality indicators. But while appreciated and much needed, a full payment update for this fiscal year does not address many years of less than adequate inflation payments that has resulted in a -6.4% total Medicare margin for Iowa hospitals. And although the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) is estimated to bring an additional $258 million to Iowa hospitals primarily from the equalization of the standardized amount and the lower labor share, policy changes that have long been supported by IHA, the fact remains that the inpatient payment system underpays Iowa hospitals as evidenced by projections that margins will continue to be over -5.6% through 2009. Many Iowa hospitals are heavily dependent on Medicare as their primary source of revenue but given the existing payment shortfalls, coupled with policies being proposed in this rule such as the expansion of the post acute care transfer provision that will reduce already inadequate payments by over $6.8 million a year, IHA once again is expressing its concern that access to care is threatened when the program does not cover its share of the cost of providing services or implements unreasonable changes that don't allow facilities to meet the needs of their communities, as with the suggested change on the relocation of critical access hospitals (CAHs).

Given the significant number of complex changes that have occurred in the Medicare inpatient payment system over the last several years as a result of legislative and regulatory actions, IHA urges CMS to closely examine the on-going effectiveness of the system. For over 20 years now, the system has been pieced together through a series of legislative and regulatory changes and the result is a cobbled structure that has a significant number of exceptions to address special circumstances which does little to promote the efficient delivery of high quality care. Despite the inadequate reimbursement, Iowa hospitals continue to demonstrate value through the provision of efficient and quality health care services, as evidenced by CMS rankings of Iowa hospital quality at number six in the nation. For the Medicare program to become

a purchaser of value, it must focus on improving the health outcomes for program beneficiaries and more effectively manage the disperse resources that Congress provides. Moreover, this focus should be on the entire array of Medicare payment systems and contemplate the value of care that is provided over a continuum of services from an inpatient hospitalization to skilled care and services in other post-acute care settings, as raised by CMS in the proposed FY 2006 SNF PPS rule in asking for feedback on the integration of such systems that will be made possible with the advent of electronic medical records.

The following are IHA's detailed comments regarding CMS' proposed changes to the inpatient payment system as well as our comments on proposed changes affecting critical access hospitals (CAHs).

FY 2006 Wage Index

In each year's rule, CMS describes the method used to compute the wage index. However, in the proposed FY 2006 rule, CMS changes a step of the calculation that is not addressed by the agency in the preamble discussion. Specifically, in step four, lines 8 and 8.01 of worksheet S-3, Part III are included in the calculation to determine the ratio of overhead hours to revised hours, yet these lines were not included in the calculation as described by CMS in the FY 2005 final rule. The impact of the change increases the ratio of overhead to revised hours and affects the overall wage index, thus impacting Medicare payments. Before CMS makes such a change, the agency must identify the rationale for this adjustment and communicate it to hospitals via a proposed rule prior to putting it into place. **IHA recommends CMS return to the method of calculating the wage index prior to this proposed rule and omit inclusion of lines 8 and 8.01 in computing the amounts of overhead wage-related costs to be allocated to excluded areas.**

Occupational Mix Adjustment

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required CMS to collect occupational mix data to be used in adjusting wage indices beginning October 1, 2004. IHA continues to support the intent of this legislative mandate based on the premise it would dull the impact of staffing decisions by increasing the wage index for lower wage areas and decreasing wage indices for higher wage areas. However, IHA does not support the methodology CMS has chosen to implement this law, as it is clear it does not accomplish what the law intended.

Although CMS is again proposing to use the same CMS wage index occupational mix survey and Bureau of Labor Statistics (BLS) data that was used for the FY 2005 wage index, **IHA opposes adjusting hospital reimbursement, even by only 10 percent, based on flawed and incomplete data.**

Using the information and data currently available, IHA believes the occupational mix adjustment will not achieve the impact intended by Congress in implementing the adjustment as evidenced with many low wage index areas experiencing an even further wage index decline while larger metropolitan areas have a lower occupational mix that results in increased Medicare payment. The explanation for the inverse outcome of the adjustment appears to be due to the data collected by CMS and the assumptions the agency is utilizing in the process. IHA also has specific concerns surrounding the process CMS instituted in collecting the occupational mix data, including vague and untimely instructions that lend themselves to further subjectivity within the wage index development; the lack of recognition of certain hospital occupational categories, e.g., radiology; and, the short time frame by which hospitals had to respond to the survey. Each of these issues intensifies concerns regarding the integrity of the data CMS collected and is using in the adjustment.

Specifically, IHA recommends the following:

- CMS immediately begin re-collecting occupational mix data.
- Prior to re-collecting this data, CMS must issue complete, concise and clear instructions allowing hospitals to complete the data submission leaving no room for interpretation or subjectivity.
- CMS include all occupational categories into the data collection tool.
- CMS use only audited data when its intended use will affect Medicare reimbursement.

[illegible] contained in section 951 of the MMA that requires CMS to furnish the data [illegible] used in calculating disproportionate share

percentages. However, IHA is concerned that CMS has been misinformed as to the availability of established procedures to obtain information needed by hospitals in order to calculate their Medicaid fraction.

In IHA's experience, this process is either hit or miss, depending on the willingness of the individual at the state or the contracted fiscal agent, to respond to the data request. IHA recommends CMS provide explicit direction the state Medicaid agencies to provide the eligibility information requested by hospitals in order to support their DSH calculation for Medicare. This direction will eliminate the varying processes and accountability depending on the state. Further, this instruction must also apply to the health plans that contract with the state Medicaid agencies so that hospitals can also have reasonable access to eligibility data on the population of Medicaid recipients enrolled in managed care.

Hospital Quality Data

Iowa hospitals are fully supportive of the reporting of quality data through the CMS initiative, as evidenced by the fact that 86 facilities are participating in the project, including 42 CAHs who are not affected by the payment reduction. However, IHA is concerned about CMS' proposal for additional requirements associated with chart validation in order to receive the full FY 2006 payment update. Although audits and data validation are necessary to ensure that the information being reported is reliable, **IHA opposes any attempt by CMS to link this validation process with the hospital update factor at this time.** CMS audits of 2004 data were often unreliable due to data problems and inconsistent definitions. These issues were not completely resolved by third quarter of 2004 which is the period that CMS is proposing to base the update on. Hospitals should not suffer a payment reduction due to technical problems with the data submission and validation process. Therefore, **IHA recommends CMS withdraw its proposal for chart-audit validation until such time as all technical issues are resolved.**

Critical Access Hospitals (CAHs)

In an agricultural state such as Iowa, many communities are less than 35 miles apart so each of the CAHs in Iowa used the state designation as a necessary provider to become a CAH. Among the criteria for this designation are requirements that the hospital is located in an area with an elderly population (65 years or older) percentage greater than or equal to the state average; demonstration that the motor vehicle accident rate or farm injury rate is greater than or equal to the state average; and, be an emergency medical services (EMS) provider or demonstrate a cooperative relationship with the local EMS provider. These state-specific criteria in 11 general categories have been crucial in identifying 71 Iowa hospitals as necessary to their communities for their ability to provide accessible care to the state's aged population as well respond to emergency situations in the community.

The proposed policy change being set forth by CMS in the proposed rule will have the affect of not allowing CAHs to replace the facility within or adjacent to the city limits of the community / population (s) they serve. To limit replacement of a CAH to the existing campus and within 250 yards of the existing building or to adjacent land purchased before December 8, 2003 hinders CAHs from making changes to address the evolution of medical care, technology, patient flow and needed community services and programs. Concerns regarding the proposed replacement policy include:

- ✓ The date restriction of December 8, 2003 for the purchase of land adjacent to the CAH campus has no link, importance or relation to when a CAH was certified and licensed, and when the CAH determines the need for replacement and the purchase of land. In fact many CAHs were certified and licensed by CMS after December 8, 2003 so this arbitrary date would prevent their replacement at any point in the future. **The December 8, 2003 deadline for purchase of land adjacent to the CAH must be removed from the policy.**

- ✓ Allowing replacement on the existing campus within 250 yards of the CAH or on adjacent land purchased before December 8, 2003 is far too restrictive and does not match the reality in rural agricultural America. In many instances, these rural hospitals are located on small parcels of land in the middle of residential neighborhoods with no room to expand, having been built at the

outskirts of town when they were constructed 40-50 years ago but are now landlocked due to community growth around the hospital. **The proposed policy should be revised to reflect that any CAH facility rebuilt within the city/town limits should be considered a replacement. Any CAH replacement within these provisions would automatically retain the necessary provider designation granted by the state where the CAH is located.** Iowa CAHs are located in communities ranging in size from a population of 891 covering 1.38 square miles to community with a population of 12,803 that covers 8.93 miles. Regardless of whether the CAH replaces on site, on adjacent property, or within the city/town limits, it is clear because of the size of the communities in which CAHs are located that the facility will continue to serve the same population and community and they should not be required to demonstrate this fact if they are relocating in accordance with this necessary change to the proposal.

The second part of the proposed policy defines relocations in such a manner as to preclude the relocation of a CAH while maintaining their necessary provider designation if the CAH can not prove that plans were begun prior to December 8, 2003. For those CAHs that can prove they began the relocation process prior to December 8, 2003, the CAH must also make a relocation application to the state before January 1, 2006, meet the same state necessary provider criteria, assure the same population will be served, and assure compliance with Medicare Conditions of Participation in the new location. Again, many CAHs were designated after December 8, 2003 which will preclude them from ever replacing their existing facility. Concerns with this proposed policy include:

- ✓ There is no relationship, importance or link to when a CAH is certified and licensed and December 8, 2003.
- ✓ Most CAHs certified and licensed by January 1, 2006 have not considered, discussed or begun to evaluate the need for replacement at another location. The application deadline of January 1, 2006 is unreasonable and again has no relationship to the evaluation of replacement in a different location.

The proposed policy should be revised to remove any reference to dates, and to specify that replacement of a CAH beyond the city/town limits where the CAH was located should be considered a relocation. In these instances, in order to retain the necessary provider designation, the CAH would have to demonstrate that it is still serving the same population with the same staff by meeting the 75% test as proposed by CMS.

The benefits of the CAH program, which are well understood by policymakers and the communities in which CAH are located, include maintaining access to needed primary and emergency care services in rural locations to respond to agricultural-related and motor vehicle accidents; enabling rural hospitals to update antiquated facilities in order to meet licensure and life safety requirements and to replace outdated diagnostic and other equipment; and, allowing rural communities to recruit and retain needed physicians, nurses and other health professionals. Years and years of inadequate Medicare reimbursement to Iowa hospitals has created a situation where many facilities that were constructed during the Hill-Burton era were not able to properly maintain their plant and equipment with Medicare revenue substantially less than costs. The average age of plant for Iowa CAHs is almost 12 years, compared to a national figure of 10.09. Even with the transition to cost-based reimbursement, some Iowa CAHs have yet to address their building and technology plans because of the need to establish a more favorable cash position prior to taking on new debt. To restrict the replacement of these facilities because of arbitrary dates selected by CMS is a disservice to the very program that has allowed hospitals to continue to bring a significant economic benefit and vital health care services to the communities they serve.

Thank you for your review and consideration of these comments. If you have questions, please contact me or Heather Olson at the Iowa Hospital Association at 515/288-1955.

Sincerely,

Tracy Warner

Tracy Warner
Vice President, Finance Policy

cc: Iowa Congressional Delegation
IHA Board of Trustees
Iowa hospitals
CMS Kansas City Regional Office

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Date: 06/20/2005

Submitter : Mr. Paul Dabrowski
Organization : Trinitas Hospital
Category : Hospital

Labor/S
W1/BD

Hefter
Hartstein
Seifert
Knight
Treitel
Kraemer
Miller

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1500-P-430-Attach-1.DOC

Attachment #430

June 20, 2005

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

Subject: Labor-Related Share

To Whom it May Concern:

I am writing on behalf of Trinitas Hospital to express our opposition to the changes that the Centers for Medicare & Medicaid Services (CMS) has proposed in the FY 2006 Medicare inpatient PPS regulation governing the labor-related share of Medicare payments to hospitals. The proposed regulation calls for reducing the labor-related share from 71.1 percent to 69.7 percent for hospitals located in areas with a wage index greater than 1.0 and would cost our hospital approximately $480,000 annually in lost Medicare revenue.

Three years ago, CMS proposed increasing the labor-related share for all hospitals from 71.1 percent to 72.5 percent. The agency, however, expressed concern over the harmful impact this would have on rural hospitals and withdrew the proposal in favor of further analysis of the methodology it used to compute this proposal. While CMS was performing this analysis, Congress passed legislation that set the labor-related share at 62 percent for hospitals with a wage index of 1.0 or less to increase payments to most rural hospitals.

In proposing to reduce the labor-related share for FY 2006 for hospitals with a wage index greater than 1.0 – primarily urban hospitals – CMS now is using the same methodology it rejected three years ago. We do not understand why a methodology rejected three years ago is now considered valid. If that methodology is now, in fact, considered valid, CMS's decision not to raise the wage index as originally proposed three years ago resulted in urban hospitals being underpaid by Medicare since that time.

Since this change will decrease Medicare revenue for all affected hospitals – those whose wage index is greater than 1.0 – CMS proposes achieving budget neutrality by redistributing this money by increasing the standardized amount for all hospitals. This approach will result in a financial windfall for *all* hospitals with a wage index of 1.0 or less – that is, for most rural hospitals. If CMS believes that 69.7 percent is the true, appropriate figure for labor-related share and hospitals with a wage index less than 1.0 are already, in effect, getting more generous payments than they should, we question the decision to give these hospitals – that is, most rural hospitals – even more than they already receive.

This proposal also raises concerns about what we view as another attempt by the federal government to penalize urban hospitals for the benefit of rural hospitals. In recent years, a number of new policies have been adopted or rejected, both by Congress and the administration, based primarily on their

damaging impact on rural hospitals. They include CMS's decision of three years ago not to raise the labor-related share because that action would hurt rural hospitals (and ignoring the benefits it offered to urban hospitals); the enormous supplemental benefits directed to rural hospitals by Congress through the Medicare Modernization Act of 2003 while that legislation virtually ignored the far greater needs of urban hospitals; the FY 2005 regulatory change that steered residency slots to rural hospitals and away from urban hospitals; and CMS's failure in recent years to meet its statutory target for outlier payments – a practice that disproportionately disadvantages urban hospitals.

These and other actions have been undertaken despite clear evidence that urban hospitals are in far worse financial condition than rural hospitals. The cumulative effects of years of caring for uninsured, under-insured, and Medicaid patients are taking their toll on urban hospitals: more and more of us are losing money. In an industry in which a positive operating margin of four percent is considered necessary to operate effectively, a 2003 study by the National Association of Urban Hospitals found that among hospitals that qualify for Medicare DSH payments, the collective financial performance of urban hospitals nation-wide is 25 times worse than that of rural hospitals. Collectively, the operating margins of urban Medicare DSH hospitals in the U.S. is *minus* 5.7 percent – a figure that suggests that without intervention, many of those urban safety-net hospitals may soon be forced to close their doors. That same study found that large urban hospitals that provide at least 15 percent of their services to Medicaid patients have an average operating margin of *negative* 8.52 percent. At the same time, there have been no credible studies that suggest that rural hospitals are being underpaid by Medicare. Most, in fact, conclude that rural hospitals are adequately reimbursed for the services they provide to Medicare beneficiaries.

For these reasons, we urge CMS not to reduce the labor-related share of the Medicare wage index.

Sincerely,
Paul Dabrowski
CFO

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Submitter : Ms. Ellen Kugler

Date: 06/20/2005

Organization : National Association of Urban Hospitals

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-432-Attach-1.DOC

Payment Rt/Outliers

Hefter
Hartstein
Treitel

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

Attachment #432

June 20, 2005

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

Subject: Outliers

To Whom it May Concern:

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

Medicare Outliers: The Situation Today

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

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

Medicare Outliers: The Proposed Change in Regulations

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

21351 Gentry Drive • Suite 210 • Sterling, VA 20166 • (703) 444-0989 • Fax: (703) 444-3029
www.nauh.org

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

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

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

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

Medicare Outliers: NAUH's Proposed Solution

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

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

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

About the National Association of Urban Hospitals

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

* * *

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

Sincerely,

Ellen J. Kugler, Esq.
Executive Director

198

Submitter : Mr. Randy Haffner

Date: 06/20/2005

Organization : Florida Hospital

Category : Critical Access Hospital

DRG/Gen Impact

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue
Kraemer

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-433-Attach-1.DOC

FLORIDA HOSPITAL
601 East Rollins Street
Orlando, Florida 32803
407/896-6611

Attachment #433

June 20, 2005

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

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

Florida Hospital is a 1,785 bed acute care hospital located in Orlando, Florida. Florida Hospital has one of the country's largest electrophysiology programs and we expect to implant over 500 defibrillators in 2005 and growing nearly 20% per year. Because inpatient electrophysiology services are a key component of what we provide, I am writing to express my concern with the proposed rule, " Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates", published by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2005. My concern is on page 50 of the proposed rule where CMS proposes to modify the DRGs for ICD implants.

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

The payment change CMS proposes would have a financial impact on Florida Hospital of approximately **$1.7 million**. This DRG has continuously been a financial challenge to Florida Hospital and the proposed changes would have a substantial effect on our electrophysiology program. This is particularly true for CRT-D devices which are ICDs that addresses both Sudden Cardiac Death and heart failure and cost more than single purpose ICDs. CMS says it is not appropriate to have all three procedures in code 37.26 drive to higher paying DRGs. It is equally inappropriate to have all three drive to lower paying DRGs.

I respectfully request that CMS withdraw the proposed ICD DRG revision and address this coding problem, with a coding solution, before attempting to make detrimental changes to the current defibrillator DRG structure that would be devastating to Florida Hospital.

Thank you for your consideration.

Sincerely,

Randy Haffner
Chief Operating Officer/Orlando

dlh

199

Submitter : Dr. Evan Benjamin **Date:** 06/21/2005

Organization : Baystate Health system

Category : Hospital

Q Data

Hefler
Hartstein
C. Bodden
M. Krushat

Issue Areas/Comments

GENERAL

GENERAL

Validation:
CMS only allows ten days for a hospital to appeal its validation; this is insufficinet time to deal with the data and validation issues. we propose allowing hospitals 30 calendar days to appeal their validation findings.

Submission of data:
We usually elect not to submit sample sizes and submit data on the entire sample. If there are isssues with a small number of patient's data (<1%), will the entire data smaple be rejected?

200

Submitter : Dr. Ernest Yoder **Date:** 06/21/2005

Organization : Providence Hospital

Category : Physician

GME/Affl

Hefter
Hartstein
Truong
Hefkowitz
Ruiz

Issue Areas/Comments

GENERAL

GENERAL

June 21, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
Room C5-14-03
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: [CMS-1500-P] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates (42 Federal Register 405, 412, 413, 415, 419, 422, and 485), May 4, 2005

To whom it may concern:

As a member of the resident teaching faculty of St. John Health (SJH), a Southeast Michigan health system with eight hospitals and over 400 interns and residents in allopathic, osteopathic, dental, and podiatry training programs, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services? (CMS) proposed rule for the 2005 Inpatient Prospective Payment System (PPS), published May 4, 2005 in the Federal Register. The adequacy of Medicare payments to cover the cost of training our future generation of physicians is essential to maintain financially viable teaching hospitals in Michigan and across the United States to ensure the adequacy of future Medicare beneficiary access.

My comment is regarding New Teaching Hospitals in Medicare GME Affiliated Groups (?413.79 (c) (1)) of the proposed rules beginning on page 23440 of the May 4, 2005 Federal Register.

CMS proposes to allow new urban hospitals that qualify for an adjustment under ?413.79 (c) (1) may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase in the new teaching hospital?s DGME and IME caps as a result of the affiliation agreement.

I fully concur with this proposed policy update. New urban teaching hospitals should be provided with the flexibility to start new teaching programs without jeopardizing their ability to count additional FTE residents training at the hospital under an affiliation agreement. This flexibility will occur if new urban teaching hospitals are allowed to enter into affiliation agreements with other teaching hospitals to increase their DGME and IME FTE caps.

By definition, a new urban teaching hospital would initially have a resident FTE cap of zero, (0). When residents from existing teaching hospitals rotate to the new urban teaching hospital, it is appropriate for the new urban teaching hospital to receive a positive, increased, adjustment to their FTE cap allowing the new urban teaching hospital to receive Medicare IME and DGME payments. These additional Medicare payments are necessary for the new teaching hospital to cover the direct and indirect costs the new urban teaching hospital will be incurring to train the ?in rotating? residents from other hospital teaching programs.

Thank you for considering my comment regarding your proposed improvement to the Medicare program?s existing payment rules for graduate medical education.

Sincerely,

Ernest L. Yoder, MD, PhD, FACP
Chair, Department of Internal Medicine
Providence Hospital

201

Submitter : Mr. Kyle Kramer

Date: 06/21/2005

Organization : Yale-New Haven Hospital

Category : Health Care Professional or Association

DRG/Gen

Hefter
Hartstein
Brooks
FASAN
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-440-Attach-1.DOC

YALE-NEW HAVEN HEART CENTER

Attachment #440

June 21, 2005

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

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

Yale-New Haven Hospital is a 944 bed acute care hospital located in New Haven, Connecticut. As a major health care provider in our area, we implant medical devices and perform other procedures on a significant number of Medicare beneficiaries, in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concern with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates", published by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2005. My concern is on page 50 of the proposed rule where CMS proposes to modify the DRGs for ICD implants.

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

The payment change CMS proposes would have a severe financial impact on Yale-New Haven Hospital and all hospitals across the country – without data to justify the change. This is particularly true for CRT-D devices which are ICDs that addresses both Sudden Cardiac Death and heart failure and cost more than single purpose ICDs. CMS says it is not appropriate to have all three procedures in code 37.26 drive to higher paying DRGs. It is equally inappropriate to have all three driving ICD related implant procedures to lower paying DRGs.

I respectfully request that CMS withdraw the proposed ICD DRG revision and address this coding problem, with a coding solution, before attempting to make detrimental changes to the current defibrillator DRG structure that would hurt hospitals across the country.

Thank you for your consideration.

Sincerely,

R. Kyle Kramer
Executive Director
Cardiovascular Services

Yale New Haven Health System

202-0
(2)

Submitter : Dr. Scott Eathorne **Date:** 06/21/2005

Organization : St John Health

Category : Physician

GME/Affl

Hefter
Hartstein
Lefkowitz
Truong
Ruiz

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-441-Attach-1.DOC

Attachment #441

June 21, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
Room C5-14-03
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: [CMS-1500-P] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates (42 *Federal Register 405, 412, 413, 415, 419, 422, and 485*), May 4, 2005

To whom it may concern:

As a member of the resident teaching faculty of St. John Health (SJH), a Southeast Michigan health system with eight hospitals and over 400 interns and residents in allopathic, osteopathic, dental, and podiatry training programs, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the 2005 Inpatient Prospective Payment System (PPS), published May 4, 2005 in the *Federal Register*. The adequacy of Medicare payments to cover the cost of training our future generation of physicians is essential to maintain financially viable teaching hospitals in Michigan and across the United States to ensure the adequacy of future Medicare beneficiary access.

My comment is regarding New Teaching Hospitals in Medicare GME Affiliated Groups (§413.79 (e) (1)) of the proposed rules beginning on page 23440 of the May 4, 2005 Federal Register.

CMS proposes to allow new urban hospitals that qualify for an adjustment under §413.79 (e) (1) may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase in the new teaching hospital's DGME and IME caps as a result of the affiliation agreement.

I fully concur with this proposed policy update. New urban teaching hospitals should be provided with the flexibility to start new teaching programs without jeopardizing their ability to count additional FTE residents training at the hospital under an affiliation agreement. This flexibility will occur if new urban teaching hospitals are allowed to enter into affiliation agreements with other teaching hospitals to increase their DGME and IME FTE caps.

By definition, a new urban teaching hospital would initially have a resident FTE cap of zero, (0). When residents from existing teaching hospitals rotate to the new urban teaching hospital, it is appropriate for the new urban teaching hospital to receive a positive, increased, adjustment to their FTE cap allowing the new urban teaching hospital to receive Medicare IME and DGME payments. These additional Medicare payments are necessary for the new teaching hospital to cover the direct and indirect costs the new urban teaching hospital will be incurring to train the "in rotating" residents from other hospital teaching programs.

Thank you for considering my comment regarding your proposed improvement to the Medicare program's existing payment rules for graduate medical education.

Sincerely,

Scott W. Eathorne, MD
Program Director
Providence Athletic Medicine Fellowship
St. John Health

203

Submitter : Dr. Donald Baim

Organization : Dr. Donald Baim

Category : Physician

Date: 06/21/2005

NT

Hefter
Hartstein
Walz
Treitel

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-443-Attach-1.DOC

CMS-1500-P-443-Attach-2.DOC

CMS-1500-P-443-Attach-3.DOC

Attachment #443

June 21, 2005

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

Gentlemen,

I am writing to make a public comment on your proposed recommendation to deny a technology add-on payment for the IntraLuminal Therapeutics SafeCross guidewire as an adjunct to crossing chronic totally occluded (CTO) coronary arteries. In that regard, I am a national expert in coronary intervention (including approaches to CTO), and served as the national Principal Investigator of the pivotal approval registry (GREAT) that led to FDA clearance of this device.

First, let me note that CTOs are one of the last unmet needs in coronary intervention. They are commonly found in patients with coronary artery disease, but the presence of one or more CTOs biases therapy away from catheter intervention (11%) and towards either medical or surgical therapy (Christofferson et al, Am J Cardiol, 2005). This is because the success rate remains quite low (60-70%) for being able to cross CTOs with conventional guidewires.

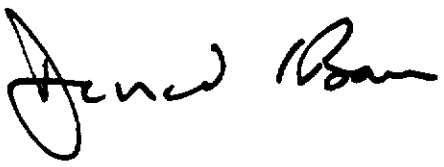
Second, the SafeCross device has been demonstrated (Baim et al, Am J Card, 2004) to increase the crossing success of CTOs where a conventional guidewire had failed. With operator experience in the 2nd half of that trial, 67% of such conventional wire failures were crossed with SafeCross. This would turn a 60% success rate with conventional wires into a 60 + (67%)*40 = 86% overall success rate. This is a high enough success rate to encourage operators to attempt and spend the required time to get these CTOs open.

Third, once the CTO has been crossed with a guidewire, the chances of placing a drug-eluting stent are nearly 100%, and the long-term patency of that intervention is excellent (2 - 5% recurrence, versus 30% with bare metal stents in CTOs) (Werner et al, J Am Coll Cardiol 2004; Nakamura et al, Am J Cardiol 2005). Moreover, a variety of clinical trials have demonstrated that successful opening of a CTO is associated with improvement in 10-year survival r ates (Suero et al, J Am Coll Cardiol, 2001) compared to leaving the vessel occluded.

From this perspective, I would argue that a device such as the SafeCross that can increase the chance of crossing a CTO and thereby enable definitive drug-eluting stenting *does represent a "substantial clinical improvement" for treating this most challenging clinical subgroup.* On the other hand, it also increases the cost of the procedure, since the cost of the wire ($1500) is more than 10-times the cost of a conventional guidewire. To avoid penalizing Hospitals when operators choose to "do the clinically correct thing " by attempting to open CTOs using the SafeCross guidewire when conventional wires fail, I feel that it *would* be appropriate to offer a technology pass-through to cover the expense of the SafeCross wire. The lack of such reimbursement should not be allowed to stand as a disincentive for operators to withhold effective treatment for CTOs and potentially refer these patients to bypass surgery when a percutaneous procedure could have sufficed.

Please feel free to contact me if you would like to discuss this matter further.

With best regards,



Donald S. Baim, MD

(4) 204-C

Congress of the United States

Washington, DC 20515

RECEIVED
JUN 24 2007

Rec'd
JUN 22 2005 BY:
L.N.W.

June 22, 2005

PBE/NICU

Hefter,
Hartstein
Morey

Mark B. McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: Provider-Based Entities -- CMS 1500-P-- Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Payment Rates; Proposed Rule (*70 Federal Register 23305*), May 4, 2005.

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the FY 2006 Inpatient Prospective Payment System (PPS), published May 4, 2005 in the *Federal Register*. We represent the children and families served by Children's Hospital of Central California and are in support of the proposed changes in the location requirement for off-campus facilities under the provider-based rules as applied to certain Neonatal Intensive Care Units (NICUs.)

Children's Hospital Central California has operated offsite NICUs in Merced and Hanford for many years but may be required to discontinue these essential services if a change in the current rule is not made. We have reviewed the comment letter submitted by Children's Hospital, we are in full agreement with the facts and opinions as stated and we endorse the approach preferred by Children's Hospital.

As you may know, the Central Valley of California is unique from other areas of the state and nation in its healthcare delivery system. Children's Hospital provides high-quality, specialized pediatric care to all children throughout the vast Central Valley, notwithstanding its highly disproportionate share of Medicaid patients. The number of infants born prematurely or with serious complications requiring the specialty and sub-specialty care that is only available through Children's Hospital would be significantly reduced if the services provided in Merced and Hanford are discontinued. Furthermore, Children's would like to explore the possibility of expanding offsite NICU services to other community hospitals in our districts in order to improve access to care throughout the Valley, but this scenario cannot even be discussed without the proposed change in the existing rule.

We respectfully encourage the adoption of the second option described in the request for comment, that is, to change the national Medicaid regulations to exempt a hospital participating in the Medicare program under Sec. 1886(d)(1)(B)(iii) of the Act, the inpatients of which are predominantly under 18 years of age, from the location provisions of Sec. 413.65(d)(7) where all other provisions of Sec. 413.65 have been met.

We appreciate the time and attention given to resolving this rare, if not unique, circumstance and we thank you for your consideration of our views.

Sincerely,

George Radanovich
Member of Congress

Dennis Cardoza
Member of Congress

Devin Nunes
Member of Congress

Jim Costa
Member of Congress

205-O

Congress of the United States
Washington, DC 20515

June 23, 2005

NT

Hefley
Hastert
Walz
Treitel

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20515

Dear Dr. McClellan,

We are pleased to submit our comments on the provisions on New Technology Applications in the fiscal year 2006 Medicare hospital inpatient prospective payment system (IPPS) proposed rule. In the interests of Medicare beneficiaries' access to a breakthrough improvement in hip replacement technology and savings to the Medicare program, we strongly urge you to consider new technology add-on payments for the Trident Acetabular System for Hip Arthroplasty.

We believe that Trident hip replacements hold particular promise for younger, active Medicare beneficiaries because the system utilizes a patented alumina ceramic-on-ceramic bearing surface rather than metal-on-plastic or metal-on-metal surfaces. Alumina is the hardest material next to diamond. The patented Trident design also captures the ceramic insert in a titanium sleeve. Taken together, it is our understanding that these innovations increase the strength of the ceramic insert by 50 percent over other designs, make the device extremely hard and scratch resistant, produce better lubrication, produce a low coefficient of friction and excellent wear resistance, result in no potential for metal or ion release, and result in less alumina particle release, thus significantly reducing the need for future hip replacements or revisions. It is our understanding that these results demonstrating a substantial improvement over existing hip replacement technologies come from extensive randomized, controlled clinical studies that meet CMS's high standards for evidence collection.

From reviewing your agency's response to Trident's add-on payment application, it appears that the concerns were based primarily on Trident's having been on the market for just over two years, which means that the two-to-three year timeframe when CMS considers a product to be "new" would end halfway through FY 2006. It is our understanding, however, that CMS has approved add-on payments for other technologies, such as a cardiac resynchronization therapy with defibrillator (CRT-D), when their period of "newness" also ended midyear. We would ask that CMS apply similar flexibility in Trident's case.

We believe that in doing so, your agency would be living up to Congress's intent in establishing IPPS add-on payments—to ensure that Medicare beneficiaries would have access to

technologies that represent a significant improvement over existing technologies, and in the case of Trident, may significantly reduce the need for and risks associated with a second hip replacement or revision.

Thank you for your attention to our comments. We look forward to hearing from you.

Sincerely yours,

Senator Carl Levin

Senator Debbie Stabenow

Rep. Fred Upton

Rep. John Dingell

Rep. Mike Rogers

Rep. Dale Kildee

Rep. Dave Camp

Rep. Joe Schwarz, M.D.

Rep. Thaddeus McCotter

Rep. Sander Levin

Rep. Vernon Ehlers

206

ERNST & YOUNG

Ernst & Young
Phillips Point, West Tower
Suite 1201
777 South Flagler Drive
West Palm Beach, Florida 33401

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

WI/DC

Hefter
Hartstein
Miller

September 20, 2004

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

Dear Ms. Miller:

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

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

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

Very Truly Yours,

Ernst + Young LLP

cc: Palm Beach County Hospitals

EXHIBIT B

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

EXHIBT 1

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

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

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

EXHIBIT B

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

EXHIBT 1

AS-PUBLISHED WAGE INDEX FACTOR FOR MIAMI, FLORIDA

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

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

EXHIBIT B

EXHIBT 2

CORRECTED WAGE INDEX FACTOR FOR WEST PALM BEACH, FLORIDA

100002	48424 - West Palm	$ 72,073,336	3,257,274	$22.1269	$842,615,230	30,887,669	$27.2800
100010	48424 - West Palm	$ 82,321,390	3,054,761	$26.9486	$842,615,230	30,887,669	$27.2800
100080	48424 - West Palm	$ 101,446,035	3,848,541	$26.3596	$842,615,230	30,887,669	$27.2800
100130	48424 - West Palm	$ 11,746,614	514,472	$22.8324	$842,615,230	30,887,669	$27.2800
100168	48424 - West Palm	$ 101,043,022	3,873,399	$26.0864	$842,615,230	30,887,669	$27.2800
100176	48424 - West Palm	$ 47,390,672	1,588,552	$29.8326	$842,615,230	30,887,669	$27.2800
100234	48424 - West Palm	$ 26,222,780	1,038,220	$25.2574	$842,615,230	30,887,669	$27.2800
100253	48424 - West Palm	$ 41,095,416	1,683,888	$24.4051	$842,615,230	30,887,669	$27.2800
100258	48424 - West Palm	$ 71,020,975	2,227,952	$31.8772	$842,615,230	30,887,669	$27.2800
100262	48424 - West Palm	$ 48,091,426	1,821,960	$26.3954	$842,615,230	30,887,669	$27.2800
100268	48424 - West Palm	$ 43,529,919	1,459,322	$29.8289	$842,615,230	30,887,669	$27.2800
100269	48424 - West Palm	$ 35,356,906	1,396,250	$25.3228	$842,615,230	30,887,669	$27.2800
100275	48424 - West Palm	$ 24,976,758	1,027,601	$24.3059	$842,615,230	30,887,669	$27.2800
100287	48424 - West Palm	$ 52,423,925	1,857,499	$28.2229	$842,615,230	30,887,669	$27.2800
100288	**33124 - Miami**	**$ 83,876,056**	**2,237,978**	**$37.4785**	**$842,615,230**	**30,887,669**	**$27.2800**
		$ 842,615,230	30,887,669				

Calculated AHW	$27.2800
Published West Palm AHW - Tables $4A_1$ & $4A_2$	$26.4833
Difference	$ 0.7967
National AHW (August 11, 2004 Federal Register)	$26.3570
Calculated WIF	1.03502
Published West Palm WIF - Tables $4A_1$ & $4A_2$	1.00460
Difference	0.03042

EXHIBIT B

EXHIBT 2

CORRECTED WAGE INDEX FACTOR FOR MIAMI, FLORIDA

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

Calculated AHW	$26.0142
Published Miami AHW - Tables $4A_1$ & $4A_2$	$26.4214
Difference	$(0.4072)
National AHW (August 11, 2004 Federal Register)	$26.3570
Calculated WIF	1.00698
Published Miami WIF - Tables $4A_1$ & $4A_2$	1.00220
Difference	(0.01521)

EXHIBIT B

08-30-2004 12:13 FROM:

Exhibit 3

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St. Suite 4T20
Atlanta, Georgia 30303-8909
(404) 562-7242

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

August 30, 2004

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

Your Reference: IPPS Hospitals in Palm Peach County

Dear Mr. Smith:

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

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

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

Sincerely,

Michael Taylor
Health Insurance Specialist
Division of Medicare Operations

EXHIBIT B

Exhibit 3

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

August 30, 2004

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

Your Reference: IPPS Hospitals in Palm Peach County

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

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

Sincerely,

Michael Taylor
Health Insurance Specialist
Division of Medicare Operations

EXHIBIT C

St. Mary's

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

Palm Beach

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

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NALTH NATIONAL ASSOCIATION OF LONG TERM HOSPITALS
150 York Street, Stoughton, Massachusetts 02072 (781) 344-0600 Boston line (617) 364-4850 FAX (781) 344-0128

LTC /DRG- HUDSON
MB/EX. HOSPS - ELLINGTON
KNIGHT
Seifert
DRG/WEIGHTS - KRAEMER
TREITEL
~~BECKA~~
HUE
Hefter
Hartstein
TRANSFERS - WALZ
HART

June 22, 2005

By Overnight Mail

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

Re: Comments on Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates - - LTCH-DRGs

Dear Dr. McClellan:

The National Association of Long Term Hospitals ("NALTH") is pleased to present the following comments on the Centers for Medicare & Medicaid Services ("CMS") proposed rule on "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates" that was the subject of a notice of proposed rulemaking ("NPRM") that appeared in the Federal Register on May 4, 2006, at 70 Fed. Reg. 23305.

As threshold matters NALTH wishes to endorse the proposal to rebase the **excluded hospital market basket**. NALTH invites changes to the long-term care hospital prospective payment system (LTCH-PPS), such as the proposed rebase of the hospital market basket which improves payment accuracy and predictability. For similar reasons, explained below, NALTH strongly recommends adjustments to the **proposed LTCH-DRG weights**. The proposed rule, contains changes in LTCH-DRG weights will result in an approximate 4.7% reduction in FY 2006 payments to LTCHs. A reduction in payments of this magnitude exceeds the 3.4% LTCH-PPS update percentage which was adopted by the Secretary on May 6, 2005.

NALTH has asked the Lewin Group to review the proposed reduction in LTCH-PPS weights for FY 2006. One finding of the Lewin Group is that the impact of using

the Version 23 DRG grouper is to reduce payments to LTCHs by 6.74% when the December FY 2004 MedPAR data is used with both the Version 22 and Version 23 groupers.[1] NALTH believes reduction in payment of the magnitude reported by the Secretary in the preamble to the proposed rule and those found by the Lewin Group results in an unacceptable level of instability in the LTCH-PPS. Prospective payment systems are supposed to provide certainty in payment levels so that hospitals can engage in a predictable financial planning process. We emphasis that in February of this year the Secretary proposed an LTCH update rule which was approved on May 6, 2005. The proposed LTCH-PPS update rule contained FY 2006 Medicare spending assumptions based on LTCH-DRG weights which were no different than the FY 2005 weights. LTCHs should, within reasonable parameters, be able to rely upon payment projections set forth in the LTCH specific update rule. NALTH believes these factors, together with the issues, created by CMS instituting a new billing system in FY 2004 which resulted in an atypical level of suspensions of LTCH claims should lead the Secretary to moderate the reduction in LTCH-PPS weights contained in the Notice of Proposed Rulemaking. NALTH believes the significant reduction in proposed LTCH-PPS weights results from distortions in claims data which are reflected in the FY 2004 MedPAR file. During FY 2004 the Centers for Medicare & Medicaid Services (CMS) converted the Medicare hospital billing system from the Arkansas Part A Standard System (APASS) to the Fiscal Intermediary Shared System (FISS). Because the FISS system is not designed to reflect LTCH-PPS adjustments a significant segment of payments to LTCH providers were suspended. Payments and related charges for erroneously suspended claims are not included in the December version of the FY 2004 MedPAR file used to calculate the proposed FY 2006 proposed weights. Payment of these claims for some hospitals did not occur until April of 2004. Accordingly, while NALTH endorses and recommends the use of more currently available MedPAR data, a recalibration of LTCH-DRG weights based on the March 2004 MedPAR file will not adequately address NALTH's concerns.

NALTH also is expressing several concerns related to the proposal to broadly expand the **IPPS transfer rule**.

Proposed LTCH-PPS Weights

A. FY 2004 MedPAR file issues

NALTH wishes to thank CMS for making available the FY 2004 MedPAR file it used to calculate proposed FY 2006 LTCH-PPS weights. NALTH tested the accuracy of this data on a NALTH member which has a relatively high level of Medicare discharges (1,165) recorded in the data. The MedPAR data was of sufficient specificity that the test hospital[2] could identify each Medicare beneficiary recorded in the MedPAR file and compare this data with hospital financial records on a patient specific basis. Patients listed in the MedPAR file also were compared with patients discharged through December 2004 as the LTCH proposed weights are based on the December 2004

[1] NALTH will, upon request, provide CMS with all Lewin Group simulations referred to in this comment letter.

[2] Medicare Provider No. 22-2027

MedPAR file. This review demonstrated that the proposed 2006 LTCH-DRG weights exclude charges that should have been included, resulting in proposed weight calculations that are lower than they should be. The 2004 MedPAR data fails to properly account for the interrupted stay cases and cases where Medicare benefits have been exhausted[3] ("crossover" cases) through December of 2004. At least two major types of errors are present in CMS' 2004 MedPAR file: 1) errors in the recording and calculation of cases involving interrupted stays and 2) errors in the recording of cases where Medicare benefits were exhausted.

B. Errors Related to Interrupted Stays

By way of example, the NALTH member hospital which tested MedPAR's fiscal year 2004 data from which the proposed 2006 LTCH-DRG weights were derived found that 102 interrupted stays were treated as follows in the FY 2004 MedPAR file.

1. 44 interrupted stays are correctly counted.

2. For 36 interrupted stays, CMS did not record the second admission. As a result, the length of stay and related charges are erroneously recorded in the MedPAR data and are lower than actual days and charges per discharge. Ten of the 36 cases were erroneously recorded as less than a seven day stay. Accordingly, these cases were erroneously excluded from the calculation of FY 2006 LTCH-PPS weights.

3. Twenty (20) interrupted stays who were discharged prior to December 2004 were not included in the MedPAR data.

4. For 2 interrupted stays the MedPAR data completely ignored interrupted stay status and, reflects 4 cases although the hospital was paid for 2 Medicare cases.

Thus, only 43 % of the LTCH's interrupted stays are accurately recorded and calculated in the MedPAR file. More than half or 57 % are not.

C. Errors Related to Medicare Benefits Exhausted

This same hospital had 35 Medicare beneficiaries for which Medicare benefits were exhausted which were discharged by December 2004. Only 17 of these cases were recorded in the MedPAR file. Sixteen were not recorded, even though the Medicare program paid for these cases as discharges in 2004. The 35 cases for which Medicare benefits were exhausted in 2004 represent cases in the higher range insofar as charges are concerned. Thus, only 49 percent of the LTCH's discharges related to the exhaustion of Medicare benefits in 2004 are accurately recorded in the 2004 MedPAR file.

---

[3] CMS records the exhaustion of Part A benefit days as "discharge" for payment purposes. See 42 C.F.R. §413.40(a)(3).

D. Errors in Recording Charges

For 84 cases, MedPAR data lists the charges incorrectly. The actual charges recorded by the hospital were approximately $4,626,000 while MedPAR lists the charges as only $4,390,000. Thus, $236,000 in charges are not recorded in the 2004 MedPAR file. The average amount by which the MedPAR understates the LTCH's charges in 2004 is $2,800 per case or 5.38%.

E. Effect of Conversion from the APASS to FISS Billing System

During FY 2004 CMS transitioned fiscal intermediaries from the APASS to FISS billing system. This transition was occurred on a staggered time basis during FY 2004. In the Fall of 2003 NALTH advised CMS of a high level of suspended claims which were occurring due to the transition. Claims appeared to be suspended as a result of the FISS system not reflecting payment adjustments which are specific to the LTCH-PPS and long-term care hospitals in general. NALTH conducted a survey of its members concerning these issues and relayed notice of these issues to CMS, including NALTH's concerns that FISS was creating errors in calculating payments. NALTH specifically requested the CMS address a high number of suspended claims related to interrupted stay cases. On January 16, 2004, CMS responded to this issue by acknowledging the problem, but stating it was an error in the common working file which was to be addressed in January 2004. The hospital which analyzed MedPAR data for NALTH did not receive payment for suspended claims until April of 2004. Thus, although Medicare patients were discharged in and prior to December 2004 and should have had their charges reflected in the December version of the 2004 MedPAR file. These charges were not included until April of 2005.

F. Review and Recalculation of Weights by the Lewin Group

NALTH identified a peer group of 29 LTCHs with similar characteristics to its test hospital, in terms based on a review of bed size, length of participation in the Medicare program, freestanding status and our understanding of the level of participation in the Medicaid program. The Lewin Group simulated the potential impact of incorrectly captured interrupted stay and "crossover" case data on the proposed LTCH-PPS weights assuming the same magnitude of error exists for all 29 hospitals. The Lewin Group therefore assumed the FY 2004 MedPAR file reflected a 35% (36 of 102) error rate for interrupted stay cases and a 46% error rate (16/35) for "crossover" cases for the 29 hospitals. The Lewin Group simulated the impact the errors affecting this small group of LTCHs would have on the proposed weights by recalculating the FY 2006 weights to correct for these errors. The Lewin Group also performed these same simulations for all LTCHs and used the following methods to conduct these simulations.

Interrupted Stays

1. Calculate the percent of cases by DRG with interrupted stay problems for the identifying hospital.

2. Calculate the impact on total charges and length of stay for the incorrect interrupted stays for the identifying hospital. That is, determine the extent to which charges and length of stay are under-reported on the MedPAR file, because only part of the stay is captured.

3. For 29 similar hospitals, adjust the lowest-cost cases in the same DRGs and for the same proportion of cases as found in Step 1. The adjustment to be applied to the charges and length of stay for these cases was found in Step 2.

4. Recalculate the weights.

5. Conduct same analysis as described in Steps 1 through 4, except use all hospitals instead of the 29 similar hospitals.

"Crossover" Stays

1. Calculate the percent of "crossover" cases by DRG omitted from the 2004 MedPAR file for the test hospital.

2. For crossover cases in the 29 similar hospitals, replicate these cases in the MedPAR file until the total number of crossover cases equals the number of cases that would have existed in the file had there not been any exclusions.

3. Recalculate the weights.

4. Conduct same analysis as described in Steps 1 through 4, except use all hospitals instead of the 29 similar hospitals.

Findings by the Lewin Group indicate the impact of the omission of "crossover" stays imputed to the 29 LTCHs is significant on the weights.

The impact of the omission of "crossover" stays is significant on the weights. Tables 1 and 2 show the estimated impact on the weights for select high-volume LTC-DRGs when applying the "crossover" problem to all LTC hospitals. Using a 2 percent change in weights as a cutoff, the Lewin Group found more LTC-DRGs with reductions in weights than with increases. Although the net effect across all LTC-DRGs is zero, the impact of the "crossover" problem has a large redistributive effect for specific LTC-DRGs and hospitals that specialize in specific cases.

Table 3 shows the impact of omitted crossover stays when the test hospital cases are applied to only 29 similar hospitals. There are big changes in weights for a select few LTC-DRGs. Therefore, the Lewin Group found a redistributive effect of the crossover problem, which could destabilize payments for hospitals that specialize in treating specific patients.

Table 4 shows the impact of the interrupted stay issue on those LTC-DRGs where the change in weight was greater than +1% or less than -0.5%. The results shown in Table 4 are based on the simulation where we used the test hospital's experience and

applied it to 29 comparable hospitals. In this case, there is also a redistributional impact on high-volume LTC-DRGs, including 452 and 316.

Table 5 shows the impact of the omission to properly account for interrupted stays problem when the extent of the problem observed for the test hospital extended to all hospitals. Only a few LTCH-DRG weights change in a material way several change significantly including high-volume LTCH-DRGs. For example, The LTCH-DRG weight for LTCH-DRG 452 (1495 cases) is estimated to increase by almost 41%. LTCH-DRG 130 (1438 discharges) is estimated to increase by 11 percent.

The foregoing analysis demonstrates that errors which NALTH found in the December version of the 2004 MedPAR file when inputted to a small peer group of hospitals has a distributive effect which is significant on FY 2006 LTCH-DRG weights. As we have indicated above, we are not confident that basing the final weights on a later version, i.e. March version of the 2004 MedPAR file will adequately address this issue, as some LTCH payments which were suspended due to FISS system conversion issues were not made until after that date.

G. Sound Equitable Bases Exists for the Secretary to Apply Principles of Budget Neutrality or a "Dampening Policy"

The preamble to the proposed rule states the impact of proposed weights is to reduce payments to LTCHs by 4.7%. The Lewin Group has estimated a higher negative impact of 6.7%. NALTH believes that the interest of stability of payment under prospective payment systems as well as apparent errors in the MedPAR data should point the Secretary to moderating the effect of the proposed FY 2006 weights. With respect to acute hospitals subject to IPPS the Secretary found that the proposed DRG grouper (Version 23) would resulted in an average IPPS DRG weight of 1.47%. In order to "normalize" payment rates and to conform to Section 1886(d)(4)(C)(iii) of the Act which requires that IPPS weights be established in a budget neutral manner, in the proposed rule the Secretary has multiplied all DRG weights by 1.47 so that the average weight is the same under grouper Versions 22 and 23. In this manner the Secretary is proposing to ensure that overall payments are the same under either DRG grouper. See 70 *Fed. Reg.* 23338. (May 4, 2005). NALTH understands that Section 1886(d)(4)(C)(iii) applies to hospitals subject to the IPPS and not to LTCHs. With respect to the LTCHs the Secretary has construed the two statutes which established the LTCH-PPS to authorize, but not require, the establishment of LTCH-DRG weights in a budget neutral manner.

> We do not believe that section 123 of the Pub. L. 106-113 requires that the annual update to the LTC-DRG classifications and relative weights maintain budget neutrality. . . . Under section 123 of Public Law 106-113 and section 307 of Publicl [sic] Law 106-554, the Secretary generally has broad authority in developing the LTCH PPS, including whether and how to make adjustments to LTCH PPS payments. Specifically, section 307(b)(1) of Public Law 106-554 provides that "the Secretary shall examine and may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic classification, outliers, updates,

and a disproportionate share adjustment [***]." We will consider whether it is appropriate for use [sic] to propose a future revision to the LTCH PPS regulations at subpart O of 42 CFR to maintain budget neutrality in the annual update of some aspects of the LTCH PPS under our broad discretionary authority under the statute to provide "appropriate adjustments to the long-term hospital payment system."

69 F.R. 48999-49000 (August 11, 2004).

The Secretary has, in fact, exercised his perceived authority to act in a budget neutral manner by establishing an annual budget neutrality adjustment which is applied during the LTCH-PPS phase-in period. In discussing the potential of a geographic reclassification procedure for LTCHs LTCH-PPS in this rulemaking the Secretary has stated it would be necessary to "evaluate the effect of a reclassification provision in terms of budget neutrality." (emphasis added) 70 F.R. 24200 (May 6, 2005). In the instant situation significant equitable considerations exist for the Secretary to exercise his discretion in a manner which is consistent with the IPPS budget neutrality procedure. These considerations include:

- The LTCH final update rule as proposed in February of 2005 and adopted on May 6, 2005 contained projected increased FY 2006 Medicare spending amounts which LTCHs rightly should be able to rely upon in their financial planning.
- The proposed reduction of 4.7% exceeds the FY 2006 LTCH update percentage. It therefore may destabilize LTCH financial planning process based on good faith reliance on the LTCH-PPS update rulemaking process.
- It is appropriate to avoid significant instability in payment during the phase-in of the LTCH-PPS.

In addition, NALTH wishes to note that its reading of the two relevant statutes which established the LTCH-PPS point to a Congressional intention that LTCH-PPS components, including the establishment of weights are to be established in a budget neutral manner, similar to the way weights are recalibrated for hospitals which are subject to the IPPS. The first of these laws is Section 123(a)(1) of the Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106-113. This law provides that the LTCH-PPS shall include a DRG based patient classification system that, inter alia, "shall maintain budget neutrality." The second law, Section 307(b)(1) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554, by its terms modifies Section 123 of the BBRA to, among other things, provide the Secretary with authority to make adjustments to DRG weights. NALTH reads Section 307(b)(1) as constituting an amendment to Section 123(a)(1) of the BBRA. Whether these statutes are read as a single law or part of the same statutory scheme we are of the view that the requirement to maintain budget neutrality attaches to each of the adjustments supplied by Section 307(b)(1) of BIPA and for this additional reason the Secretary should make a budget neutrality adjustment to the proposed FY 2006 weights to assure the same level of payments projected in the FY 2006 LTCH update regulation.

Alternatively, CMS should consider adopting a **dampening policy** similar to the policy applied by CMS to APCs under the outpatient prospective payment system in the 2003 final outpatient prospective payment rule. CMS adopted a dampening policy to moderate reductions in payments that otherwise would have occurred under the proposed 2003 outpatient prospective payment system rule. See 67 *Fed. Reg.* 66750 (November 1, 2002). The dampening policy adopted in the final rule mitigated the reduction in payment rates as follows:

- If median cost of an APC would have fallen by 15 percent or more between 2002 and 2003, CMS decreased the reduction in the median cost by one half of the difference between the value derived from the claims data and 15 percent.
- APCS which contained procedures involving devices that represented a high portion of the overall costs (80 percent or more) were adjusted to determine the weighted average cost of the device, the adjusted cost of the device was then added to the unadjusted cost of the procedure, to calculate the total cost of the procedure.

In addition, CMS used more recent data and carefully selected claims to use in relative weight calculations Id. at 66750 and 66764. A similar dampening policy easily could be and should be considered for application to LTCH-DRG weights.

H. Postacute Care Transfers

NALTH is concerned about CMS' proposal to expand the number of DRGS that are subject to the transfer policy from 30 DRGs to include approximately 223 DRGs. Although technically the postacute transfer rule does not directly affect LTCHs, it indirectly affects LTCHs where an acute care hospital appropriately transfers a patient to an LTCH setting early in the patient's stay based on medical necessity and the clinical judgment of the patient's treating physician as to the best setting for the patient at that time.

The proposed expansion of the transfer policy presents a number of issues. First, the proposed transfer policy is unfair because an acute care hospital would not know or have any reason to know that a patient received postacute care such as SNF care or home health services within 3 days of discharge if the acute care hospital did not include such postacute care in its discharge planning for the patient. For example, an acute care hospital may in good faith discharge a patient to his/her home without any orders or recommendations for postacute care. A decision could subsequently be made by e.g., a family member or the patient's physician, to obtain homecare services within 3 days of discharge or to admit the patient to a SNF for rehabilitation services, without any notice of the same provided to the acute care hospital. The proposed rule creates an irrebuttable presumption that the acute hospital knew or should have known about such postacute care, where the acute hospital would not have known or had any reason to know. The proposed rule presents serious due process concerns in a situation where an acute care hospital would bill the full DRG for the patient and then be subject to an overpayment action. In light of these considerations, because the acute hospital would not know or

have any reason to know that the patient received postacute care subject to the transfer rule where an acute hospital's discharge planning records show that the patient was discharged to a site where the transfer rule does not apply, CMS should provide an acute hospital with a waiver of liability in such situations. The waiver of liability should be provided irrespective of whether the number of DRGs subject to the transfer rule remains at 30 or the transfer rule is expanded to include additional DRGs.

Second, the proposed expansion of the postacute care transfer policy to include 223 DRS amounts to a penalty imposed on acute care hospitals for appropriately discharging a patient to a postacute setting such as a LTCH, SNF, or home under a written plan of care for home health services to be provided within three days of discharge. All hospitals, whether acute or LTCHs engage in a discharge planning process in accordance with federal and state law. CMS should not penalize acute care hospitals by imposing a statistical methodology for the purpose of expanding the transfer policy without any examination of the clinical basis for such transfers.

Third, CMS' proposed policy distorts the average of cases that are to be paid less than costs by including cases that legitimately should be discharged to postacute care settings in the postacute care transfer policy.

Finally, CMS' proposed methodology for changing the statistical basis on which DRGs are selected to be subject to the postacute care transfer rule appears to be unrelated to CMS' policy goal in adopting the postacute transfer rule -- to identify cases where patients are transferred from an acute care hospital to a postacute care setting early in the patients' stay for the purpose of minimizing costs while obtaining full payment of the DRG. While the proposal would reduce payments to acute care hospitals by $880 million dollars there is no indication that the proposed reduction in fact relates to inappropriate transfers.

For the above reasons, NALTH urges CMS to refrain from expanding the postacute care transfer policy. NALTH supports the position of the American Hospital Association on the issue of the proposed postacute care transfer policy.

NALTH thanks the Secretary for his consideration of these comments.

Sincerely,

Edward D. Kalman
General Counsel

Table 1: Selected High-Volume LTC-DRGs with > 2% Increase in Weights due to Omission of "Crossovers" (Test Hospital Cases Applied to All LTCHs)

DRG	Dichsgs	Descriptions	Lewin Estimate Proposed Weight	Lewin Exhausted Stay Model (Adjusted)	Difference Exhausted Stays
90	127	SIMPLE PNEUMONIA & PLEURISY AGE >17 W/O CC	0.5502	0.5838	6.1%
430	2401	PSYCHOSES	0.5620	0.5914	5.2%
76	1763	OTHER RESP SYSTEM O.R. PROCEDURES W CC	2.5438	2.6419	3.9%
321	116	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W/O CC	0.5595	0.5786	3.4%
20	408	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.0575	1.0863	2.7%
87	5065	PULMONARY EDEMA & RESPIRATORY FAILURE	1.1467	1.1779	2.7%
440	370	WOUND DEBRIDEMENTS FOR INJURIES	1.3325	1.3630	2.3%
429	422	ORGANIC DISTURBANCES & MENTAL RETARDATION	0.6390	0.6528	2.2%
264	175	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W/O CC	0.9728	0.9935	2.1%

Table 2: Selected High-Volume LTC-DRGs with > 2% Reduction in Weights due to Omission of "Crossovers" (Test Hospital Cases Applied to All LTCHs)

DRG	Dichsgs	Descriptions	Lewin Estimate Proposed Weight	Lewin Exhausted Stay Model (Adjusted)	Difference Exhausted Stays
239	262	PATHOLOGICAL FRACTURES & MUSCULOSKELETAL & CONN TISS MALIGNANCY	0.7454	0.7307	-2.0%
256	495	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES	0.7804	0.7650	-2.0%
287	402	SKIN GRAFTS & WOUND DEBRID FOR ENDOC, NUTRIT & METAB DISORDERS	1.1193	1.0968	-2.0%
238	1820	OSTEOMYELITIS	0.8191	0.8020	-2.1%
12	5843	DEGENERATIVE NERVOUS SYSTEM DISORDERS	0.7007	0.6857	-2.1%
126	596	ACUTE & SUBACUTE ENDOCARDITIS	0.8281	0.8090	-2.3%
296	1203	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	0.7308	0.7137	-2.3%
331	415	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W CC	0.7902	0.7713	-2.4%
89	4862	SIMPLE PNEUMONIA & PLEURISY AGE >17 W CC	0.7087	0.6916	-2.4%
462	5174	REHABILITATION	0.5799	0.5656	-2.5%
14	433	INTERCRANIAL HEMORRHAGE OR STROKE WITH INFARCT	0.7774	0.7576	-2.5%
204	426	DISORDERS OF PANCREAS EXCEPT MALIGNANCY	0.9644	0.9395	-2.6%
249	6290	AFTERCARE, MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	0.6580	0.6410	-2.6%
316	2384	RENAL FAILURE	0.8204	0.7981	-2.7%
127	3735	HEART FAILURE & SHOCK	0.6917	0.6712	-3.0%
138	300	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W CC	0.6323	0.6131	-3.0%
277	1921	CELLULITIS AGE >17 W CC	0.6337	0.6141	-3.1%
92	268	INTERSTITIAL LUNG DISEASE W CC	0.6816	0.6596	-3.2%
78	301	PULMONARY EMBOLISM	0.6924	0.6699	-3.3%
294	814	DIABETES AGE >35	0.7281	0.7040	-3.3%
704	281	Low Volume Quintile 4	1.1647	1.1245	-3.5%
172	477	DIGESTIVE MALIGNANCY W CC	0.8272	0.7966	-3.7%
242	364	SEPTIC ARTHRITIS	0.7932	0.7637	-3.7%
243	620	MEDICAL BACK PROBLEMS	0.6119	0.5888	-3.8%
248	364	TENDONITIS, MYOSITIS & BURSITIS	0.6574	0.6323	-3.8%
82	641	RESPIRATORY NEOPLASMS	0.7439	0.7133	-4.1%
88	5020	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0.6662	0.6373	-4.3%
101	367	OTHER RESPIRATORY SYSTEM DIAGNOSES W CC	0.8088	0.7703	-4.8%
203	272	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS	0.7373	0.6584	-10.7%

Table 3: Selected High-Volume LTC-DRGs with > 2% Change in Weights due to Omission of "Crossovers" (Test Hospital Cases Applied to 29 Comparable LTCHs)

DRG	Dichsgs	Descriptions	Lewin Estimate Proposed Weight	Lewin Exhausted Stay Model (Adjusted)	Difference Exhausted Stays
90	127	SIMPLE PNEUMONIA & PLEURISY AGE >17 W/O CC	0.5502	0.5937	7.90%
15	156	NONSPECIFIC CVA & PRECEREBRAL OCCULUSION WITHOUT INFARCT	0.8099	0.8537	5.40%
413	137	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W CC	0.8758	0.9216	5.23%
701	383	Low Volume Quintile 1	0.5025	0.5246	4.40%
20	408	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.0575	1.1035	4.35%
703	369	Low Volume Quintile 3	0.7922	0.8217	3.72%
403	345	LYMPHOMA & NON-ACUTE LEUKEMIA W CC	0.8937	0.9194	2.87%
430	2401	PSYCHOSES	0.5620	0.5748	2.29%
18	327	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	0.7545	0.7708	2.16%
521	38	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	0.4561	0.4470	-2.01%
13	111	MULTIPLE SCLEROSIS & CEREBELLAR ATAXIA	0.7003	0.6858	-2.08%
280	185	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W CC	0.6799	0.6635	-2.40%
203	272	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS	0.7373	0.6871	-6.81%
321	116	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W/O CC	0.5595	0.5213	-6.82%

Table 4: Selected High-Impact LTC-DRGs Due to Interrupted Stay Issue (Test Hospital Cases Applied to 29 Comparable Hospitals)

DRG	Dichsgs	Descriptions	Lewin Estimate Proposed Weight	Lewin Weights (Interrupted Stay Model)	Difference
18	327	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	0.7545	0.7925	5.0%
317	77	ADMIT FOR RENAL DIALYSIS	0.9993	1.0299	3.1%
452	1495	COMPLICATIONS OF TREATMENT W CC	0.9400	0.9674	2.9%
20	408	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.0575	1.0744	1.6%
490	68	HIV W OR W/O OTHER RELATED CONDITION	1.5826	1.5981	1.0%
15	156	NONSPECIFIC CVA & PRECEREBRAL OCCULUSION WITHOUT INFARCT	0.8099	0.8058	-0.5%
27	32	TRAUMATIC STUPOR & COMA, COMA >1 HR	0.9507	0.9458	-0.5%
316	2384	RENAL FAILURE	0.8204	0.8161	-0.5%
236	123	FRACTURES OF HIP & PELVIS	0.6475	0.6431	-0.7%

Table 5: Selected High-Impact LTC-DRGs Due to Interrupted Stay Issue (Test Hospital Cases Applied to All LTC Hospitals)

DRG	Dichsgs	Descriptions	Lewin Estimate Proposed Weight	Lewin Weights (Interrupted Stay Model)	Difference
452	1495	COMPLICATIONS OF TREATMENT W CC	0.9400	1.3218	40.61%
18	327	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	0.7545	1.0342	37.07%
317	77	ADMIT FOR RENAL DIALYSIS	0.9993	1.1188	11.95%
20	408	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.0575	1.1821	11.78%
130	1438	PERIPHERAL VASCULAR DISORDERS W CC	0.6824	0.7552	10.67%
316	2384	RENAL FAILURE	0.8204	0.8043	-1.97%
245	54	BONE DISEASES & SPECIFIC ARTHROPATHIES W/O CC	0.4998	0.4896	-2.04%
475	13171	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	2.0745	2.0257	-2.35%

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June 22, 2005

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

TRANSFERS - WALZ
HART

WI/Bd - MILLER

Re: File Code CMS-1500-P

Comments to Proposed Rule 70 FR 23306, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

We appreciate the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the May 4, 2005 Federal Register.

DRG Reclassifications

We agree with the proposal to split DRG 209, Major Joint and Limb Reattachment Procedures of Lower Extremity, into two new DRGs based on replacement or revision. As noted in the proposed rule, the Provider's data supports the referenced MedPAR data that hip and knee revisions require more resources than the initial replacement procedure. The proposed change reflects the disparity in required resources.

We agree with CMS's intention to reimburse for multiple stents associated with DRGs 516, 517, 526, and 527 (516 and 526 proposed to be replaced with four new DRGs). Currently the DRG classification of cases involving coronary stents does not provide adequate reimbursement relative to the resources provided. As noted in the proposed rule, this issue was addressed in the FY 2005 IPPS rule. According to CMS's proposed plan, the earliest reimbursement for multiple stents will occur is FY 2008—when FY 2006 MedPAR file is used to recalibrate weights. During this three year period, hospitals will be inadequately reimbursed for multiple stent procedures. We respectfully request the results of the proposed data collection be reviewed, and incorporated into the FY 2007 recalibration of weights.

Post Acute Care Transfers

We respectfully disagree with CMS's proposal to expand the DRG post-acute care transfer rule and recommend that these changes not be made at this time. While we recognize the statutory requirement for CMS to implement the policy, we firmly believe CMS's proposal is outside its statutory authority provided under Section 1886(d)(5)(J)(iv)(II) of the Social Security Act.

CMS has proposed two options for expanding the current policy. Option 1 is to subject all DRGs to the policy to provide consistent treatment to all DRGs. Option 2 is to modify the existing criteria, which would increase the number of DRGs subject to the policy from 30 to 231. CMS determined that these 231 remaining DRGs had three common characteristics that make them appropriate for inclusion in the policy:

- At least 2,000 total post-acute care transfer cases
- At least 20 percent of all cases in the DRG were discharged to post-acute care settings
- (At least) 10 percent of all discharges to post-acute care were prior to the geometric mean length of stay for the DRG

As a result of these characteristics, CMS proposes the following changes to the existing criteria for inclusion of the policy:

- Decreasing the minimum number of post-acute care transfer cases from 14,000 to 2,000
- Adding the requirement that at least 20 percent of the cases in the DRG are discharged to post-acute care

To determine the 231 of the possible 550 DRGs in the proposed rule subject to the policy, CMS excluded certain DRGs that have been deactivated, reported no volume, maintained a geometric mean length of stay less than 3.0 days, or had fewer than 100 short-stay transfer cases. In our opinion, option 2 essentially applies the policy to all DRGs as the excluded DRGs have either minimal or no impact upon the policy. Therefore, our comments are applicable to both options 1 and 2.

We disagree with the above revisions to the existing criteria. We believe these revisions are contrary to statutory language and not within the intent of Congress. Section 1886(d)(5)(J)(iv) of the Social Security Act provides the authority to expand the post-acute transfer rule as follows: "The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of....diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause." Further observation of 1886(d)(5)(J)(iii)(I) provides the referenced criteria necessary to expand the post-acute transfer rule.

Under section 1886(d)(5)(J)(iii)(I) of the Act, the DRGs subject to the policy are to be based upon two distinct criteria: "a high volume of discharges... **and** (emphasis added) a disproportionate use of post discharge services". We believe CMS's proposed changes do not satisfy both of these statutory requirements collectively.

It is necessary to first qualify the statutory term of "high volume." Since this term is not explicitly defined in the statutory language, the argument can be made that the Secretary has the authority to make this determination. In the selection of the original 10 DRGs for FY 1999, CMS established a threshold of 14,000 cases with discharges to post-acute care (63 FR 40975).

Although CMS was limited to identifying 10 DRGs in the original establishment of the policy, CMS identified 20 DRGs that had a "relatively large number of discharges to post-acute care."

The 14,000 cases were determined to be the lower limit established by CMS. We therefore argue that CMS has established a measurable standard for the definition of "high volume" with these 14,000 cases. By decreasing the case requirement from 14,000 to 2,000, CMS has arbitrarily and without justification significantly altered the definition for high volume of discharges and is not in agreement with Congressional intent of the policy.

Secondly, it is also necessary to qualify the statutory term of "disproportionate use." This term is also not defined in the statutory language, but the determination of the previous 30 DRGs could be used as a comparable basis. Of the initial 10 DRGs, excluding DRG 264 since it was paired with DRG 263, the lowest percentage of cases with post-acute care utilization was 45.3 percent (63 FR 40975). When the DRGs were expanded to 30, also ignoring the paired DRGs, the lowest percentage was 34.86 percent (68 FR 45409). We therefore recommend that this percentage be not less than 34.0 percent to be used as the threshold for determining a disproportionate use of post discharge services. In response to previous comments, CMS has stated that in many areas of Medicare program policy, a threshold of one standard deviation or less is employed in order to qualify for inclusion to or exclusion from certain provisions. CMS further stated that higher thresholds were deliberately chosen in order to ensure that only those DRGs with the highest rate of short-stay post-acute care transfers would be included in the policy. We believe that the proposed criterion to lower the threshold to 20 percent is a departure from previous CMS policies and not in accordance with the objective of the post-acute care transfer policy. Therefore, we believe that the common characteristic identified in this proposed rule does not represent a "disproportionate use" of post-acute care services prior to the geometric mean length of stay. By decreasing the threshold, CMS has arbitrarily and without justification significantly altered the definition for disproportionate use of post discharge services and is not in agreement with Congressional intent.

We also disagree with CMS's proposal to remove the criteria for DRGs not already included when there is at least a 7 percent decline in its geometric mean length of stay during the most recent 5-year period. In the proposed rule, CMS states that not all DRGs that experience an increase in post-acute care utilization also experience a decrease in the geometric mean length of stay, and some have even experienced an increase in the geometric mean length of stay. We believe the removal of this requirement is not within the intention and objective of the policy. Based upon the language in the FY 1999 Final Rule, the objective of the policy is to adjust inpatient PPS payments to account for reduced hospital lengths of stay due to a discharge to another setting. Therefore, if data demonstrates that post-acute care utilization for a specific DRG does not contribute to a significant decrease in the geometric mean length of stay, the DRG should not be subject to the policy.

Under section 1886(d)(5)(J)(iv)(II) of the Act, the Secretary is given authority to expand beyond 10 DRGs. We believe this section only authorizes the Secretary to add DRGs to the policy that meet the qualifications of high volume of discharges and disproportionate use of post discharge services as originally defined by the Secretary. This allows flexibility to include additional

DRGs based upon changes in hospital discharge patterns and use of post-acute care. We disagree with CMS that the intent of this section was to allow the Secretary to arbitrarily re-define the criteria. We request CMS to satisfactorily justify its proposed decision to re-define "high volume" of discharges from 14,000 to 2,000 (86 percent decrease) and "disproportionate use" of post discharge services from 34.86 percent to 20 percent (43 percent decrease).

As stated in MedPAC's 2003 report to Congress concerning the post-acute transfer payment policy, one of the factors that probably entered into Congress' decision to expand the inpatient transfer payment policy to post-acute care settings was the substantial decrease in the average length of stay (22 percent) for Medicare beneficiaries between 1990 and 1995.[1] The report further stated that the decrease in average length of stay was also accompanied by a dramatic growth in use and spending of post-acute care by Medicare beneficiaries. In addition, hospitals' Medicare inpatient margins had risen to record levels. An analysis by MedPAC and ProPAC demonstrated that "declines in inpatient lengths of stay were greatest for DRGs in which post-acute care use was most prevalent."

It is our belief, based upon the language in the statutes and reports from ProPAC, that Congress created the post-acute care transfer policy for those DRGs where there was a significant utilization of post-acute care settings upon discharge from a hospital. The mere presence of post-acute care discharges within a DRG does not constitute a significant utilization. While we understand that the Secretary believes CMS is given broad authority to expand the DRGs subject to the policy, we believe this does not provide a basis to arbitrarily include all DRG's without meeting the statutory criteria.

CMS estimates the impact of the proposed changes to be a 1.1 percent decrease in payments to hospitals overall or $880 million (70 FR 23661). In comparison, the estimated impact for FY 1999 related to the initial 10 DRGs was $480 million (63 FR 40977), and the FY 2004 expansion to 30 DRGs was $205 million (68 FR 45660). Cumulatively, this represents an overall impact in excess of $1.57 billion to hospitals in FY 2006 as a result of the post-acute care transfer policy. We understand expansion to the policy for those DRGs that meet statutory criteria. However, we believe the current proposal is beyond CMS's statutory authority, and the impact of the changes proposed by CMS will have substantial ramifications to fiscal policy for hospitals.

We also recommend CMS modify its current policy regarding the inclusion of both DRGs in a CC/non-CC pair. CMS's rationale for including the paired DRGs is to "preclude an incentive for hospitals to code cases in ways designed to avoid triggering the application of the policy, for example, by excluding codes that would identify a complicating or comorbid condition in order to assign a case to a non-CC DRG that is not subject to the policy." (70 FR 23416) By including all paired DRGs when one of the paired DRGs meets the criteria for inclusion in the policy, CMS is making the assumption that transfer payments for the CC DRG are always lower than the full payment for the non-CC DRG. Many of the CC DRGs that are subject to the special payment methodology have a greater transfer payment for a length of stay of one than the full payment for

[1] The Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2003, Page 44

the non-CC DRG. Under the special payment methodology, the DRG payment is based upon 50 percent of the full DRG plus the single per diem for the first day and 50 percent of the per diem for the remaining days up to the full DRG amount.

For example, paired DRGs 442 and 443 would be subject to the special payment methodology under the proposed rule. For DRG 442, the GMLOS is 6.0 with a relative weight of 2.5647. If, for example, a case has a length of stay of only one day (the lowest possible transfer payment), the transfer weight for DRG 442 (CC) would be 1.7098. However, this transfer weight is greater than the full relative weight for DRG 443 (non-CC) of .9911. As such, there is no incentive for hospitals to downcode this case to avoid triggering of the policy, as the hospital would have received a greater payment by using DRG 442. Therefore, if the CC DRG meets the criteria for inclusion in the policy, we recommend that CMS only include the non-CC of paired DRGs when the transfer weight of the CC DRG would be greater than the full DRG payment of the non-CC DRG. This recommendation would make the policy agree with CMS's rationale for the inclusion of paired DRGs and also exclude those DRGs that do not meet criteria.

Therefore, we provide the following recommendations to CMS with regards to the post-acute care transfer policy:

- Do not proceed with implementation of option 1 to apply the policy to all DRGs
- Do not modify the existing criteria under option 2 to determine DRGs subject to the policy
- Clearly define "disproportionate use" criteria to be at least 34.0 percent of the cases within the DRG are discharges to post-acute care. This definition is consistent with previous CMS policy.
- Modify the current policy of including paired DRGs if to only include the non-CC of paired DRGs when the transfer weight of the CC DRG would be greater than the full DRG payment of the non-CC DRG.

Wage Data

We disagree with the described formula used to calculate the wage index, described on page 23373. The formula used to allocate overhead costs to excluded areas (described in step four) has been changed from prior years to include line 8 and 8.01 in the denominator. The formula, while budget neutral from CMS's standpoint, has material impacts on the individual facility.

This formula change is not explained in the rule, and was not formally proposed. Without providing a better explanation of the formula change, we recommend the wage index calculation not reflect the revised formula stated in the proposed rule.

Hospital Quality Data

Although we agree that submission of electronically produced data for hospital quality reporting, as proposed in section V.B.1, is a laudable goal and has the potential to reduce the medical records review labor requirements; as submission requirements and data standards are created,

the perspective of the primary use of the data needs to be maintained. Will the primary focus of the electronic medical record be to collect data for reporting? Will it be to generate data for internal quality improvement? Or will the primary focus be to document care to best meet the needs of the patient. Unless one envisions only collecting measures that are applicable to a broad class of patients, condition-specific measures could clearly complicate data systems. With the current reliance on diagnosis codes for principal diagnoses derived from discharge abstracts to identify patients for measurement, many patients who are discharged with congestive heart failure may not present with this condition as the only problem at admission and may not be prospectively identified to capture all the detail to be reported in some collection format. Similarly, there is an implicit assumption that all acute myocardial infarction patients will present at admission with "classic", unambiguous symptoms. On the other hand, the requirements for community acquired pneumonia include the qualification that pneumonia was a working diagnosis at admission. Accommodation for exceptions needs to be included in the design of measurement requirements.

It is our understanding that many JCAHO-approved vendors had a difficult time meeting the timeframes for redesigning their data collection systems to meet the specification changes for calendar year 2005 discharges with only five months notice of the CMS-JCAHO requirements. Furthermore, system specifications were different for discharges in early 2004, late 2004, early 2005 and late 2005. In moving to direct electronically produced data at the hospital level, the number of entities developing these systems will expand substantially. CMS would need to make changes and expansions to the requirements at a much less frequent schedule (every 2-3 years?) and give longer advanced warning (release specifications one year in advance).

The specifications of the reliability criteria for the chart audit validation process are unclear. In section V.B.2 it states, "We will estimate the percent reliability based upon a review of five charts and then calculate the upper 95% confidence limit for the estimate." A 95% confidence limit for a sample size of five units will always be large. Is the intention to actually consider each data element of each chart to be an individual assessment of reliability? Does this mean that acute myocardial infarction will be given more weight in the process than pneumonia or congestive heart failure because there are more elements collected? Is there any differential weighting used for elements that are more subject to interpretation and innately have higher interrater variability? For example, more patients have potential contraindications for ACE-inhibitors than for aspirin. Therefore, one would expect that more disagreements will occur upon audit of the reasons for not providing ACE-inhibitors. Similarly, congestive heart failure discharge documentation, although not currently publicly reported, will have lower rates of interrater reliability due to the nature of the documentation requirements. Clarification is necessary. An example of the process would be helpful.

Graduate Medical Education

We request clarification on the simultaneous match concerning the initial residency period. CMS proposes to revise 413.79(a)(10) to state "when a hospital can document that resident matched in an advanced residency training program beginning in the second residency year prior to commencement of any residency training, the resident's IRP will be determined based on the

period of board eligibility for the specialty associated with the advanced program, without regard to the fact that the resident had not matched for a clinical base year training program." What supporting information will be needed to provide the documentation? We are concerned that there may be confusion during audits if there is not an identified documentation standard.

For simultaneous matching through the National Resident Matching Program (NRMP), documentation can be acquired with some ease. However, for the San Francisco match, what documentation can be used? We feel this matching process should have available some type of documentation or reports that are consistent with the NRMP documentation.

The following topics related to GME were not addressed in the proposed rule, but we believe further comment or instruction is appropriate:

CMS did not address the topic of unused resident cap or the redistribution of residents FTE in the proposed rule. Guidance or information should be addressed for the providers who have applied for the unused resident cap redistribution. CMS stated that this would be effective July 1, 2005, however, no direction has been communicated to providers for these changes. Providers need to know what type of documentation of the redistribution slots will be needed, and how will these additional slots be applied. We feel these changes will complicate the already complex calculation and reimbursement formulas for Indirect Graduate Medical Education and Direct Graduate Medical Education and would like some type of communication for our cost reporting filings and our Affiliation Agreements that are submitted yearly.

Council on Graduate Medical Education (COGME) recommends gradually increasing the cap over the next decade, as increasing numbers of both osteopathic and allopathic graduates enter residency training from our US medical schools. All recent studies point to an increasing physician shortage over the next 15-20 years. Medicare should be involved in the process, since the increased need for physicians will be driven in large part by the growing number of elderly. Multiple bodies have changed their recommendations recently based on these data, including the Association of American Medical Colleges (AAMC) and COGME, reversing earlier recommendations to the contrary.

The AAMC and COGME are recommending a 15% increase in the number of US graduates over the next decade, with no further restrictions on International Medical Graduates entering residency training. They recommend a parallel increase in the cap, which would be a 15% increase over 10 years. Because many metropolitan-based GME programs will likely not benefit from the one time cap increase to be announced shortly, there still will be a demand for further cap expansion. We recommend an analysis to determine the validity of these recommendations, and appropriate action in a future rule.

We also recommend a review of the current formulas to determine IME and GME payments. We suggest a more simplified approach be created for IME and DME reimbursement and cost report settlement. The current formulas require documentation efforts that are burdensome to maintain, and are one of the primary reasons for dispute between the Fiscal Intermediaries and Providers.

Although not addressed in the proposed rule, we would like to comment on the removal of pass through payments for second year pharmacy students that occurred two years ago. With all due respect to the CMS program, we believe that CMS's assumption of pharmacy programs is incorrect and does not reflect the merits of the accredited pharmacy program. In a pharmacy residency program the pharmacist learns advanced skills to enhance medication safety and to maximize the benefits of medication therapy. The majority of hospitals look only to hire pharmacists that have the completed a pharmacy residency program. The person who has that certification is a better-trained practitioner, is more equipped to handle the expectations of a hospital pharmacy, and can more quickly adapt to the changing environment of the health care field.

Removing this pass-through reimbursement and replacing it with reimbursement wrapped up in the administrative operating costs of the DRG payment conflicts with the January 12, 2001 final rule. In those rules CMS maintained that Medicare would generally provide reasonable cost reimbursement for "programs of long duration and designed to develop trained practitioners in a nursing or allied health discipline." Discontinuing reasonable cost reimbursement for accredited pharmacy programs will probably cause a number of programs throughout the nation to discontinue their pharmacy residencies, as it would be too costly to maintain. If that should happen, we would expect patient care outcomes to drop as has been documented that pharmacists who complete accredited residencies save money and improve patient outcomes. It should also be noted that a number of certification agencies look to the education levels of the clinical staff to ascertain the ability to provide quality and safe patient care. The accredited pharmacy program is part of that education.

Thank you for the opportunity to comment on this proposed rule and for consideration of our comments. If you have any questions, please contact Chris Tholen at 507-284-0940 or me at 507-284-4627.

Very truly yours,

Ronald Grousky

Ronald Grousky
Medicare Coordinator

bcc: Michael Troska, Mayo Foundation
Chris Tholen, Mayo Foundation
Bruce Kelly, Mayo Foundation

HANYS Healthcare Association of New York State

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Daniel Sisto, President

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June 24, 2005

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

Dear Dr. McClellan:

This letter responds to the May 4, 2005 *Federal Register* call for comments regarding the validation specifications for Requirements for Hospital Reporting of Quality Data: Issue Identifier: **Hospital Quality Data.** The Healthcare Association of New York State (HANYS) and the hospitals in New York State strongly support the Hospital Quality Alliance (HQA) and the Centers for Medicare and Medicaid Services (CMS) Hospital Quality Initiative. HANYS and our members concur that valid data is paramount in this initiative. However, in our opinion, the current validation process fails to meet a reasonable threshold for accuracy, reliability, and consistency. Until improvements are made, HANYS finds that it must oppose, at this time, the proposal to link the validation requirements to receive the full Medicare marketbasket Annual Payment Update (APU).

HANYS, in conjunction with our hospital members, has identified several significant areas of concern. These concerns pertain to the data validation process, appeals process, and vendor issues. In our opinion, there is some ambiguity and a legitimate need for information regarding the Clinical Data Abstraction Center (CDAC) abstraction process. Moreover, the appeals process does not sufficiently address many of the issues that have arisen during the initial phases of data submission. Finally, there are noteworthy vendor issues that call for a systemic solution. Our specific comments regarding each of these areas follows.

Transparency and Information Needs

To provide valid data, clear, comprehensive, and adequate definitions and documentation are needed. The process and element documentation must be clear and easily available for reference.

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Unclear Element Definitions: Unfortunately, there are many examples where clear, comprehensive, and adequate definitions and documentation are lacking. The most notable example occurs in the CDAC abstraction reports. CDAC references "QIOSC" in its educational comments, whereas vendors and hospitals refer to the *Hospital Data Collection: Specification Manual for National Hospital Quality Measures Version 2.1* Data Dictionary or Pneumonia Abstraction definitions. The QIOSC reference refers to QNet Quest, an online questions and answers database, part of Process Improvement Quality Improvement Organization Support Center. Most hospitals are unaware of the QIOSC reference. In fact, neither the hospitals nor vendors that HANYS contacted were aware of QIOSC. Further, it is unclear who at QIOSC answers posted questions and whether there is final resolution of issues. The QIOSC questions and answers are not ordered by date, are hard to search, and some contain old (invalid) information. Likewise, the CDAC Helpdesk does not refer content experts to assist hospitals with the validation process. CDAC and hospitals should have access to the same information and element documentation. Further, we find some information in the available data dictionaries regarding elements to be confusing and difficult to interpret. There should be no ambiguity regarding the sources of element definitions to ensure valid submission of data.

Double Jeopardy: In many validated charts, when the parent element is incorrect or not answered, the subsequent child elements are considered wrong as well, which constitutes double jeopardy. For example, if a chart has a working diagnosis of pneumonia, a series of follow-up child elements are validated. If a hospital abstractor does not identify a working diagnosis and CDAC does, the chart appears to be penalized for all 16 or 17 elements. In fact, most vendors following the Joint Commission on Accreditation of Healthcare Organizations/CMS algorithm will not allow hospitals to complete these child elements. Hospitals should not be penalized for the missing child elements, when the hospital abstractor considered the parent element to be missing or not available. Further, the parent elements are not clearly described as such in many vendor products.

Ineligible Charts: In some cases, CMS/CDAC have requested charts that are not eligible (e.g., age, recoded, or discharged to hospice). The impact of these charts on the validation process is unclear and seems to be handled on an individual basis. Given that many hospitals are providing less than one percent of their eligible charts for validation, the impact of one such chart could be catastrophic, if it is counted against the hospital. HANYS suggests that charts be carefully reviewed for eligibility and accepted into the warehouse only if a relevant measure can be calculated.

Validation Reports: Validation reports should be clear and contain all the relevant information that pertains to the elements included in the percentage agreement reported for both the HQA and the APU. Currently, the summary results do not provide the numerator and denominator of the APU elements; nor are the elements included clearly documented.

Appeals Process
Given the lack of clarity previously noted in the available documentation, it is important that hospitals be provided adequate opportunities to appeal all mismatches. It is important for hospitals to understand the logic behind each element, if hospitals are to use the information to improve and provide the best care possible. It is also valuable for CMS to understand where better guidance can be provided.

We urge CMS to provide a succinct summary report on how it assesses "inter-rater" reliability. For example, it is important to evaluate whether CDAC abstractors are consistent across hospitals, using real hospital charts (especially complicated and/or failing charts). It is not clear that such evaluations of inter-rater reliability are currently conducted. It is difficult to justify deference to the CDAC review process as the "gold" standard without this documentation. HANYS believes that CDAC inter-rater reliability studies should be ongoing, published regularly, described thoroughly, and communicated in a timely manner.

Vendor Issues Beyond Hospital Control
HANYS understands that the data reporting vendors have contractual agreements with hospitals to perform services, not with CMS. Hospital/vendor contracts generally include a range of products and services, of which the CMS/HQA initiative is one. Vendors have continuously communicated to hospitals and HANYS that instruction from CMS on this multi-faceted project has been confusing, untimely, and contains unrealistic expectations. Further complicating matters is the fact that the CDAC abstractors accessed by hospitals through Quest and the QNet Helpdesk can be different than those advising vendors on the same issues. It is important for CMS to standardize data submission algorithms and provide guidance (if not recourse) for hospitals adversely affected by vendor issues beyond their control. The following two situations are examples of vendor issues that are outside the immediate control of hospitals.

Unstandardized "Skip Logic" Algorithms: Vendors do not have a consistent approach to the use of skip logic. One vendor provides skip logic that turns off child elements based on the parent element response. Another does not have any skip logic. Others have a combination of both. In the instance of a working diagnosis of pneumonia, it is evident that a chart's validation results will depend on the vendor and its use of skip logic. When tied to validation, these discrepancies can mean the difference between a hospital passing validation or failing. The process must be consistent at the vendor level.

Timeliness: Recently, due to an unexpected staffing constraint, one vendor was unable to submit data in a timely manner for many hospitals to have complete data at the CMS warehouse by the deadline. Hospitals were not aware of the problem until the data submission deadline had past. Although this situation was resolved, this experience clearly shows how vulnerable hospitals are to vendor problems.

Additional Concerns

During the first week of June 2005, CMS posted the validation results for the third quarter of 2004. The hospital-specific reporting was incorrect and included information from other states, including patient health information. The posting caused significant confusion and concern among hospitals. Subsequently, CMS modified this methodology, corrected the error, and reposted validation results. At that point, we were advised that all New York State hospitals passed validation. One week later, one hospital that was initially told it had passed validation was verbally informed that it had actually failed. The hospital has been unable to reconstruct how the validation elements passed one review, but failed another. There was no educational explanation attached to the updated report.

These examples are provided as examples to underscore the current inadequacies and frailties of the CMS validation process. These areas must be addressed before hospital reimbursement can be fairly linked to the validation process.

HANYS recognizes the significant efforts that CMS has invested in developing the validation process and appreciates the improvements that have been made to date, such as the 95% confidence interval calculation. However, our experience with the validation process leads us to conclude that hospital reimbursement will be unfairly and randomly jeopardized based on inconsistencies in the current process. HANYS opposes using the validation process as it is currently designed to determine marketbasket APU updates.

HANYS appreciates the opportunity to comment on the proposed rules regarding hospital quality data. Please contact me at (518) 431-7757 or at mtherria@hanys.org with any questions or comments.

Sincerely,

Mary Therriault, B.S.N., R.N.
Director, Quality Indicator Project
Quality and Research Initiatives

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CBSAs - HEFTER HARTSTEIN

GLADES GENERAL HOSPITAL

June 13, 2005 Overnight Mail Tracking No: 700322600000117987706

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

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

Dear Sir or Madam:

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

Glades General Hospital is a JCAHO accredited, 73-bed acute care facility located in Palm Beach County Florida. 24 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

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

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

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

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

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

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

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

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

2. BACKGROUND

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

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

Therefore, the hospitals within this CBSA could reclassify from one Metropolitan Division to another if they met the remaining application criteria. These new CBSAs, created in 2003 by OMB, had replaced Consolidated Metropolitan Statistical Areas (CMSAs) previously established by OMB in 1990.

B. The Prior Year FY 2005 Final IPPS Regulation

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

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

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

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

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

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

- the West Palm Beach Metropolitan division is not currently automatically considered a CSA by the OMB;
- the West Palm Beach Metropolitan division was not previously considered a CMSA; and

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- the final regulation removed allowing urban hospital groups located within a CBSA to seek reclassification to another area within the same CBSA (that is, to another Metropolitan Division).

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

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

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

Also, the application for urban group reclassification was due to be filed by September 1, 2004. The final FY 2005 regulations were not published until August 11, 2004. The hospitals in the West Palm Beach Metropolitan Division could not have waited until the final regulations were published on August 11, 2004 to organize the entire county knowing that the application was due to be sent only 20 days later, on August 31, 2004. It is a very complex process to organize what are normally competitive organizations to

join a common initiative. It takes much longer than 20 days. Therefore, based on the FY 2005 proposed regulations and the fact that the hospitals in the metropolitan division were eligible for an urban group reclassification, tremendous efforts and costs were invested by the hospitals in the West Palm Beach Metropolitan Division to achieve a county-wide reclassification.

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

A. Urban Group Hospital Reclassifications

The FY 2006 proposed IPPS regulation proposes to delete the reference to the CMSA urban group reclassification criterion. The regulation states in part that "beginning with FY 2006, it is proposed to require that hospitals must be located in the counties that are in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation".

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

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

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

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single labor market area definition for all aspects of the wage index and reclassification".

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

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

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

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

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

We understand, through review of the August 22, 2000 Federal Register and discussions with OMB staff, that the criteria for an area to "automatically" be considered a CSA is when the employment interchange (commuting) measure

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between adjacent CBSAs is at least 25%. Also, adjacent CBSAs that have an employment interchange measure of at least 15% and less than 25% will combine as a CSA if local opinion, as reported by the congressional delegations in both areas, favors combination. The Federal Register states that the OMB will seek local opinion regarding the CBSA combination (CSA). The Federal Register also states that after a decision has been made regarding the CBSA combination (CSA), the OMB will not request local opinion again on the issue until the next redefinition of CBSAs.

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

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

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

5. CONCLUSION

Based on the aforementioned information we request that CMS incorporate the revisions, as written in section one of this document, in the FY 2006 final IPPS regulation. The requested revisions are critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and will effect payments to all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2005.

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

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HOSPITAL

Respectfully,

Dan Aranda
CEO
Glades General Hospital

Logan Campus
812 North Logan Avenue
Danville, IL 61832-3788
217 443-5000 Tel

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PROVENA
United Samaritans
Medical Center

GEO RECLASS – KENLY
HEFTER
HARTSTEIN

June 23, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
7500 Security Boulevard
Attention: CMS-1500-P
P.O Box 8011
Baltimore, Md 21244-1850

Re: Provena United Samaritans Medical Center
Provider Number 14-0093, Danville, Vermilion, Illinois

Dear Sir or Madam:

There seems to be once again an error in the Proposed Regulations regarding the Medicare Geographic Reclassification of Provena United Samaritans Hospital. This same error was made last year and finally corrected in the Revisions to the Final Regulations. Provena United Samaritans Medical Center applied for and received approval for reclassification to MSA 1400 (05C0159) for FY's 2005-2007 as per Case Status Listing dated 4/29/2004. Due to the general confusion regarding the error made in the prior years Proposed and Final Regulations, another application for FY 2006 was filed and then withdrawn before any board ruling (06C0048). Please correct this major error in the final requlations to be published in September of 2005. If you have any questions or require any further documentation, please call me at (217) 443-5000, ext 4614. Many thanks for your assistance in this matter.

Sincerely,

Anne E. Little
Regional Director, Reimbursement
Provena Health-Central IL Region
812 North Logan Avenue
Danville, IL 61821

MEDICARE GEOGRAPHIC CLASSIFICATION REVIEW BOARD
CASE STATUS LISTING BY YEAR

Run Date: April 29, 2004

CASE NUMBER	PROVIDER NUMBER	PROVIDER NAME	DEC. CODE	FORM NO.	FROM MSA	TO MSA
05C0139	26-0017	Phelps County Regional Medical Center	DEC	F170	26	7040
05C0140	30-0003	Mary Hitchcock Memorial Hospital	DEC	F170	30	1123
05C0141	39-0052	Clearfield Hospital	DEC	F170	39	0280
05C0142	52-0088	Agnesian HC, Inc. fka St. Agnes Hosp.	DEC	F170	52	5080
05C0143	36-0002	Samaritan Regional Health System	DEC	F173	36	1680
05C0144	44-0192	White County Community Hospital	DEC	F170	44	5360
05C0145	39-0013	Evangelical Community Hospital	DEC	F170	39	3240
05C0146	01-0150	L.V. Stabler Memorial Hospital	DEC	F170	01	5240
05C0147	01-0143	Woodland Medical Center	DEC	F170	01	1000
05C0148	01-0126	Edge Regional Medical Center	DEC	F170	01	5240
05C0149	18-0139	Kentucky River Medical Center	DEC	F170	18	4280
05C0150	42-0036	Springs Memorial Hospital	DEC	F170	42	1520
05C0151	44-0185	Cleveland Community Hospital	DEC	F170	44	1560
05C0152	45-0653	Scenic Mountain Medical Center	DEC	F170	45	5800
05C0153	03-0033	Payson Regional Medical Center	DEC	F170	03	2620
05C0154	32-0006	Eastern New Mexico Medical Center	DEC	F170	32	7490
05C0155	19-0164	Byrd Regional Hospital	DEC	F170	19	0220
05C0156	18-0132	Lake Cumberland Regional Hospital	DEC	F170	18	4280
05C0157	19-0131	River West Medical Center	DEC	F170	19	5560
05C0158	44-0067	Lakeway Regional Hospital	DEC	F170	44	3840
05C0159	14-0093	Provena United Samaritans Medical Center	DEC	F176	14	1400
05C0160	23-0054	Marquette General Hospital, Inc.	DEC	F170	23	3080
05C0161	44-0151	River Park Hospital	DEC	F170	44	5360
05C0162	27-0003	St. Peter's Hospital	DEC	F170	27	3040
05C0163	26-0116	Mineral Area Regional Medical Center	DEC	F170	26	14
05C0164	26-0183	Saint Francis Medical Center	DEC	F170	26	7040
05C0165	44-0035	Gateway Health System, Inc.	DEC	F175	1660	5360
05C0166	18-0117	Parkway Regional Hospital	DEC	F174	18	26
05C0167	18-0104	Western Baptist Hospital	DEC	F170	18	1660
05C0168	16-0089	Ottumwa Regional Health Center	DEC	F170	16	2120
05C0169	26-0110	Southeast Missouri Hospital Association	DEC	F176	26	7040
05C0170	18-0124	Greenview Hospital, Inc.	DEC	F170	18	5360
05C0171	11-0168	Redmond Park Hosp. d/b/a Redmond RMC	DEC	F170	11	0520
05C0172	36-0010	Union Hospital	DEC	F170	36	0080
05C0173	45-0098	East Texas Medical Center-Pittsburg	DEC	F170	45	4420
05C0174	34-0127	Granville Medical Center	DEC	F170	34	6640
05C0175	45-0194	East Texas Medical Center - Jacksonville	DEC	F170	45	1920
05C0176	24-0018	Fairview Red Wing Hospital	DEC	F176	24	5120
05C0177	14-0160	Freeport Memorial Hospital	DEC	F170	14	6880
05C0178	18-0018	St. Claire Medical Center	DEC	F170	18	4280
05C0179	14-0058	Passavant Area Hospital	DEC	F170	14	7880
05C0180	18-0027	Murray-Calloway County Hospital	DEC	F170	18	1660
05C0181	26-0094	Skaggs Community Health Center	DEC	F170	26	7920
05C0182	05-0045	El Centro Regional Medical Center	DEC	F173	05	7320
05C0183	36-0259	Bay Park Community Hospital	DEC	F173	8400	2160
05C0184	01-0118	Vaughn Reg Med Center Parkway Campus	DEC	F170	01	5240

MEDICARE GEOGRAPHIC CLASSIFICATION REVIEW BOARD
CASE STATUS LISTING BY PROVIDER

Run Date: February 18, 2005

PROVIDER NUMBER	CASE NUMBER	PROVIDER NAME	DEC. CODE	FORM NO.	CURRENT AREA	REQUESTED AREA
14-0040	06C0185	Galesburg Cottage Hospital	REQ	F184	14	37900
14-0058	06C0057	Passavant Area Hospital	DEC	F170	14	41180
14-0061	06C0167	Red Bud Regional Hospital	DEC	F170	14	41180
14-0064	06C0189	Saint Mary Medical Center	DEC	F170	14	37900
14-0084	06G0023	Victory Memorial Hospital	AOAA	F175G	29404	16974
14-0093	06C0048	Provena United Samaritans Medical Center	REQ	F120	19180	45460
14-0100	06G0023	Midwestern Regional Medical Center	AOAA	F175G	29404	16974
14-0110	06C0152	Community Hospital of Ottawa	DEC	F170	14	16974
14-0130	06G0023	Lake Forest Hospital	AOAA	F175G	29404	16974
14-0161	06C0188	Saint James Hospital	DEC	F170	14	16974
14-0202	06G0023	Condell Memorial Hospital	AOAA	F175G	29404	16974
14-0233	06C0191	St. Anthony Medical Center	DEC	F170	40420	16974
14-0291	06C0154	Good Shepherd Hospital Advocate	DEC	F170	29404	16974
14-0291	06G0023	Good Shepherd Hospital Advocate	AOAA	F175G	29404	16974
15-0011	06C0125	Marion General Hospital	REQ	F184	14	26900
15-0035	06C0140	Porter Memorial Hospital	DEC	F174	23844	16974
15-0048	06C0120	Reid Hospital and Health Care Services	REQ	F184	15	17140
15-0088	06G0035	Saint John's Health System	DEC	F172G	11300	26900
15-0089	06C0127	Ball Memorial Hospital	DEC	F174	34620	26900
15-0096	06C0117	LaGrange Community Hospital	DEC	F174	15	21140
15-0113	06G0035	Community Hospital of Anderson & Madison (	DEC	F172G	11300	26900
15-0133	06C0136	Kosciusko Community Hospital	DEC	F170	15	23060
15-0146	06C0049	Comm. Hosp. of Noble County, Inc. dba PNH	DEC	F170	15	23060
16-0001	06C0166	Marshalltown Medical & Surgical Center	DEC	F170	16	11180
16-0147	06C0032	Grinnell Regional Medical Center	DEC	F170	16	19780
17-0033	06C0024	Central Kansas Medical Center	DEC	F170	17	48620
17-0058	06C0050	Mercy Health System of Kansas, Inc.	DEC	F170	17	28140
17-0068	06C0008	Southwest Medical Center	DEC	F170	17	11100
17-0116	06C0111	Allen County Hospital	REQ	F120	17	28140
17-0142	06C0082	Mercy Regional Health Center	DEC	F170	17	28
18-0017	06C0163	T.J. Samson Community Hospital	DEC	F170	18	21060
18-0019	06C0135	Meadowview Regional Medical Center	DEC	F170	18	17140
18-0020	06C0197	Middlesboro Appalachian Regional Hosp.	AOAA	F112	18	28940
18-0024	06C0155	Spring View Hospital	DEC	F170	18	31140
18-0043	06C0104	Memorial Hospital	DEC	F174	18	28940
18-0048	06C0038	Ephraim McDowell Regional Medical Center	DEC	F170	18	30460
18-0080	06C0132	Baptist Regional Medical Center	DEC	F170	18	28940
18-0116	06C0173	Jackson Purchase Medical Center	DEC	F170	18	14
19-0025	06C0081	Savoy Medical Center	DEC	F174	19	10780
19-0060	06C0112	Lake Charles Memorial Hospital	DEC	F174	29340	13140
19-0078	06C0177	Eunice Regional Hospital	DEC	F184	19	29180
19-0090	06C0020	Winn Parish Medical Center	DEC	F174	19	10780
19-0099	06C0122	Avoyelles Hospital	DEC	F170	19	12940
19-0106	06C0101	Oakdale Community Hospital	DEC	F170	19	10780
19-0144	06C0172	Minden Medical Center	DEC	F184	19	43340
19-0191	06C0171	Doctors Hospital of Opelousas	DEC	F170	19	12940

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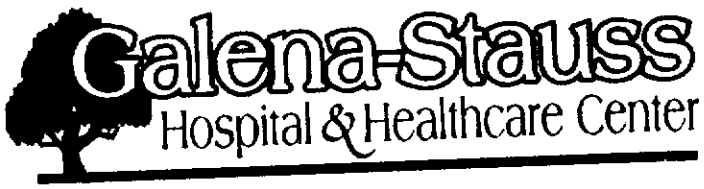

CAH/RELOC - COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

June 21, 2005

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

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

The Galena-Stauss Hospital & Healthcare Center is a 25 bed necessary provider, critical access hospital, with an attached medical office building, community fitness center, 57 bed nursing home, 24 apartment assisted living and adult day care center. All of our long term care services are operating at capacity and have waiting lists. Galena Stauss Hospital is the largest employer in the city of Galena with 153 employees and an annual payroll of over three million dollars.

The current hospital was built in 1962 and today provides us with a plethora of challenges including inefficient design, only semi private patient rooms, no in room shower or bathing accommodations, HVAC inadequacies, ADA issues, asbestos abatement challenges, suboptimal fire protection (not sprinkled), an antiquated mechanical infrastructure and no surgical, dialysis or obstetrical services. Our current campus is landlocked, topographically challenging and does not allow for critically needed current and future expansion of services. The hospital is located in a residential area that presents visibility and accessibility issues particularly for emergency services for which Galena Stauss Hospital is the sole provider in our county of 23,000 people. We suffer from community image problems associated with the out-dated facility and recruitment challenges particularly as related to physicians. This lack of physicians results in the inability to provide progressive patient care to our community. The construction costs for replacing our current facility on the present campus would be significantly higher than rebuilding on a new site, due to the multi-year phasing required in demolishing and rebuilding the existing facility.

After a thorough and in depth strategic planning process it has been determined that a replacement hospital is required to allow for continued delivery of adequate emergency, acute in-patient, outpatient and long term care services. A new campus will accommodate the replacement hospital, wellness center and medical office building. By "opening up" our current campus we will be able to provide for much needed future expansion and enhancement of the long term care services for a growing and aging community.

215 Summit Street • Galena, Illinois 61036 • (815) 777-1340 • FAX (815) 776-7274

To date we have completed the land due diligence, preliminary zoning discussions, team selection (architects, construction firm, project management firm, investment banker, financial advisors. programming, block plans/site design, total budget estimate, schedule, and a financial proforma. We plan to begin detail programming, full design, financing arrangements and a certificate of need (CON) application in August of 2005 with a scheduled ground breaking the first quarter of 2006 and estimated occupancy in the second quarter of 2007.

We have negotiated a purchase option agreement on approximately 35 acres northwest of our current campus 2.4 (two and four tenths) miles. Reasons for selection include: appropriate topography (we are located in a very hilly glaciated corner of northwest Illinois), site consistency with the city and county's comprehensive growth plans, proximity to a proposed city bypass exchange, major highway frontage with good visibility and accessibility, property size (allowing for future growth) and reasonable land price.

I am writing today on behalf of Galena Stauss Hospital and the communities we serve to express our strong opposition to the proposed inpatient hospital rule that would prevent most Critical Access Hospitals (CAHs) from rebuilding their facilities more than 250 yards from their current location. While we understand the need to maintain CAH facilities in specific service areas, we believe the 250-yard rule is arbitrary and should be replaced with a more flexible rule that allows CAH hospitals to modernize.

The proposed rule also explicitly grandfathers existing CAH programs with construction projects under development before December 8, 2003. While Galena Stauss Hospital can demonstrate this, we believe CMS should consider other options that allow more flexibility for CAHs that did not meet this deadline. Maintaining the current 250-yard requirement is not appropriate to meet the needs of CAHs or the patients they serve. Necessary provider CAHs should be allowed to relocate as appropriate to improve the care of their communities. We urge CMS to remove the proposed restrictive date requirements and establish reasonable criteria to ensure that the hospitals are moving within their services areas.

The ability to build a replacement hospital with enhanced services on a site that is visible and accessible is crucial for the Galena Stauss Hospital to remain a viable, rural, provider of healthcare services and to continue to meet the growing healthcare needs of our community.

Sincerely,

Kurt J Hill

Kurt "Jeff" Hill
Chief Executive Officer
Galena Stauss Hospital & Healthcare Center
215 Summit Street
Galena, Illinois 61036

815-776-7266

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THE UNIVERSITY OF TENNESSEE
MEDICAL CENTER

• *University Memorial Hospital*
• *Graduate School of Medicine*

Brain and Spine Institute
1924 Alcoa Highway, Box 52
Knoxville, TN 37920-6999
865.544.8045
Fax: 865.544.6801

June 23, 2005

DRG/GEN - BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

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

Dear Sirs,

As the Executive Director of the Brain and Spine Institute at the University of Tennessee Medical Center in Knoxville, Tennessee, I am requesting you consider increasing the Medicare reimbursement for advanced stroke treatment provided in acute care hospitals.

In 2004, the University of Tennessee Medical Center treated 498 patients with stroke related diagnoses. Because of the high volume of patients seen from our eighteen county region, we have created a multidisciplinary team to address the needs of the patient suffering from stroke. We are also in the process of seeking designation as a primary stroke center. It is our goal to reduce mortality and morbidity from stroke in the region we serve.

Key to achieving this goal is the provision of reperfusion therapy. Community education continues to focus on early presentation to the Emergency Department. This early presentation offers an opportunity for reperfusion which demonstrates the ability to improve patient outcomes, reduce life altering impairments, and save health care dollars. Despite the savings to the patient and the community, it is expensive for hospitals to provide the quick diagnostic and therapeutic modalities related to reperfusion. The high cost serves as a disincentive to develop systems and services to provide this stroke care.

I would encourage CMS to investigate the long term savings to Medicare by creating a new DRG for reperfusion of strokes.

Thank you for your attention to this important issue impacting the Medicare beneficiaries you represent. Please contact me if I can be of assistance or provide you with additional information.

Sincerely,

Ann Giffin

Ann Giffin, PT, MS
Executive Director

NSA National Stroke Association

Dedicated to reducing the incidence and impact of stroke

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DRG/GEN - BROOKS
FAGAN
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HEFTER
HARTSTEIN

June 23, 2005

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

RE: Stroke DRG 14/15

Dear Colleagues,

The National Stroke Association (NSA) wants to thank you and your colleagues at the Centers for Medicare and Medicaid Services (CMS) for being receptive to our support of changes to Medicare hospital inpatient reimbursement for advanced stroke treatment.

Stroke is a devastating disease that affects more than 750,000 people annually in the United States, and as you are aware, costs the U.S. medical system more than $52 billion annually in post-acute care. NSA, as the leading, independent national nonprofit organization devoting 100 percent of its efforts and resources to stroke, firmly believes the administration of reperfusion therapies has been proven to reduce the poor outcomes in stroke patients thus, reducing the burden of post-acute and rehabilitative care.

By changing the current structure of stroke DRGs 14 and 15, CMS can make a significant impact on stroke treatment while also reducing the long-term costs to Medicare. There are two primary ways that the coding could be changed, either by redefining the two current codes to include reperfusion therapies or by creating a new DRG for the administration of reperfusion therapies.

Since CMS' request for additional data last spring, there has been additional review of several sources including the MedPar Database, the Premier Perspective Database and survey results from NSA's Stroke Center Network members. This additional data indicates a higher administration of thrombolytic therapy, as much as two to three times than is reported by the ICD-9 code 99.10.

This is an exciting time for stroke with the development of new programs nationwide for prehospital providers, stroke center development and data review. Changes to the reimbursement for stroke would be timely and historical in the coalition's objective to improve care of stroke patients.

Regards,

Jim Baranski
Chief Executive Officer / Executive Director
National Stroke Association

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Dartmouth-Hitchcock Medical Center
Mary Hitchcock Memorial Hospital

Shared Services
One Medical Center Drive
Lebanon, New Hampshire 03756
603-653-1210 *fax 603-653-1111*

June 22, 2005

TRANSFERS – WALZ
HART

DRG/GEN – BROOKS
HEFTER
HARTSTEIN

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

RE: Postacute Care Transfers

The purpose of this letter is to comment on the Medicare proposed rule concerning the Hospital Inpatient Prospective Payment System as published by CMS in the Federal Register of Wednesday, May 4, 2005.

By way of background, the Dartmouth-Hitchcock Medical Center (DHMC) is comprised of Mary Hitchcock Memorial Hospital, a 300 bed teaching hospital, the Dartmouth-Hitchcock Clinic, a large academic group practice, Dartmouth Medical School, and the Veterans Administration Hospital. Mary Hitchcock is the only academic tertiary care hospital in the state of New Hampshire, and is one of only a few major rural teaching hospitals in the country.

We are writing to comment on CMS' proposed expansion of the Post-Acute Care Transfers to an additional 223 DRGs. We strongly urge CMS to eliminate the post acute care transfer policy as the DRG based payment system was designed on averages. Providers tend to lose money when patients are discharged after the geometric mean length of stay, and now CMS is seeking to expand the transfer policy to further penalize hospitals for transferring patients prior to the geometric mean length of stay. In addition, we contend that CMS has significantly reduced the financial incentive, of transfers, by implementing prospective payment systems in the post acute care setting.

Though we feel strongly that the post acute care transfer policy should be eliminated, we ask CMS to consider the following options:

1. *Remove Home Health Agencies* - We are confused as to how CMS could compare the intensity of care provided in an acute care setting to the level of care provided by home health agencies. The transfer payment formula basically equates the intensity of care between an acute care hospital and home health care. We propose that CMS remove home health agencies from the post acute care transfer policy.

2. *DRGs that qualify for Special Payment* - We propose that CMS expand the number of DRGs that qualify for the special payment. CMS has made a distinction that if a DRG exhibits an even higher share of costs very early in the hospital stay that it should be reimbursed at a higher rate early in the stay (50% of DRG rate). We agree with CMS and contend that all surgical DRGs, in addition to certain medical DRGs, should qualify for this payment. The cost of care is front loaded into the patient stay for all surgical DRGs.

We would like to conclude by proposing that CMS eliminate the post acute care transfer policy. However, if a transfer policy is to remain, we strongly recommend that home health agencies be removed from the policy and that CMS increase the number of DRGs that qualify for the special payment.

Thank you for consideration of these comments.

Sincerely,

John G. Kelleher

John G. Kelleher
Director, Shared Services

JGK/kjn

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TRANSFERS — WALZ
Q DATA HART
HEFTER
HARTSTEIN
L, Bodden
M. Krushat

June 21, 2005

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

Dear Mr. McClellan,

On behalf of the Peninsula Regional Health Care System, we are strongly opposed to any expansion of the transfer policy and we support the establishment of an explicit process for the submission and validation of quality data.

Specifically for the post-acute transfer policy proposal, we believe it would limit hospital reimbursement, undermine clinical decision-making, and penalize hospitals for ensuring that patients get the most appropriate care in the most appropriate setting. We believe that ***any*** expansion of the inpatient transfer policy would fundamentally weaken incentives inherent in the inpatient PPS and disrupt the continuum of care typical of quality delivery.

With respect to processes for data submission and validation, the ability of hospitals and their vendors to comply with the requirements for timely and accurate data submission is challenged by miscommunication, technical ambiguities, and other issues. Therefore, we believe that the final FY '06 inpatient PPS should establish a clear documentation and communications process for this purpose. Further, we believe hospitals should not be penalized when technical issues specific to the CMS or Quality Improvement Organizations (QIOs) hinder their ability to meet specific data requirements.

For Example:

- An explicit, step-by-step process for data submission should be established—including exact specifications, all edits or audits to be applied, and other related information. Hospitals and vendors must be privy to such parameters to ensure timely data submission. Further, CMS should communicate any changes to submission file requirements no less than 120 days prior to the effective/implementation date. No changes should be permitted once a submission quarter has begun, as this puts process integrity at risk.

- For greater reporting accuracy, we believe that a test process for validating data file submissions and measuring calculations should be established. Hospitals and submission agents should be provided with a test file in the appropriate format for internal verification *prior* to testing a submission. The process should permit submission of test file(s) to verify file formats, accuracy of data calculations, and other audit criteria related to data submission. An appropriate test process should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Consequently, if hospitals that do *not* sample elect to submit all of their qualifying cases for a given study (i.e., 425 pneumonia cases for a given quarter) and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that *every* one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

- An explicit, step-by-step validation process should be established—including clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well-documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and change their attendant processes. We propose that any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- We believe that the validation process should incorporate *only* data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may earn an *overall* quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably *lower*. In this way, payments risk being based on inconsistent calculations and inaccurate data.

- Further, we believe that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation

documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data were submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

- Under the proposed rule, CMS only allows ten days for a hospital to appeal its validation; however, the agency fails to specify whether the reference is to "business" or "calendar" days. We believe that *neither* case offers sufficient time for hospitals to respond. Therefore, we propose allowing hospitals 30 calendar days to appeal their validation findings.

- Many hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). We believe that all communications and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIOs) simultaneously. Such a strategy would simplify and standardize message generation. It would also eliminate the confusing and often contradictory communications typical of the current process, which requires state QIOs to interpret a given communication before forwarding it to hospitals.

Thank you for this opportunity to express our views on these important matters.

Sincerely,

Douglas H. Wilson, Ph.D.
Director, Planning, Business Development and Government Relations

DHW/ddfw

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TCMC
TENNESSEE CHRISTIAN MEDICAL CENTER
NASHVILLE • PORTLAND

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JUN 24 2005

June 20, 2005

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

CAH/RELOC — BY:

COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

To Whom it May Concern:

Under the Medicare Prescription Drug Improvement and Modernization Act (MMA), enacted 12/3/03, as of 1/1/06, new necessary provider Critical Access Hospitals (CAHs) will no longer be granted and all future CAHs must meet federal eligibility tests (including mileage). While the MMA permitted necessary providers to retain their CAH status, it appeared to only deal directly with those remaining at their present location. As such, the healthcare industry in general, lacked a consensus in its interpretation of the MMA and its impact on necessary providers planning to relocate after 1/1/06. A common belief was regional CMS offices had the authority to approve the relocation of necessary providers after 1/1/06 on a case-by-case basis.

The new CMS proposal seeks to clarify the issue of relocations and offers the stark reality that only a few CAHs will be grandfathered prior to the cut-off date of 1/1/06, with no other exceptions. To maintain their CAH status, all necessary providers must submit an application to CMS for relocation prior to 1/1/06 and be able to: (1) demonstrate at the new location they will continue to meet the necessary provider criteria that was used to originally receive a State waiver, serve at least 75% of the same service area, offer 75% of the same services, utilize 75% of the same staff, maintain compliance with all conditions of participation (42 CFR 485), and (2) demonstrate that construction plans were under development prior to the enactment of the MMA. CAHs moving within 250 yards of their current building, or to contiguous land that was owned prior to 12/3/03 will be exempted from the relocation rules.

Our concern is that the CMS Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (FY 2006) prohibits any CAH operating with a Necessary Provider Designation from relocating its hospital and maintaining its CAH status unless the move is completed by January 1, 2006, or grandfathered. Necessary provider CAHs which had construction plans already under development as of December 3, 2003 and can demonstrate this in their application for relocation to be submitted to CMS prior to January 1, 2006 is the only exception proposed.

With the exception of a select group of CAHs which may receive grandfather status under the relocation sunset provision, this proposal makes it virtually impossible for any CAH operating, including Tennesse Christian Medical Center – Portland, with a Necessary Provider Designation to ever afford an off-site replacement facility project, as it would immediately become ineligible for cost-based reimbursement.

If the Proposal is approved as-is, the impact would derail the modernization of a major percentage of America's antiquated CAHs that face limited on-site renovation or replacement options. If enacted, many small rural hospital's will be faced with the choice of either undertaking often more costly, space-constrained, operationally inefficient on-site construction projects, or relinquish their cost-based reimbursement, the "financial life preserver" necessary to offer quality healthcare to their communities. This would put rural hospitals at a major disadvantage in competing with larger more financially secure hospitals in attracting physicians and patients in order to preserve market share and remain operationally viable.

Sincerely,

Edward A. Smith
Administrator
Tennessee Christian Medical Center - Portland

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an Adventist Health System / Sunbelt, Inc. facility

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Docket Management Comment Form

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

Temporary Comment Number: 17706

Submitter: Ms. Andrea Serra **Date:** 06/21/05

Organization: Gaston Memorial Hospital

Category: Hospital

Issue Areas/Comments

General

See Attachment

Attachments

CMS-1500-P-T17706-Attach-1.doc

Print | Comment on Another Docket | Exit

Print - Print the comment
Exit - Leave the application

Q DATA -
BODDEN
KRUSHAT
HEFTER
HARTSTEI

Q DATA - BODDEN
KRUSHAT

June 21, 2005

Dear Sir:

The ability of hospitals and our vendors to comply with the requirements for timely and accurate data submission is challenged by miscommunication, technical ambiguities, and other issues. Therefore, the final FY '06 inpatient PPS should establish a clear documentation and communications process for this purpose. Further, hospitals should not be penalized when technical issues specific to the CMS or Quality Improvement Organizations (QIOs) hinder our ability to meet specific data requirements.

- An explicit, step-by-step process for data submission should be established—including exact specifications, all edits or audits to be applied, and other related information. Hospitals and vendors must be privy to such parameters to ensure timely data submission. Further, CMS should communicate any changes to submission file requirements no less than 120 days prior to the effective/implementation date. No changes should be permitted once a submission quarter has begun, as this puts process integrity at risk.

- For greater reporting accuracy, a test process for validating data file submissions and measuring calculations should be established. Hospitals and submission agents should be provided with a test file in the appropriate format for internal verification *prior* to testing a submission. The process should permit submission of test file(s) to verify file formats, accuracy of data calculations, and other audit criteria related to data submission. An appropriate test process should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Consequently, if hospitals that do *not* sample elect to submit all of their qualifying cases for a given study (i.e., 425 pneumonia cases for a given quarter) and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that *every* one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

- An explicit, step-by-step validation process should be established—including clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation

specs and requirements were clear and well- documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. Any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- The validation process should incorporate *only* data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may earn an *overall* quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably *lower*. In this way, payments risk being based on inconsistent calculations and inaccurate data.

- Further, we believe that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data was submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

- Under the proposed rule, CMS only allows ten days for a hospital to appeal its validation; however, the agency fails to specify whether the reference is to "business" or "calendar" days. Neither case offers sufficient time for hospitals to respond. Allowing hospitals 30 calendar days to appeal their validation findings would be adequate.

- Many hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). All communications and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIOs) simultaneously. Such a strategy would simplify and standardize message generation. It would also eliminate the confusing and often contradictory communications typical of the current process, which requires state QIOs to interpret a given communication before forwarding it to hospitals.

Andrea K. Serra, CHE
Vice President
Gaston Memorial Hospital
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June 23, 2005

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

NT - Walz
Treitel
HEFTER
HARTSTEIN

Re:

Patient:	**Emerson M. Thompson, III**
Procedure:	**L4-5 Charite Artificial Disk Replacement**
Date of Operation:	**February 14, 2005**
Insurance Carrier:	**The Guardian (through MedCost)**
Treating Physician:	**Dr. Daniel Murrey-OrthoCarolina**
Hospital:	**Presbyterian Orthopedic Hospital-Charlotte, NC**

To Whom It May Concern:

I had the Charite artificial disk implanted in my spine at L4-5 approximately four months ago. This was the third operation that I had undergone at the L4-5 level. My first procedure occurred in June of 1999 and involved bilateral foraminotomies and a diskectomy. The second surgery was in August of 2002 and involved laminectomies at L4-5 and L5-S1. Both of these operations were performed by a neurosurgeon, Dr. Michael Hagland, of Duke University Medical Center. During the entire year of 2004, I experienced continued problems at the L4-5 level and was beginning to undergo diagnostic testing for a boney fusion using the BAK device at Duke. However, I was closely monitoring the FDA's approval of the Charite artificial disk during 2004, and I was extremely pleased when I learned that the FDA finally approved the use of this device at the end of October 2004. Because the neurosurgeon who had operated on me twice before at that level was not trained to implant this device, I started seeing an orthopedic surgeon in Charlotte, Dr. Dan Murrey at OrthoCarolina, for consideration as a candidate for this surgery.

When I was undergoing all of the diagnostic testing, Dr. Murrey pointed out several important things to me that he had learned through his specialized training in implanting artificial disks. First, he told me that patient selection was critical in this process. He pointed out that the manufacturer of the artificial disk, DePuy Spine, had trained him to look for other signs of instability around the spine other than the diseased disk, and he also felt like age played a factor in patient selection. In my case, there was some instability in the facet joints at that level of my spine and he wanted to ensure that the disk would work for me notwithstanding the instability.

Secondly, he said that physician training and the physician's intimate knowledge of all of the aspects of this artificial disk were critical in this type of procedure. When I first saw Dr. Murrey, he had not undergone the training in Ohio that DePuy Spine requires of any physician before he or she is certified to implant the Charite artificial disk. He subsequently obtained that training in December of 2004 and notified me that I would be a candidate for the procedure because the trainers at the site in Ohio felt like my facet instability would not be an issue. Also, along these lines, Dr. Murrey told me that the physician responsible for implanting this artificial disk has to place it perfectly in the spine or there is a chance that the plastic core of the disk may dislodge. I was very confident with Dr. Murrey's abilities and, based on the fact that he had been involved in a clinical study for the implantation of the ProDisk artificial disk in the cervical spine, I was absolutely confident that he knew what was involved in this type of procedure.

As a defense lawyer who practices primarily in the area of insurance defense and health care, I see a number of disabled individuals who have back problems, who are young, who are dependent upon either Medicaid because they are too poor to afford any type of health insurance coverage, or they are qualified as being disabled by Medicare and therefore receive Medicare benefits. I am absolutely certain that if these patients meet the criteria that I have generally outlined above, and particularly if they are in the hands of a qualified surgeon who has been certified by DePuy Spine to implant the Charite artificial disk, this would allow these disabled individuals to have an outstanding recovery with a goal that they return to work as productive citizens and lead a healthy normal life.

I think it is important for you to understand my situation and how bad I had become prior to the artificial disk replacement (ADR) operation this past February in order to appreciate how well the artificial disc has worked for me. Prior to this surgery, I had lost my ability to completely walk up a flight of stairs in my home. I simply had no strength left in my legs and I was having various problems with pain at the L4-5 level where I had been previously operated on. Because I am a lawyer, and I needed my mind to be able to work during the days, I never sought prescription drugs from my physicians to help me deal with pain issues. Quite frankly, though, my bigger problem was the loss of use of my muscle and function in my legs, and there was no medicine that could repair that. My problem with my legs dates back to 1984, more than twenty years ago, when I helped my parents move from one home to another. We had rented a U-Haul, and my father and I moved almost all of the furnishings and the articles in our home. I immediately had back pain at the L4-5 level. Within a year after that, I noticed a problem in my gait, and one year after that, I had lost my ability to stand up on my right toes. Following that, I developed a very noticeable limp, I leaned forward, my toes were downgoing as I would walk, and I had tingling down the backs of my legs and into the bottom part of my feet. I also had a noticeable sensation problem in the right front aspect of my right leg. Within the year prior to the ADR operation, I had complete tingling in my bottom left foot, I had lost the ability to stand up on my left toes so that I was completely flatfooted. I had no desire to walk more than two blocks. In fact, at the time of my operation, my right calf measured 2" smaller than my left calf 3" below each kneecap.

Following the ADR procedure, I have now regained 3/4" of muscle in my right calf over a period of only four months, I am standing up straighter, I have absolutely no back pain at L4-5, and I am regaining my strength to be able to walk up and down stairs. I also now have the desire and ability to walk two to three miles. I returned to work on a limited basis after 2 1/2 weeks following the surgery, and I have slowly worked my way back into a full time work week.

Prior to my ADR procedure, my doctor's office had submitted all of the appropriate forms with my insurance company, The Guardian, through its PPO provider, MedCost. Two weeks prior to the operation, I was notified by MedCost that the procedure was not certified, and it would not be covered by insurance. They could not give me a reason to support the denial and they had an emergency room doctor review my case. I wrote a number of letters to The Guardian, I involved our law firm's insurance broker, and my doctor spoke to a number of physicians who were panel physicians for The Guardian about this procedure. Two weeks after my operation, The Guardian notified me that it would be covering the entire procedure and that it would be paying for all other appropriate candidate's artificial disk replacement operations using the Charite artificial disk in the future. The problem was that The Guardian did not understand or appreciate this new procedure even though it had been approved by the FDA. My insurance broker told me that once the higher-ups got involved in my case and understood the procedure, they covered it without any further questions. I am still amazed and astounded that professionals in the medical and insurance industry have not taken the appropriate time to understand the remarkable success that this disk has had and will continue to have on the appropriate patients through properly trained physicians. While I clearly understand that there are risks involved with this procedure, I certainly believe that the benefits far outweigh the risks for any patient who has suffered from back problems related to a diseased disk.

While I have read several articles relating to various concerns about the wear and tear on the artificial disk, my physician pointed out to me that the spine has $1/100^{th}$ of the movement of the hip or knee, and he believes that this artificial disk will still be in my body and functioning even if I live a normal life span. I would also point out that the Charite disk provides movement in all planes that mimics the movement of a natural disk. As I have undergone physical therapy following this procedure, I have noticed the natural movement that is allowed by this disk, and I have actually regained more of my natural movement than I had before this surgery.

My hope and desire is that professionals in the medical field ranging from private health insurance companies to Medicare to primary physicians out in the field will focus and pay attention to this wonderful new procedure that is going to provide much needed relief and recovery to numerous back patients. While I do not believe that this artificial disk is right for every patient nor do I believe that any surgeon should be able to implant it, I believe that through certain guidelines, this disk should be covered as a totally insured event. Otherwise, the insurance industry is acting in bad faith and looking away from a procedure that could provide remarkable results now and in the future.

I am more than happy to meet with anyone to discuss my recovery and my thoughts about this procedure. I have no financial interests in Johnson & Johnson, DePuy Spine or any other entity connected with them. I am giving you this recommendation for the coverage of the ADR procedure because I have had an unbelievable result, and I feel like those people who are responsible for whether others can undergo this procedure in the future need to know about the success of this device.

With kind regards, I am

Sincerely yours,

Emerson M. Thompson, III
FOR THE FIRM

EMT/pac

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Texas Back Institute

Friday, June 17, 2005

NT Hefter Hartstein Walz Treitel

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

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

I would like to introduce myself as a Spine surgeon of twenty-two years who is one of the original founders of the Texas Back Institute. I have been actively involved in the North American Spine Society and currently serve as its' Second Vice President. More importantly, I have followed the advancement in spine surgery over the last 20 years, and have found that the most important advance in the treatment of spinal disorders has been the development of the artificial disc. My associates and I at the Texas Back Institute became first interested in this in 1990 when we learned of the Charite' artificial disc. As you well know, it took ten years for the disc study to begin and finally was approved by the FDA in October of 2004.

Currently, for our patients with symptomatic degenerative disc disease, the treatment option has been that of fusion. Not only does this entail a longer hospitalization, but also entails a much longer recovery period in which activities are limited and the patients need to be braced until the fusion is healed which can be as early as six months, but can be as long as twelve months or more. The Charite' FDA prospective study showed that the artificial disc patients got out of the hospital a half a day earlier and in the study at the Texas Back Institute we showed that these patients returned to work and normal activities in half the time of the fusion patients. In addition, it is our hope that the theoretical advantage of the artificial disc will be proven out, which is to prevent abnormal stresses on the level above. There is strong 10 and 11 year data from Europe that shows that these artificial discs continue to function after this period of time.

Although it has not been fully delineated, there are preliminary studies that show that the cost of a fusion for degenerative disc disease can range up to twice as much as that for a disc replacement. In fact, I reported this data at the Spinal Arthroplasty Society in May of 2005.

Currently, I do not see a large number of Medicare-aged patients receiving the artificial disc. With the excellent medical care the population is now receiving and the fact people are living longer, I believe that the numbers may increase. Still I would estimate the number of patients in my practice that are Medicare age that are receiving the artificial disc would be somewhat less than 5%. Medicare patients that have received the artificial disc have been as grateful as any other patient, and, in fact, in many ways they benefit more from the accelerated and faster return to activities which is beneficial to general well being.

Finally, because of the current DRG assignment, I believe that Medicare patients will be denied access to such care due to the fact that current reimbursement does not take into account the magnitude of the surgery and the cost of the implant.

Hopefully, you and your committee will look favorably upon the reassignment of the Charite' to the fusion DRG's of 497/498.

Sincerely,

Richard D. Guyer, M.D.

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

221

DISC DYNAMICS

RECEIVED
JUN 24 2005

BY:.....

NT - Hefter
Hartstein
Walz
Treitel

June 21, 2005

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

Dear Sir or Madam,

I am President and CEO of Disc Dynamics, an emerging medical device company which has developed an implantable device called the DASCOR™ Disc Arthroplasty System (a partial spinal disc prosthesis). DASCOR™ is a minimally invasive surgical procedure for the relief of chronic back pain often caused by degenerative disc disease, (ICD-9-CM 84.64, insertion of partial spinal disc prosthesis, lumbosacral). We did offer comments on the DRG assignment for this code last year (CMS-1428-P) and are asking CMS to reconsider the DRG classification for this year.

The DASCOR™ is currently seeking an IDE approval by the FDA and we believe the procedure will be granted a Category B designation by the FDA (there is a total disc prosthesis that has FDA approval). However the DRG assignment for the cases that would qualify for the clinical trial would fall into DRGs 499 and 500 which do not have any surgical procedures with implantable devices.

The clinical trial for the partial spinal disc prosthesis randomizes patients with degenerative disc disease who would normally be candidates for spinal fusion into the control group (spinal fusion or total disc replacement) or the test group (non-fusion, partial spinal disc prosthesis). Last year CMS would not consider grouping the partial disc prosthesis procedure into the "fusion" DRGs because they said these are not "clinically cohesive" procedures. Unfortunately, there are no "non-fusion" DRGs that reimburse for a procedure and an implantable device. The difference between these fusion and non-fusion procedures are the devices, but the consumption of resources at the hospital is the same (see Figure I).

Because of the similarities in charges between the partial disc prosthesis procedure and spinal fusion procedures (see Figure II), we are requesting that CMS reconsider the suggested DRG placement for ICD-9-CM code 84.64 and group this procedure into DRGs 497 or 498, "spinal fusion except cervical with complications or without complications." DRGs 497 and 498 more closely reflect the cost to the hospital and include the cost of an implantable device. If these ICD-9 codes are not reassigned to more appropriate DRGs such as DRG 497 and 498, Medicare Beneficiaries may not have access to these new technologies.

9600 West 76th Street • Suite T • Eden Prairie, MN 55344 • PH 952-345-2999 • FAX 952-345-2990 • www.discdyn.com

Figure I

	DRG 498 Spinal Fusion w/o Complications Except Cervical 2003 MedPar Charge Data*	Partial Spinal Disc Prosthesis Estimated Charge Data**
General Care	$3,126	$3385
Special Care	$405	$855
OR	$9,681	$4553
Anesthesia	$1,545	$1608
Lab	$1061	$56
Radiology	$795	$1304
Medical Supplies	$21,123	??????
Pharmacy	$2,851	$1605
Other	$1,433	$1024
Total	**$42.017**	**$14,360**

*Source: Solucient
** Source: Clinical trial site estimated charges

Figure II

2003 MedPar Charge Data* for DRG 498

75th percentile	50th percentile	25th percentile
$58,383	**$39,998**	**$27,385**

*Source: Solucient

Thank you for the opportunity to comment on the proposed rule. We look forward to continuing to work with CMS to ensure Medicare Beneficiaries will benefit from this new technology.

Sincerely,

Steven J. Healy
President and CEO
Disc Dynamics

UPMC | University of Pittsburgh Medical Center

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TRANSFERS — WALZ
HART
HEFTER
HARTSTEIN
Seifert
GME/IRP / TRUONG
GME/AFFIL / LEFKOWITZ
GME/RHRC RUIZ
IME Knight
LABOR/SN Kramer
WI/Bd - MILLER
PYMT RTS/OUTLIER - TREITEL

Edward T. Karlovich
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June 21, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop: C424-02
Baltimore, MD 21244-1850

ATTENTION: CMS-1500-P

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

Dear Sir or Madam:

On behalf of the University of Pittsburgh Medical Center (UPMC) we are submitting one original and two copies of our comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule (70 FR 23305-23774, 5/04/2005) "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates."

The following is a summary of UPMC concerns and issues with the FY 2006 proposed rules.

I. Postacute Care Transfer Payment Policy

The proposed expansion of the postacute care transfer policy would increase the number of DRGs covered by this policy from the current 30 to 223. The changes in the proposed rule limit clinical decision making and will penalize hospitals for providing care in the most appropriate setting. Furthermore, it is contrary to the PPS payment system that is based on average payments that potentially provide adequate payment for low cost as well as high cost cases. Another factor to be considered is that cost reductions associated with discharging patients to postacute care facilities are reflected in the annual recalibration of DRG weights and average lengths-of-stay.

II. Outlier Payment Threshold

CMS is proposing a new methodology to calculate the outlier fixed-loss threshold for FY 2006. The proposed rule would result in the fixed-loss outlier threshold for FFY 2006 to be equal to the DRG payment plus IME and DSH payments and new technologies, plus $26,675. The threshold for FFY 2005 was equal to the DRG payment plus IME and DSH payments and new technologies, plus $25,800. An increase in the threshold for FFY 2006 appears questionable considering that outlier payments for the past two years were less than the target of 5.1 percent of operating payments. We urge CMS to reevaluate this proposal.

III. Medical Education Issues

A.) Direct GME Initial Residency Period (IRP) – Simultaneous Match Issue. CMS historically held the position that the IRP for residents in specialties that require a general clinical training year (for example, radiology, anesthesiology, and dermatology) is determined based on the specialty of the first residency program they enter, rather than the second year program, which reflects their intended specialty of training. CMS's proposed rule broadens current policy for hospitals that can document that a resident simultaneously matched for one year of training in a specialty program and for a subsequent period of training in a different specialty. We believe an IRP should be assigned based on the specialty the resident enters in the second year of training, regardless of when the resident matches to the advanced specialty program.

B.) New teaching hospitals currently do not participate in a Medicare GME affiliated group – CMS believes these facilities should be part of an affiliated agreement only if there is a positive adjustment that is higher than the hospital's base year resident cap. We urge CMS to consider including adjustments both positive and negative to the affiliated caps for new urban teaching facilities with a temporary exclusion for the first three to five years to satisfy any circumventing of existing or proposed regulations.

C.) Resident caps for hospitals changing geographic status – CMS is proposing that providers rescinding the rural status should forfeit any IME cap adjustment it received during its rural status. We believe that urban teaching hospitals that reclassify to rural status for a significant period of time before returning to urban status (3-5 years, for example) should be permitted to retain any upward IME cap adjustments that occurred during the rural period.

D.) IME adjustments for TEFRA hospitals converting to IPPS hospitals – CMS is proposing that the (FI) will determine an IME FTE cap for TEFRA hospitals converting to IPPS, but does not specify applicability to excluded units that convert to IPPS. CMS should clarify the applicability of excluded units in the final rule.

E.) IME resident caps for formerly inpatient PPS-excluded hospitals and units – CMS proposes that for PPS-excluded hospitals that subsequently become subject to the inpatient PPS, the IME cap that will be established for them will equal the resident count that was used to establish their DGME cap. We believe a more appropriate

solution may be to incorporate the IME cap that CMS calculates as part of the psychiatric and rehabilitation facility prospective payment systems. Using the same cap would maintain consistency across payment systems.

IV. Wage Index

There continues to be significant concerns with the current wage index methodology. Recently, CMS has made amendments to the wage index such as the One-Time Wage Index Classification, Section 508 of the Medicare Improvement and Modernization Act (MIMA); the Wage Index Adjustment Reclassification Reform, Section 505 Of MIMA; and the wage index changes in the final IPPS rule published August 11, 2004. As opposed to the amendments published in the August 11, 2004 final rule, the Centers for Medicare and Medicaid Services (CMS) should consider major reforms to the Medicare wage index system since it does not fairly distribute the available funds based upon the provider's cost, labor market, and geographic location. In addition, the data within the wage index is not based upon consistent data nationwide. The Medicare wage index is the starting basis for the Medicare Inpatient Prospective Payment System (IPPS). Since the Medicare wage index is budget neutral, alterations to the wage index calculations result in the shift of dollars among IPPS facilities nationwide. This shift not only impacts the base Medicare DRG, but also impacts the Medicare Indirect Medical Education (IME) and Disproportionate Share (DSH).

Below please find detailed comments for your consideration. We appreciate your review and consideration of our comments prior to the completion of the final guidelines.

Postacute Care Transfer Issue: Expansion of Postacute Care Transfer Policy from the Current 30 DRGs to 223 DRGs (Pages 23411-23424)

Proposed Rule: In this year's proposed rule CMS indicated they conducted an extensive analysis of the data on the number of postacute care transfers across all DRG's. As a result of this analysis, CMS believes that substantial revisions to the criteria for including a DRG in the postacute care transfer policy is warranted. Therefore, CMS is considering two options for revising current criteria. Option 1 is to include all DRGs in the postacute care transfer policy in order to provide consistent treatment to all DRGs; and Option 2 that excludes DRGs that have a small number or proportion of cases transferred to postacute care. Option 2, which is being formally proposed by CMS, includes 223 DRGs that have a relatively high volume and a relatively high proportion of postacute care utilization. CMS evaluated these 223 DRGs to determine common characteristics that were then used to develop new proposed selection criteria for postacute care transfer cases. CMS is inviting providers to comment on these two options.

Response: We do not support the expansion of the postacute care transfer policy beyond its current level of 30 DRGs, nor do we support the change in qualifying criteria. We urge CMS to withdraw both options discussed in this proposal, as well as the proposed criteria change. While we recognize that section 1886(d)(5)(J)(iv) of the Act authorizes the Secretary to expand the postacute care transfer policy beyond the initial 10 DRGs, it is not required to do so. We believe

this proposed policy expansion limits clinical decision-making and penalizes hospitals for providing the most appropriate care in the most appropriate setting. The proposals to expand postacute care transfer policy to all 550 DRGs, or 223 DRGs, is contrary to the fundamental principles of the PPS system which is based on the methodology of average payments with some stays greater than the geometric length-of-stay (GLOS) and others less. Under both of these proposals, hospitals will be financially penalized when the patient is discharged to a postacute setting with a length-of-stay shorter than the average LOS. The elimination of potential margins on the shorter stay cases penalizes hospitals, as there would be no offset to costs that exceed the average on longer-stay cases. We also believe the annual recalibration of DRG weights and average lengths-of stay reflects these postacute care transfers.

Outlier Payment Threshold Issue: Increase in Fixed-Loss Cost Outlier Threshold (Pages 23469-23470)

Proposed Rule: The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus $26,675. The threshold would be applicable for both operating and capital outlier payments. In FFY 2005, the threshold was the DRG payment plus any IME and DSH payments, plus new technology payments, plus $25,800.

Response: The FFY 2006 proposed cost threshold is 3.4 percent higher than the level in FFY 2005. Outlier payments are funded through a 5.1 percent reduction in the PPS standardized payment amount. Consequently, CMS sets the outlier cost threshold at a level that it believes will result in outlier payments that equal 5.1 percent of total DRG payments. However, CMS estimates that outlier payments represented only 3.5 percent of total DRG payments in FFY 2004. Further, CMS believes that outlier payments for FFY
2005 will be approximately 4.4 percent of actual total DRG payments, 0.7 percentage point lower than the 5.1 percent projected in setting the FFY 2005 outlier threshold. Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals.

Considering that the outlier threshold was set too high during the last two years resulting in total outlier payments that were less than the target of 5.1 percent of operating payments, we believe your proposed FY 2006 outlier threshold should be reevaluated. It is unclear whether the threshold should be further increased, or potentially decreased for FFY 2006.

Graduate Medical Education – Direct GME Initial Residency Period (IRP) Limitation: Simultaneous Match (Pages 23438-23440)

Proposed Rule: The proposed rule broadens the current CMS policy regarding "simultaneous match". In last year's FY 2005 IPPS final rule, CMS stated that effective for portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident "simultaneously matched" for one year of training in a particular specialty residency program and for a subsequent period of training in a different specialty program, the resident's IRP will be determined based

on the period of board eligibility associated with the second program. This proposed rule broadens this CMS policy by allowing hospitals that can document that a resident matched to an advanced residency program beginning in the second year prior to the commencement of **any** training, the resident's IRP will be determined based on the advanced specialty, even if the resident had not matched for a clinical base year program.

Response: This proposal would broaden the current CMS policy, which allows for only "simultaneous match" situations. However, we believe that a much more straightforward, and administratively less burdensome, solution is that for residents whose first year of training is completed in a program that provides a general clinical year of training, an IRP should be assigned based on the specialty the resident enters in the second year of training, regardless of when the resident matches to the advanced specialty program.

Graduate Medical Education – New Teaching Hospitals Participation in Medicare GME Affiliated Groups (Pages 23440 – 23441)

Under current regulations, existing teaching hospitals that meet specified criteria may enter into Medicare GME affiliation agreements by which they combine their respective resident caps and then redistribute them according to their agreement—with the provision that the sum of the new caps cannot exceed the aggregate combined cap. Currently, 42
C.F.R. §413.79(e)(1)(iv) specifies that new teaching hospitals that are located in urban areas cannot be part of Medicare GME affiliated groups. New rural teaching hospitals may enter into these agreements but only if the rural hospital provides training for at least one-third of the FTE residents in all of the joint programs of the affiliated hospitals.

CMS states that its rationale for the new teaching hospital provision is to prevent "gaming" by current teaching hospitals that might encourage non-teaching hospitals to become teaching hospitals, receive a resident cap, and then enter into a GME affiliation agreement in which they would transfer many of their cap slots to the existing teaching hospital. A more flexible standard is provided for new rural teaching hospitals because rural hospitals may not have sufficient patient volume to support residency training programs.
Proposed Rule: The proposed rule would allow new urban teaching hospitals to enter into GME affiliation groups but only if there is a "positive adjustment" to its direct GME and/or IME cap; that is, the new teaching hospital's revised cap pursuant to the affiliated agreement must be higher than its base year cap.

Response: While we appreciate that a positive action has been made, we continue to believe this policy is unnecessary. Hospitals do not decide to become teaching institutions and go through the rigors of the accreditation process without extensive thought and analysis. So the proposed recognition of only "positive adjustments" in an affiliation agreement for new urban teaching providers still seems excessively restrictive, without allowing for unforeseen future circumstances. Therefore we would urge CMS to alleviate their concerns by considering replacing the permanent exclusion of negative adjustments for new urban teaching facilities with a temporary

exclusion for the first three to five years. This would ultimately provide new urban teaching facilities the same training program flexibility that is currently allowed new rural teaching providers.

Graduate Medical Education – Resident Caps for Hospitals Changing Geographic Status (Pages 23441-23443, and 23433-23434)

Currently, under the resident cap provisions, rural hospitals' resident caps equal 130 percent of their base year (generally 1996) resident counts and their resident caps are increased if the rural hospital starts a new residency program. These provisions do not apply to urban teaching hospitals.

Proposed Rule: As a result of labor market definitional changes, some rural teaching hospitals are now considered urban. Under the proposed rule, these hospitals would retain their 130 percent cap determination, as well as any new program cap expansions that occurred while they were classified as rural.

Also, urban hospitals that received cap increases for rural training track programs may retain those increases even if the rural "track" has been re-designated as urban due to new labor market definitions.

The situation is different for an urban hospital that had applied and been approved to be reclassified as rural under section 1886(d)(8)(E) (codified at 42 C.F.R. §412.103) and then returns to being urban. First, according to CMS, urban hospitals that reclassify to rural under this section may receive the rural cap adjustments (130 percent and new program expansions), but only for their IME cap. This is because under the statute the reclassification affects only payments made under section 1886(d) of the Medicare statute. While IME payments are authorized under this section, DGME payments are authorized under section 1886(h). Consequently, CMS states that only the IME cap is affected by the change to rural status.

If the hospital subsequently rescinds its rural reclassification status and returns to being urban, CMS proposes that the hospital would forfeit any IME cap adjustment that it received during its rural status.

Response: CMS believes it is appropriate to allow rural hospitals that become urban due to labor market definitional changes to retain permanently any upward cap adjustments that occurred while they were considered rural because the labor market changes were not within their control. This is in contrast to those urban hospitals that voluntarily chose to change their status to rural under section 1886(d)(8)(E) and then return to urban status. CMS is concerned that some hospitals would seek rural status for a short period only to receive the upward cap adjustment. If this is the concern, it seems that urban teaching hospitals that reclassify to rural status for a significant period of time before returning to urban status (for example, 3-5 years), should be permitted to retain any upward cap adjustments that occurred during the rural period.

IME Adjustment - IME Adjustment for TEFRA Hospitals Converting to IPPS Hospitals (Pages 23432 – 23433)

Proposed: CMS is proposing to adopt into regulation that a fiscal intermediary (FI) will determine an IME FTE cap for TEFRA hospitals converting to IPPS, since no IME count was originally required for exempt hospitals. So beginning with the hospital's payments under the IPPS, the FI will base the IME FTE count on residents during the cost reporting period(s) used to determine the hospital's direct GME FTE Cap. The new IPPS hospital's IME FTE cap would be subject to the same rules and adjustments as any IPPS hospital's IME FTE Cap per section § 412.105(f).

Response: While the proposed rule indicates its application to TEFRA hospitals that convert to IPPS it does not state it's applicability to excluded units that convert to IPPS. We believe the same policy should apply, and that CMS should clarify this in the final rules.

IME Adjustment – IME Resident Caps for Formerly Inpatient PPS-Excluded Hospitals and Units

Proposed: CMS proposes that for PPS-excluded hospitals that subsequently become subject to the inpatient PPS, the IME cap that will be established for them will equal the resident count that was used to establish their DGME cap.

Response: If CMS ultimately chooses this option, we believe it also should be the method for determining the IME cap for units. We believe a more appropriate solution may be to incorporate the IME cap that CMS calculates as part of the psychiatric and rehabilitation facility prospective payment systems. Under the inpatient psychiatric facility (IPF) PPS, which includes an IME adjustment, an IME cap is established based on the number of residents training in the IPF as reported by the hospital or unit in its most recently filed cost report before November 15, 2004 (See IPF PPS Final Rule, 69 Fed. Reg. at 66955). If a psychiatric PPS-excluded hospital or unit subsequently becomes subject to the inpatient acute care PPS, using this same cap would maintain consistency across payment systems.
In the 2006 inpatient rehabilitation facility (IRF) proposed rule, CMS proposes that an IME adjustment be added. It also proposes that an IRF resident cap be established, based on the number of residents reported by the IRF on its most recent cost reporting period on or before November 15, 2003. Depending upon the policies that are determined in the 2006 IRF final rule, we believe consistency dictates that for those IRFs, which lose or change their status and become subject to the acute care inpatient PPS, the IME cap which should be utilized should be that which was used under IRF PPS.

Wage Index – Proposed Decrease to the Labor-Related Share (Pages 23391-23394)

CMS defines labor-related share as the national average proportion of operating costs that are related to, influenced by, or vary with local labor markets. We believe that the operating cost categories that are related to, influenced by, or vary with local labor markets are wages and salaries, fringe benefits, professional fees, contract labor, and

Wage Index – Proposed Decrease to the Labor-Related Share (Pages 23391-23394)

CMS defines labor-related share as the national average proportion of operating costs that are related to, influenced by, or vary with local labor markets. We believe that the operating cost categories that are related to, influenced by, or vary with local labor markets are wages and salaries, fringe benefits, professional fees, contract labor, and labor intensive services. Currently, for hospitals with wage indices above 1.0, the labor related share that is adjusted by the wage index is 71.1 percent. The labor share for hospitals with wage indices less than 1.0 is 62 percent, as dictated by the Medicare Modernization Act (MMA).

Proposed Rule: CMS proposes to decrease the labor related share from 71.1 percent to 69.7 percent. Because of the MMA mandate, the labor share for hospitals with wage indices below 1.0 will remain at 62 percent.

Response: As noted in our summary, major reforms should be considered to the current Medicare wage index methodology as opposed to amendments to the current system. However, absent sweeping changes in the Medicare wage index methodology, in addition to decreasing the labor related share from 71.1 percent to 69.7 percent for hospitals with wage indices above 1.0, we request that CMS decrease the labor related share from 62 percent to 50 percent for hospitals with wage indices under 1.0.

Conclusion

We appreciate the opportunity to submit these comments on your proposed changes to the Acute Care Hospital Inpatient Prospective Payment System for fiscal year 2006, and request that our concerns be considered before final regulations are published.

If you have any questions regarding our comments please contact Christine Lewandowski, Director of Reimbursement at (412) 647-2306.

Sincerely,

Edward T. Karlovich
Chief Financial Officer
Academic and Community Hospitals

cc: P. Castillo
C. Lewandowski
T. Nigra
P. Stimmel

Congress of the United States
Washington, DC 20515

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June 23, 2005

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

Re: File Code CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; *Comments on New Technology Applications*

Dear Dr. McClellan:

On behalf of Members of the New Jersey Congressional Delegation, we are pleased to submit comments on the Fiscal Year (FY) 2006 Medicare hospital Inpatient Prospective Payment System ("IPPS") proposed rule. In particular, we wish to express our serious concerns about the Centers for Medicare and Medicaid Services' (CMS) continued frustration of Congressional intent in implementing add-on payments for new technologies.

Congress established these add-on payments to encourage medical technology innovation; provide relief to hospitals that take advantage of such innovation; and thereby ensure access to new technologies for Medicare beneficiaries. While Congress gave CMS significant flexibility to design and structure the specifics of the add-on payments, CMS's unfortunate lack of consistency in implementing the law, and its narrow reading of it, threatens to render the payments meaningless. The proposed denial of an add-on payment for the Trident® Acetabular System for Hip Arthroplasty (Trident®) is an example of such inconsistency and narrowness of interpretation.

Trident® holds the promise that younger, active Medicare beneficiaries who require hip replacements could receive hip implants that would last for the rest of their lives, without the need for costly revisions after 10-15 years. It is the type of medical device Congress envisioned when it created add-on payments to guarantee Medicare patient access to breakthrough technologies. We therefore urge CMS to fully reconsider Trident's® new technology application prior to drafting the final rule.

Background and Legislative History

To help compensate for the period of time during which medical procedure costs are not fully reflected in Medicare's data, and to ensure that Medicare patients have access to the latest medical technologies and procedures, Congress created the Medicare inpatient new technology add-on payment as part of the "Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000." As implemented by CMS, technologies receiving the add-on payment must meet the following criteria:

1) The technology must be "new" (according to CMS, a technology is deemed "new" during the two- to three-year period immediately following its market introduction);
2) The existing Diagnosis Related Group (DRG) payment must not adequately reflect the costs of the new technology, as determined by a formula (i.e., a charge threshold) developed by CMS; and
3) The technology must represent a "substantial improvement" in patient diagnosis or treatment over existing technologies.

Implementation of the Law

Since the inception of the add-on payments in FY 2003, only 26 applications have been filed. This is a relatively low number, as CMS appropriately has set high standards for meeting the new technology definition, including conducting randomized, controlled clinical trials to prove that the product is a "substantial improvement" over existing technologies. However, despite the low number of applications filed, CMS has approved only four of them. Of the eight new applications filed under this year's proposed rule, none were approved. CMS proposed to deny five applications and postponed decisions on the other three pending further analysis prior to the final rule.

As stated above, while Congress gave CMS the flexibility necessary to implement the add-on payments, Congress did intend for the payments to be used to encourage medical technology innovation; provide relief to hospitals that take advantage of such innovation; and ensure beneficiary access to new technologies. Unfortunately, CMS's lack of consistency in implementing the law and narrow reading of it threaten to undermine congressional intent.

CMS's Preliminary Denial of an Add-On Payment for Trident®

In the FY 2006 IPPS proposed rule, CMS made a preliminary decision to deny an add-on payment for Trident®. While it does not disagree with the applicant's assessment that Trident® exceeds the charge threshold, CMS argues that the technology is neither "new" nor a "substantial improvement" over existing technologies.

Determination of "New"

Since Trident® was available on the market in April 2003, CMS asserts that the product will fall outside of the three-year "new" window halfway through FY 2006. However, on multiple other occasions in the past, CMS has approved add-on payments for products when the "new" cutoff date also fell halfway through the given payment year. Last year, for example, CMS approved add-on payments for cardiac resynchronization therapy with defibrillator (CRT-D). One of the CRT-D devices in question received Food and Drug Administration (FDA) approval in May 2002. CMS deemed this device to be "new" since the FY 2005 add-on payment year would represent the third year of the two-to-three year "new" window after the date of FDA approval. Moreover, as CMS states in this year's proposed rule, "We also noted that we would extend new technology add-on payments for the entire FY 2005 even though the 2-3 year period of newness ended in May 2005 for CRT-D since predictability is an important aspect of the prospective payment methodology and, therefore, we believe it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year."

It is difficult to find a distinction between the timeframe at issue in the case of Trident® and the timeframe that existed in the case of CRT-D. Trident® was available on the market in April 2003 and is being considered for an FY 2006 add-on payment. As with the CRT-D device, Trident's® two-to-three year period of newness would end in the middle of the third and final year of eligibility for an add-on payment. Using CMS's interpretation of its own regulations, not only is Trident® still within the two-to-three period during which a technology can be considered "new," it is eligible for an add-on payment for the full fiscal year. Moreover, it is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

Determination of "Substantial Improvement"

CMS additionally asserts that Trident® represents only an "incremental advance" over similar technologies, despite the fact that there are no peer-reviewed, published studies about the increased longevity and decreased wear allegedly produced by the "similar" products to which the agency alludes. Unlike these other products,

Trident® has been subjected to extensive randomized, controlled clinical studies that meet the high standards for evidence collection that CMS has set. It is inconsistent for CMS to set a gold standard for the quality of clinical trial design and data collection and then give a failing grade to an add-on payment application that has met that standard by comparing it to a product that has not.

If properly implemented, new technology add-on payments have the potential to harness the benefits of breakthrough medical technologies for Medicare beneficiaries. A consistent and appropriate reading of the statute would go a long way toward helping patients live longer, healthier, and more productive lives. We therefore strongly urge CMS to carefully reconsider Trident's® application for a new technology add-on payment before drafting the FY 2006 final IPPS rule. We look forward to your response.

Sincerely,

Rep. Scott Garrett

Rep. Frank Pallone

Rep. Steve Rothman

Rep. Bob Menendez

Rep. Rush Holt

Rep. Mike Ferguson

Rep. Chris Smith

Rep. Jim Saxton

Rep. Frank LoBiondo

Rep. Bill Pascrell

Rep. Rob Andrews

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

Re: CMS-1500-P
Trident New Technology Add-On Application &
CMS Response

Dear Dr. McClellan:

I am writing in response to CMA proposed ruling to deny an add-on payment for ceramic on ceramic hip prosthesis. Ceramic bearing surfaces offer the opportunity to potentially eliminate the need for future (revision) hip procedures.

I am experienced in total hip replacement surgery, having served as president of the Hip Society and devoting the far majority of my practice over the last 37 years to surgery of the hip. I am personally disappointed with the CMS' proposed ruling to deny new technology as an add-on assignment for the Trident implant. I was one of the initial investigators of the Trident implant for its FDA study and have followed patients closely as to their functional and radiographic outcomes. They continue to enjoy unlimited activities and no evidence of wear, migration or deterioration. If it is the wish of CMS to ultimately assign the technology of ceramics to a higher paying DRG, I would recommend that change. However, in the interim, while charge data is being gathered to support a DRG reassignment, there needs to be an avenue for hospitals

to financially finance this new technology. Our hospitals ~~will be~~ substantially underpaid for this resource intensive hip arthroplastic technology. The advantages of the ceramic on ceramic bearing are that the material has undergone the scrutiny of an extensive prospective, randomized control clinical study and the Trident study was the first to be approved by the FDA.

In the proposed ruling I read there will be additional ICD-9 codes to support two new DRG's, so revisions total hip and knee arthroplasty can be segmented from primary arthroplasty. I support this in the hopes that revisions will see better reimbursement as supported by the data used to demonstrate the additional costs associated with revision procedures. The primary goal of utilizing ceramic on ceramic bearing surfaces in the younger patient population (including the young and active Medicare beneficiary) is to eliminate revisions procedures in the future. The additional costs that result from revision procedures, which CMS has correctly identified, could be prevented if patients have access to ceramic on ceramic technology.

CMS refers to other technologies on the market that gap the improvement of ceramic bearings making the ceramic technology an incremental advancement. I agree there are other technologies that are on the market that show great promise. I am very careful to balance the use of technologies that show promise to those that have strong peer reviewed published data. I am careful to review the trial designs of clinical studies to understand what endpoints are analyzed and documented and do not see clinical data today that would allow me to consider comparing other bearing technologies to ceramic on ceramic. This may change in the future, but for patients who are young and active today, I feel they deserve products that have been proven.

I'm available for telephone or e-mail consultation should you have questions in reference to this letter.

Sincerely yours,

Benjamin E. Bierbaum, M.D.

BEB:gs

bbierbau@caregroup.harvard.edu

United States Senate
WASHINGTON, DC 20510

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(Hip)

Hetler
Hartstein
Brooks
Fagan
Gruber
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Hue
Walz
Treitel

June 23, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20515

Re: File Code CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; *Comments on New Technology Applications*

Dear Dr. McClellan:

We are pleased to submit our comments on the provisions on New Technology Applications in the fiscal year 2006 Medicare hospital inpatient prospective payment system (IPPS) proposed rule. In the interests of Medicare beneficiaries' access to a breakthrough improvement in hip replacement technology and savings to the Medicare program, we strongly urge you to reconsider CMS's preliminary decision to deny new technology add-on payments for the Trident Acetabular System for Hip Arthroplasty.

We believe that Trident hip replacements hold particular promise for younger, active Medicare beneficiaries because the system utilizes a patented alumina ceramic-on-ceramic bearing surface rather than metal-on-plastic or metal-on-metal surfaces. Alumina is the hardest material next to diamond. The patented Trident design also captures the ceramic insert in a titanium sleeve. Taken together, it is our understanding that these innovations increase the strength of the ceramic insert by 50 percent over other designs, make the device extremely hard and scratch resistant, produce better lubrication, produce a low coefficient of friction and excellent wear resistance, result in no potential for metal or ion release, and result in less alumina particle release, thus significantly reducing the need for future hip replacements or revisions. It is our understanding that these results, which demonstrate a substantial improvement over existing hip replacement technologies, come from extensive randomized, controlled clinical studies that meet CMS's high standards for evidence collection.

It is our understanding that your agency's denial of Trident's add-on payment application was based primarily on Trident's having been on the market for just over two years, which means that the two-to-three year timeframe when CMS considers a product to be "new" would end halfway through FY 2006. It is our understanding, however, that CMS has approved add-on payments for other technologies, such as a cardiac resynchronization therapy with defibrillator (CRT-D), when their period of "newness" also ended midyear. We would ask that CMS apply similar flexibility in Trident's case.

We believe that in doing so, your agency would be living up to Congress's intent in establishing IPPS add-on payments—to ensure that Medicare beneficiaries would have access to technologies that represent a significant improvement over existing technologies, and in the case of Trident, may significantly reduce the need for and risks associated with a second hip replacement or revision.

Enclosed please find a letter from Stryker detailing their concerns and requests. We respectfully request that you review this letter and appreciate your immediate consideration of this critical issue. Thank you for your attention to this matter. We look forward to hearing from you.

Sincerely,

FRANK R. LAUTENBERG

JON S. CORZINE

325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

Orthopaedics

June 16, 2005

Senator Frank R. Lautenberg
324 Hart Senate Office Building
Washington, DC 20510

Senator Jon S. Corzine
502 Hart Senate Office Building
Washington, DC 20510

Dear Senators Lautenberg and Corzine:

We are writing to you to express our serious concerns about the Centers for Medicare and Medicaid Services' (CMS) continued frustration of Congressional intent in implementing add-on payments for new technologies under the Medicare Inpatient Prospective Payment System ("IPPS"). In its recently released inpatient proposed rule, CMS proposes to deny an add-on payment for the Trident® Acetabular System for Hip Arthroplasty (Trident®). CMS's rationale for this proposed denial is a prime example of the way in which the agency has inconsistently and narrowly interpreted the statutory language.

Trident® holds the promise that younger, active Medicare beneficiaries who require hip replacements could receive hip implants that would last for the rest of their lives, without the need for costly revisions after 10-15 years. It is the type of medical device Congress envisioned when it created add-on payments to guarantee Medicare patient access to breakthrough technologies. We therefore urge you to ask CMS to fully reconsider Trident's® new technology application prior to drafting the final rule.

Background and Legislative History

To help compensate for the period of time during which medical procedure costs are not fully reflected in Medicare's data, and to ensure that Medicare patients have access to the latest medical technologies and procedures, Congress created the Medicare inpatient new technology add-on payment as part of the "Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000." As implemented by CMS, technologies receiving the add-on payment must meet the following criteria:

1) The technology must be "new" (according to CMS, a technology is deemed "new" during the two- to three-year period immediately following its market introduction);
2) The existing Diagnosis Related Group (DRG) payment must not adequately reflect the costs of the new technology, as determined by a formula (i.e., a charge threshold) developed by CMS; and
3) The technology must represent a "substantial improvement" in patient diagnosis or treatment over existing technologies.

Implementation of the Law

Since the inception of the add-on payments in FY 2003, only 26 applications have been filed. This is a relatively low number, as CMS appropriately has set high standards for meeting the new technology definition, including conducting randomized, controlled clinical trials to prove that the product is a "substantial improvement" over existing technologies. However, despite the low number of applications filed, CMS has approved only four of them. Of the eight new applications filed under this year's proposed rule, none were approved. CMS proposed to deny five applications and postponed decisions on the other three pending further analysis prior to the final rule.

While Congress gave CMS the flexibility necessary to implement the add-on payments, Congress did intend for the payments to be used to encourage medical technology innovation; provide relief to hospitals that take advantage of such innovation; and ensure beneficiary access to new technologies. Unfortunately, CMS's lack of consistency in implementing the law and narrow reading of it threaten to undermine congressional intent.

CMS's Preliminary Denial of an Add-On Payment for Trident®

In the FY 2006 IPPS proposed rule, CMS made a preliminary decision to deny an add-on payment for Trident®. While it does not disagree with the applicant's assessment that Trident® exceeds the charge threshold, CMS argues that the technology is neither "new" nor a "substantial improvement" over existing technologies.

Determination of "New"

Since Trident® was available on the market in April 2003, CMS asserts that the product will fall outside of the three-year "new" window halfway through FY 2006. However, on multiple other occasions in the past, CMS has approved add-on payments for products when the "new" cutoff date also fell halfway through the given payment year. Last year, for example, CMS approved add-on payments for cardiac resynchronization therapy with defibrillator (CRT-D). One of the CRT-D devices in question received Food and Drug Administration (FDA) approval in May 2002. CMS deemed this device to be "new" since the FY 2005 add-on payment year would represent the third year of the two-to-three year "new" window after the date of FDA approval. Moreover, as CMS states in this year's proposed rule, "We also noted that we would extend new technology add-on payments for the entire FY 2005 even though the 2-3 year period of newness ended in May 2005 for CRT-D since predictability is an important aspect of the prospective payment methodology and, therefore, we believe it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year."

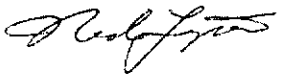
It is difficult to find a distinction between the timeframe at issue in the case of Trident® and the timeframe that existed in the case of CRT-D. Trident® was available on the market in April 2003 and is being considered for an FY 2006 add-on payment. As with the CRT-D device, Trident's® two-to-three year period of newness would end in the middle of the third and final year of eligibility for an add-on payment. Using CMS's interpretation of its own regulations, not only is Trident® still within the two-to-three period during which a technology can be considered "new," it is eligible for an add-on payment for the full fiscal year. Moreover, it is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

Determination of "Substantial Improvement"

CMS additionally asserts that Trident® represents only an "incremental advance" over similar technologies, despite the fact that there are no peer-reviewed, published studies about the increased longevity and decreased wear allegedly produced by the "similar" products to which the agency alludes. Unlike these other products, Trident® has been subjected to extensive randomized, controlled clinical studies that meet the high standards for evidençe collection that CMS has set. It is inconsistent for CMS to set a gold standard for the quality of clinical trial design and data collection and then give a failing grade to an add-on payment application that has met that standard by comparing it to a product that has not.

If properly implemented, new technology add-on payments have the potential to harness the benefits of breakthrough medical technologies for Medicare beneficiaries. A consistent and appropriate reading of the statute would go a long way toward helping patients live longer, healthier, and more productive lives. We therefore strongly urge you to request that CMS carefully reconsider Trident's® application for a new technology add-on payment before drafting the FY 2006 final IPPS rule.

Sincerely,



Ned Lipes
Executive Vice President

WINSTON & STRAWN LLP

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Geo Reclass (multicamp)

Hefter, Hartstein Kenly

June 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1500
Room 45-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code: CMS-1500-P:
Geographic Reclassifications

Ladies and Gentlemen:

We welcome the opportunity to submit comments on the Hospital Inpatient Prospective Payment System Proposed Rule for Fiscal Year 2006 on behalf of our client, Evanston Northwestern Healthcare Corporation ("ENH"). ENH operates a multicampus hospital in the northern Chicago suburbs with campuses in Evanston, Glenview, and Highland Park, Illinois.

ENH applauds CMS' proposed revisions to § 412.230 and urges CMS to adopt these revisions in the final rule. As noted in the preamble, the CMS revisions provide an avenue for individual campuses of multicampus hospitals that are assigned to a new wage area to apply for reclassification. By permitting multicampus hospitals to submit a supplemental Form S-3, CMS is affording multicampus hospitals the same right as all other hospitals to apply for reclassification.

ENH believes that some clarification regarding the rule would be helpful.

(1) Effect of FY 2006 Reclassification

New § 412.230(d)(2)(iii) provides that a multicampus hospital that submitted an application for reclassification for FY 2006 may use "composite wage data for the entire multicampus hospital system as its hospital-specific data." Generally, a hospital is granted

reclassification for a three-year period. 42 C.F.R. § 412.274. Please clarify that a decision to grant the reclassification of an individual campus of a multicampus hospital for FY 2006 will similarly be effective for a three-year period.

(2) Applications for Reclassification Beginning FY 2007

It appears that generally CMS requires a hospital seeking reclassification to submit wage data for the fiscal years 3-5 years prior to the fiscal year for which reclassification is sought (*e.g.* reclassification applications for FY 2006 required wage data from FYs 1999-2001). A multicampus hospital seeking reclassification for FY 2007 will likely be required to submit wage data for FYs 2000-2002. A multicampus hospital that receives a three-year reclassification beginning FY 2006 will have to refile for reclassification for FY 2009 and, thus, will likely be required to submit a supplemental Form S-3 for FYs 2002-04. We suggest that the final rule address the following questions:

- whether a multicampus hospital should begin submitting supplemental Forms S-3 for prior years or wait until it anticipates filing an application for reclassification, and

- whether a multicampus hospital that is granted reclassification should begin filing supplemental Forms S-3 annually with its cost report.

Again, ENH applauds the proposed revisions to § 412.230. Allowing multicampus hospitals to submit a supplemental Form S-3 will permit individual campuses of multicampus hospitals to apply for reclassification. This furthers Congressional intent in establishing the administrative process for geographic reclassification to permit hospitals paying higher wages to receive reimbursement commensurate with their higher wages.

Sincerely,

Marion Kristal Goldberg

227

Michigan
ORTHOPEDIC
SPECIALISTS

21031 Michigan Avenue
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PH 313 277 6700
FAX 313 277 2483

Lawrence G. Morawa, M.D.
Eric T. Silberg, M.D.
Joseph C. Finch, D.O.
Marc J. Milia, M.D.
Kelli L. Crawford, ATC, P.A.-C.
Shaunnah E. Yeihey, P.A.-C.
Carol Tylutki, R.N., B.S.N., O.N.C.

June 16, 2005

Re: File Code CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; *Comments on New Technology Applications*

DRG/Gen (Hip)

Hefter
Harstein
Brooks
FASAN
Gruber
Kelly
Hue

To Whom It May Concern:

Re: Medicare CMR

I recently read your ruling with respect to additional charges for hard on hard bearing surfaces and I feel there are some very important points that should be considered and should be potentially modified.

Currently, the major cost to a hospital is for revision total hip surgery. Under the current DRG reimbursements, the hospital loses a considerable amount on each and every case that is a revision because of the low reimbursement. I do not feel that needs to be changed, but we need a system by which we can decrease the number of revisions being done, particularly, since the population is aging, and more and more total hips are being done, both at an earlier age and in a very active senior age group.

The number of revisions without the ability to insert the hard on hard bearing surfaces, which would put the hospital on a significant disadvantage particularly in the current climate that is very tight with respect to profit margins and ability to continue to operate successfully with the current reimbursement that is available. Hospitals now operate on a very small percentage of profit margin to 2% to 3%. Any loss items become a concern for the hospital.

We also have the hospital looking at what the patients are receiving in their hip. If there is a cost variation on a current total hip with a better bearing surface, the hospital is reluctant to approve the procedure. Frequently, they will deny the surgeon from placing a hard on hard bearing surface to accommodate a patient that is very young or active. This would mean a revision later on and another loss to the hospital that is even more significant than the original cost of the bearing surfaces.

I think this is a very significant reason to consider. The hospital should have a premium on having the hard on hard bearing surfaces put in the younger patients and seniors that are very active with a longer life expectancy. This should decrease the number of revisions and ultimately would be a cost savings. It would also allow the physician to continue to make choices based on patients and not economics which I find distasteful.

I would hope you would reconsider your decision and allow us to look at a premium charge. We do appreciate the fact that you have allowed us to now do tracking which in time will prove with ICD 9 codes, that these will last longer and be more successful than the current bearing technology we have.

Sincerely,

Lawrence G. Morawa, MD
LGM:amh
LGM:

SECTION 508 HOSPITAL COALITION

(52) 228-0

June 24, 2005

Geo Reclass
Hosp Redes.

Hefter
Hartstein
Kenly
Miller

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

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

Dear Sir or Madam:

Please accept these comments from the 50 hospitals that comprise the Section 508 Hospital Coalition regarding Geographic Reclassifications, and specifically the timing and duration of our special wage index reclassifications.

Under Section 508 of the *Medicare Modernization Act* ("MMA"), hospitals that qualified for wage index reclassification are reclassified for the period April 1, 2004 through March 31, 2007. Most of the hospitals that qualified for reclassification under Section 508 cannot otherwise qualify for wage index reclassification, and their pending reclassifications will expire March 31, 2007, unless Congress takes action to extend their reclassifications. However, some hospitals that qualified for reclassification under Section 508 can qualify for wage index geographic reclassification under one of the opportunities available through 42 C.F.R. Part 412, Subpart L. These hospitals need CMS to clarify when they should apply for reclassification under a Subpart L opportunity.

Specifically, CMS needs to direct us as to whether we should apply in September 2005 or September 2006, and when reclassification requests made during one of these reclassification cycles will become effective. We propose that CMS resolve this matter by allowing Section 508 hospitals to apply either September 1, 2005 or September 1, 2006 for a reclassification to be effective beginning April 1, 2007. CMS should likewise make reclassifications sought under this exception effective for 2.5 years, rather than the usual 3 years, so as to return these hospitals back to the usual reclassification cycle.

This clarification is necessary because our pending reclassifications will expire in the middle of a federal fiscal year, on March 31, 2007. Unless CMS establishes an accommodation for Section 508 hospitals, we will be confronted with a difficult dilemma. If we apply September 1, 2005 for reclassification to be effective October 1, 2006, we may be forced to forfeit six months worth of our Section 508 reclassification (*i.e.*, for the period October 1, 2006 through March 31, 2007). If we apply September 1, 2006 for reclassifications to be effective October 1, 2007, we will be without a reclassification for the six months between March 31, 2007, when our Section 508 reclassifications expire, and October 1, 2007, when our new Subpart L reclassifications activate. Both outcomes

carry significant financial consequences, and neither is practical. We urge CMS to implement a solution that does not force us to make this difficult choice, and which provides us with the full benefit of our Section 508 reclassification, as intended by Congress.

In enacting Section 508, Congress demonstrated a determination that the eligible hospitals suffered from inequitable wage index classifications, and needed extraordinary assistance to rectify our various situations. Congress clearly intended to extend this assistance for three years. Congress likewise was fully aware that some hospitals eligible for Section 508 reclassification could also qualify for reclassification under existing Subpart L opportunities. CMS appropriately reflected this congressional intent when it made clear that hospitals qualifying under criteria described in sections 2(a), 2(b), 2(f)(3), and 2(g) of the One-time Appeal Process would not be precluded from qualifying on the ground that they had an existing reclassification. Congress could not have intended for these hospitals to be confronted with either forfeiting six months of Section 508 reclassification or six months of any reclassification. Rather, Congress clearly wanted hospitals that could qualify for Section 508 and Subpart L reclassification to have three years of benefit from Section 508, and to then return to their *status quo ante* position without significant disruption. If CMS were to now not adequately accommodate Section 508 hospitals that can qualify under Subpart L opportunities, the Agency would be disregarding clear congressional intent.

Please contact Eric Zimmerman at 202.756.8148 or ezimmerman@mwe.com if you have any questions regarding this important matter.

Sincerely,

Bridgeport Hospital, Bridgeport, CT
Griffin Hospital, Derby, CT
Hospital of St. Raphael, New Haven, CT
John Dempsey Hospital-University of Connecticut, Farmington, CT
Covenant Medical Center, Waterloo, IA
Mercy Medical Center – North Iowa, Mason City, IA
Berkshire Medical Center, Pittsfield, MA
Alpena General Hospital, Alpena, MI
Bon Secours Hospital, Grosse Point, MI
Botsford General Hosp, Farmington Hills, MI
Cottage Hospital, Grosse Point Farms, MI
Detroit Receiving Hospital, Detroit, MI
Harper University Hospital, Detroit, MI
Henry Ford Hospital, Detroit, MI
Henry Ford Wyandotte, Wyandotte, MI
Huron Valley-Sinai Hospital, Commerce Township, MI
Oakwood Heritage Hospital, MI
Oakwood Hospital, Detroit, MI
Oakwood Southshore Medical Center, Trenton, MI
Providence Hospital, Southfield, MI
Sinai-Grace Hospital, Detroit, MI
St. John Detroit Riverview Hospital, Detroit, MI
St. John Hospital & Medical Center, Detroit, MI
St. John Oakland Hospital, Warren, MI
MidState Medical Center, Meriden, CT
St. Mary's Hospital, Waterbury, CT
St. Vincent's Medical Center, Bridgeport, CT
Waterbury Hospital, Waterbury, CT
Yale-New Haven Hospital, New Haven, CT
St. Joseph Mercy Oakland, Pontiac, MI
W.A. Foote Memorial Hospital, Jackson, MI
William Beaumont Hospital, Royal Oak, MI
William Beaumont Hospital, Troy, MI
Hackettstown Comm. Hosp., Hackettstown, NJ
St. Clare's – Sussex, Sussex, NJ
St. Clare's Hospital – Denville, Denville, NJ
Warren Hospital, Phillipsburg, NJ
North Shore University Hospital, Manhasset, NY
Memorial Mission Hospital, Asheville, NC
Trinity Hospitals, Minot, ND
Bay Area Hospital, Coos Bay, OR
The Bloomsburg Hospital, Bloomsburg, PA
Community Medical Center, Scranton, PA
Geisinger Wyoming Valley Medical Center, Wilkes-Barre, PA
Mercy Hospital Scranton, Scranton, PA
United Regional Health System, Wichita Falls, TX
Carilion Medical Center, Roanoke, VA
Norton Community Hospital, Norton, VA

United States Senate

WASHINGTON, DC 20510

(11) 2290

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

June 24, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445 G
200 Independence Avenue, SW
Washington, DC 20201

RE: Proposed Rule, Hospital Inpatient Prospective Payment System for FY 2006

Dear Dr. McClellan:

We are writing today to express our opposition to the proposed inpatient hospital rule that would prevent most Critical Access Hospitals (CAHs) from rebuilding their facilities more than 250 yards from their current location.

As of January 1, 2006, section 405 of the Medicare Modernization Act discontinues the "necessary provider" status option, which allows states to waive the location requirement of the CAH program. CAHs that are designated necessary providers could be in jeopardy of losing their CAH status if the changes, which are included in the fiscal year 2006 proposed inpatient PPS rule, are implemented. The proposal would essentially bar any CAH with necessary provider status from rebuilding its facilities anywhere other than its current location unless the project was under development before December 8, 2003. While we understand the need to maintain CAH facilities in specific service areas, we believe the 250-yard rule is arbitrary and should be replaced with a more flexible rule that allows hospitals to modernize.

CAHs are the sole providers of inpatient acute-care services and offer outpatient and long-term care services in their communities. CAH status has afforded these hospitals with an effective reimbursement system that, in many cases, has maintained access to essential services for rural Americans. Loss of CAH status will force many of them to close or reduce essential services.

Many of these CAHs were not able to rebuild facilities prior to gaining CAH status. The older buildings they occupy need to be improved to reflect current hospital practices in modern facilities. Without more flexibility to upgrade facilities, improve quality, and occupational safety, we believe CAHs will not be able to offer patients the quality care they deserve.

The law explicitly grandfathers existing CAH programs with construction projects under development before December 8, 2003. We believe CMS should consider other options that allow more flexibility for CAHs that did not meet this deadline. Maintaining the current 250-yard requirement is not appropriate to meet the needs of CAHs or the patients they serve. Necessary provider CAHs should be allowed to relocate as appropriate to improve the care of their communities. We urge CMS to remove the proposed restrictive requirements and establish reasonable criteria to ensure that the hospitals are moving within their services areas.

Sincerely,

TOM HARKIN
United States Senator

PAT ROBERTS
United States Senator

JEFF BINGAMAN
United States Senator

CHUCK HAGEL
United States Senator

DEBBIE STABENOW
United States Senator

NORM COLEMAN
United States Senator

PATTY MURRAY
United States Senator

RICK SANTORUM
United States Senator

KEN SALAZAR
United States Senator

BEN NELSON
United States Senator

MARK DAYTON
United States Senator

RUSS FEINGOLD
United States Senator

TIM JOHNSON
United States Senator

HERB KOHL
United States Senator

CARL LEVIN
United States Senator

BYRON DORGAN
United States Senator

JOHN THUNE
United States Senator

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June 24, 2005

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

Re: File Code-1500-P

Dear Administrator McClellan:

Aurora Health Care welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 rates." 42CFR Parts 405, 412, 413, 415, 419, 422, and 485.

Our letter comments on the proposed expansion of the Post Acute Care transfer rule, reduction of the labor related share of the PPS rate, and the submission of quality data.

Post-acute Care Transfers

Aurora Health Care is opposed to the expansion of the post-acute Care transfer policy from 30 to 223 DRG's based upon the expansion of the criteria of the DRG's eligible to be paid under the post-acute care transfer policy.

Such a policy penalizes the hospitals that ensure Medicare patients receive treatment in the most appropriate setting. This proposal also undercuts the fundamental principle of the Prospective Payment System, which is that some cases will cost more than the DRG payment, while others will cost less, but overall the payment should be adequate. It is also important to recognize that there are cost reductions with transferring patients to a post-acute care setting, due to the patient being in a lower cost setting, and the reduction in the DRG payment through a lower length of stay, which will lower the DRG payment through the recalibration process.

Labor Related Share

Aurora Health Care is opposed to the reduction of the labor related share of the DRG payment from 71.3% to 69.73% for labor areas with a wage index above 1.00. This would unfairly reduce the payment for high cost labor areas when the labor areas with a

wage index below 1.00 continue to benefit from public law 108-173 amended sections 1886(d)(3)(E), which sets their labor related portion at 62%.

Hospital Quality Data

Processes for data submission and validation

The ability of hospitals and their vendors to comply with the requirements for timely and accurate data is challenged by miscommunication, technical ambiguities, and other issues. The final 2006 Inpatient PPS rule should establish clear documentation guidelines and clearer communication to clear up problems hospitals may be having with their data submissions. We also believe that hospitals should not be penalized when CMS and the Quality Improvement Organizations technical issues hinder the hospitals ability to meet specific data requirements. Below are the guidelines we believe need to be established for hospital data submissions.

- An explicit step by step process needs to be established for data submission. This would include exact specifications, edits or audits to be applied, and other related information. CMS should communicate any changes to file requirements no less than 120 days prior to the effective date. No changes should be allowed once the data submission quarter has begun. This would put the process integrity at risk.

- For greater reporting accuracy, we believe that a test process for validating data file submissions needs to be established. Hospitals and vendors should be supplied with a test file in the appropriate format for internal verification prior to testing a submission. The process should permit submission of test files to verify formats, accuracy of data calculations, and other audit criteria related to the submission. This processes should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule there is no mention of a minimum sample size for hospitals that elect to sample. Consequently, if hospitals that do not sample elect to submit all of their qualifying cases for a study and three got rejected, will they still meet the data requirements, or must such hospitals correct the case errors so that every one gets into the data warehouse? Under our understanding, these hospitals do not have to correct the errors, just as long as such hospitals have met the minimum number of cases required by the JCAHO/CMS sampling requirements.

- An explicit step-by step validation process should be established including clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly what is being validated so they can adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarters validation, they have already moved on to the next quarters data collection, and cannot make any changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well documented, hospitals could be proactive in

their data submissions. Any changes must be communicated clearly and within a sufficient timeframe in order for the hospitals to react and change their processes. We propose that modifications to the technical processes be published at least 120 days prior to the effective date.

- Aurora Health Care believes that the validation process should incorporate only data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may have an overall quality score of 80%, however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be much lower. In this way, payments risk being based upon inconsistent calculations and inaccurate data.

- Hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data extraction period. The validation rules applied by CMS as of June 6, 2005 were applied retroactive to the July – September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation document for the July 1, 2004 discharges was dated April 29, 2005. Since this data was submitted at the end of January, 2005, the hospitals did not have any time to make the appropriate change.

- Under the proposed rule, hospitals are only allowed 10 days to appeal its validation. However, CMS failed to specify whether the reference is 10 calendar or business days. We believe that neither is sufficient time for hospitals to respond. Therefore we are proposing to allow hospitals 30 calendar days to appeal their validation findings.

- Communication relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA) has been inconsistent across the country. We believe that all communication and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIO's) simultaneously. Such a strategy would simplify and standardize message generation. It would eliminate the confusion and often contradictory communication typical of the current process, which requires the QIO to interpret communication before forwarding it to the hospitals.

Aurora Health Care appreciates the opportunity to comment on the 2006 IPPS proposed rules. Should you have any questions regarding this letter, please feel free to call me at 414-647-6445 or Steve Kowske at 414-647-3429.

Sincerely,

Paul Nannis
Vice President, Government and Community Relations
Aurora Health Care

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NT

Hefter
Hartstein
Walz
Treitel

June 22, 2005

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

SENT VIA FED EX

Dear Dr. McClellan:

RE: File Code CMS-1500-P: Comments to the Proposed Rule Published on MAY 4, 2005 For the CHARITE™ Artificial Disc New Technology Add-On Payment Application

DePuy Spine is an operating company of DePuy, Inc., a Johnson & Johnson company, one of the world's leading designers, manufactures and suppliers of orthopaedic devices and supplies. We are known throughout the medical world for the development, manufacture, and marketing of innovative solutions for a wide range of spinal pathologies. We are pleased to have the opportunity to provide comments concerning the new technology add-on payment for the CHARITÉ™ Artificial Disc and appreciate CMS's efforts to continue to review the application based on public comments and continued analysis.

There are three criteria that CMS requires in order to satisfy the new technology add-on payment: newness, cost and substantial clinical improvement over existing technology. CHARITE™ Artificial Disc meets these criteria and therefore qualifies for the add-on payment or for reassignment to the spinal fusion DRGs 497 and 498 that are more similar from a clinical and cost perspective than the current DRGs to which the CHARITÉ Artificial Disc is assigned.

Section 1886(d)(5)(K) of the Social Security Act states that that **prior** to establishing an add-on payment for a new medical service or technology the agency "shall seek to identify one or more diagnosis related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis related group where the average costs of care most closely approximate the costs of care using the new technology."

As clearly supported by the 308 cases of hospitals claims for cases involving the CHARITÉ Artificial Disc submitted as part of this application, the hospital resources involved with the CHARITÉ Artificial Disc technology are most closely comparable to those in DRGs 497 and 498. The Proposed Rule would reimburse hospitals for spinal fusions at a significant premium over spinal disc prosthesis -- a 162% premium for comparable cases with complications and co-morbidities (CC) and a 208% premium for the non-CC cases. CMS should act in the Final Rule to remove this economic disincentive to use the CHARITÉ Artificial Disc technology either through a temporary DRG reassignment or a new technology add-on payment.

We will specifically comment on each of these criterion and provide updated information that will address the concerns raised in the Proposed Rule: 1) whether CHARITÉ™ represents a substantial clinical improvement over spinal fusion, 2) would the Medicare population be contraindicated due to osteoporosis and 3) would the clinical results cited from the IDE study be generalized for the Medicare population, since the study did not enroll patients over 60 years of age.

Newness Criterion

On October 26, 2004, the FDA approved the CHARITÉ™ for single level spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) between L4 and S1. **In the Proposed Rule, CMS stated that CHARITÉ™ Artificial Disc meets the newness criterion.**

Cost Criterion

To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. CMS published the threshold charges in Table 10 of the Proposed Rule. Based on actual claims data that assigns ICD-9 Procedure Code 84.65, the CHARITÉ Artificial Disc maps to DRGs 499/500. The thresholds for DRGs 499 and 500 are $24,828 and $17,299 respectively.

DePuy Spine engaged two independent consulting firms to collect and analyze hospital claims for the CHARITÉ Artificial Disc. Both consultants confirmed that the DRG threshold is exceeded for the New Technology Add-On Application. Also, the results of the projects confirmed that a more appropriate DRG assignment for the CHARITE technology is DRGs 497/498.

The results from the two sources indicate that the mean standardized charge for 308 cases substantially exceeds the relevant new technology threshold (Table 1):

Table 1 – Charges and Standardized Charges for CHARITÉ Artificial Disc

	Direct Research	Navigant Consulting	Total
Total Claims	94	214	308
Medicare	3	6	9
Percent Medicare	3.0%	2.8%	3.0%
Average Standardized Charge	$43,065	$45,791	
DRG 499 Threshold	$24,828	$24,828	
Amount in Excess of Threshold	**$18,237**	**$20,963**	

In addition to the standardized charge analysis, the consultants determined that:

1) there are more than enough claims to provide adequate statistical precision
2) charges from the CHARITÉ implant hospitals appear to be typical of charges from all US hospitals
3) as requested by CMS, substituting the CHARITÉ supply charges to the MedPAR supply charges demonstrates that the mean standardized charges substantially exceeds the relevant DRG threshold
4) an alternative analysis excluding outliers also demonstrates that the mean standardized charges substantially exceeds the relevant DRG threshold
5) there is significant geographic variation in both the distribution of participating hospitals and in the distribution of claims

Conclusion on Cost Criterion

Based on several different methodologies to analyze the charge data, it has been demonstrated that the CHARITÉ Artificial Disc procedure meets the cost thresholds criterion established by CMS for new technology add-on payments. A detailed analysis is provided in Appendix A and B.

Appendix A: Memorandum from Christopher Hogan, Direct Research, LLC, June 2, 2005.
Appendix B: Final Report, CHARITÉ Artificial Disc Reimbursement Analysis New Technology Add-On Payment, June 13, 2005, Prepared by Navigant Consulting, Inc.

Substantial Clinical Improvement Over Existing Technology Criterion

Published Peer-Reviewed Articles

The FDA approval for the CHARITÉ Artificial Disc was issued on October 26, 2004. Two months later, DePuy Spine filed the application and tracking form to qualify for the new technology add-on payment. At that time, the pivotal study publications were **pending** approval from *Spine* and the published evidence supporting substantial clinical improvement over the existing technology was somewhat limited. On May 4, 2005, CMS commented in the Proposed Rule that they would continue to review the information on whether the CHARITÉ Artificial Disc represents a substantial clinical improvement over existing technology for certain patient population. The following two new articles will be **published** in *Spine* on July 15, 2005 and will add substantially to a better understanding of the clinical improvement criterion.

- Blumenthal et al. "A Prospective, Randomized, Multi-Center FDA IDE Study of Lumbar Total Disc Replacement with the CHARITÉ Artificial Disc vs. Lumbar Fusion: Part I – Evaluation of Clinical Outcomes."
- McAfee et al. "A Prospective, Randomized, Multi-Center FDA IDE Study of Lumbar Total Disc Replacement with the CHARITÉ Artificial Disc vs. Lumbar Fusion: Part II – Evaluation of Radiographic Outcomes and Correlation of Surgical Technique Accuracy with Clinical Outcomes."

A summary of the conclusions drawn from Part 1 – Evaluation of Clinical Outcomes and Part II - Evaluation of Radiographic Outcomes and Correlation of Surgical Technique Accuracy with Clinical Outcomes are as follows:

- The CHARITÉ Artificial Disc obviates the iliac crest bone graft donor site morbidity. 18.2 % of the control subjects experienced pain at the donor site.

- The CHARITÉ Artificial Disc preserves segmental motion in flexion/extension through 24 months post implantation.

- The CHARITÉ Artificial Disc provided superior maintenance of post-operative disc height through 24 months compared to anterior interbody fusion; disc space height was maintained in greater than 99% of CHARITÉ Artificial Disc subjects through 24 months follow-up.

- By maintaining motion, CHARITÉ has the potential to reduce second surgical procedures for adjacent disc disease. We intend to investigate this possibility further.

- The CHARITÉ Artificial Disc provides superior early improvement in pain and function as measured by the Oswestry Disability Index compared to anterior interbody fusion at 6 weeks, 3 months, 6 months and 12 months.

- The CHARITÉ Artificial Disc provides superior improvement in pain reduction measured by Visual Analog Scale compared to anterior interbody fusion at 6 weeks, 3 months, 6 months and 12 months.

- The CHARITÉ Artificial Disc provides superior improvement in quality of life on the Physical Component Score (PCS) of the SF-36 outcome tool at 3 months, 6 months and 24 months.

Appendix C: Summary of Substantial Clinical Improvements in the IDE Study

IDE Study Results – Clinical Evidence for the Medicare Population

Since the IDE study did not enroll patients over the age of 60 years old, CMS is interested in knowing whether or not the results from the IDE study can be generalized to the Medicare population. To address this issue, DePuy Spine engaged Navigant Consulting, Inc. to conduct a survey to capture important clinical information related to the Medicare ≥65 years old and the Medicare Disabled populations that were implanted with the CHARITÉ Artificial Disc. Both populations are statutorily covered by Medicare.

The result of this series of 18 Medicare beneficiaries provides evidence that the CHARITÉ Artificial Disc is not only applicable to this population, but the clinical outcomes are similar to those reported in the IDE study. The surgeons reported that 94.4% of the patients demonstrated improvement in all three categories: overall outcome, pain and function after CHARITÉ implantation. The surgeons also noted that 100% of the patients reported an improved level of activity: 50% achieved **full** recovery, while 50% achieved an improved level of activity when compared to their pre-operative status. Finally, 100% of the surgeons recommended CHARITÉ Artificial Disc for other Medicare patients who meet the clinical indications.

Conclusion on Substantial Clinical Improvement Criterion

As noted in the Proposed Rule, Page 23354, Section 412.87(b)(1) of the CMS regulations "provides that a new technology is an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." The combination of the results from

the IDE study and the surveys demonstrate to CMS that there are substantial clinical improvements that the CHARITÉ Artificial Disc offers over a fusion procedure, including Medicare beneficiaries.

Appendix D: Final Report, CHARITÉ Artificial Disc Medicare Patient Outcome Analysis New Technology Add-On Payment, June 22, 2005, Prepared by Navigant Consulting, Inc.

Contraindication of Osteoporosis

CMS requested comments in the Proposed Rule regarding the contraindication for osteoporosis, noting that this is quite common in the Medicare population.

As indicated in the FDA Summary of Safety and Effectiveness, osteoporosis is a contraindication for the CHARITÉ Artificial Disc procedure. While the prevalence of osteoporosis is expected to be higher in the older age group of Medicare patients, implanting surgeons report seeing many patients over the age of 65 who are extremely active and do not have any signs osteoporosis, as validated by a Dexascan.

There is also supporting evidence in the European literature that addresses osteoporosis. J.P. Lemaire[1] reports on the radiological results in his series of 100 patients; 41 men and 59 women. Although, "sixteen of the women are currently menopausal" thereby putting them at higher risk for osteoporosis, "no radiological signs of osteoporosis have been noted."

It is also worth noting that osteoporosis is a contraindication for some spinal fusion devices and a precaution for others. The Contraindications Section for the Brantigan I/F Cage states that "severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant...The decision whether to use these devices in such condition must be made by the physician taking into account the risks versus the benefits to the patient." While we agree that osteoporosis is more prevalent in the Medicare population than the population as a whole, Medicare should not deny a new technology add-on payment on the basis that the technology is not appropriate for every Medicare beneficiary who needs disc surgery. Package insert enclosed.

Medicare Disabled Beneficiaries

The findings from the clinical survey performed by Navigant Consulting indicate the majority of the Medicare patients that have been implanted with the CHARITÉ Artificial Disc to date have been disabled beneficiaries. We believe that Medicare patients with disabilities are most likely to benefit from CHARITÉ Artificial Disc, at least in the initial early years of the product's introduction. The disabled population, which represents approximately 14% of all Medicare patients or five million individuals, could benefit from the significant clinical improvements offered by the CHARITÉ technology.

We note that disabled patients represent a significant portion of all Medicare patients currently receiving spinal fusion treatments. As exhibited in Table 2 below, 21,286 disabled patients or 21.8% of all discharges in DRGs 496, 497 and 498 received a spinal fusion procedure in FY 2004. It is likely that a significant number of these patients could benefit from the CHARITÉ Artificial Disc procedure as well. CMS should act to improve the DRG reimbursement for this procedure so that hospitals do not have an economic disincentive to provide the technology to this important segment of the

[1] Lemaire JP. SB Charité III intervertebral disc prosthesis: biomechanical, clinical, and radiological correlations with a series of 100 cases over a follow-up of more than 10 years. Rachis [French] 2002; 14:271-85.

Medicare population. We also note, that despite the contraindication or precaution of osteoporosis for fusions, there were nearly 98,000 fusion procedures performed in FY2004.

Table 2: Disabled Patients Represent Over 20% of Total Spinal Fusion Discharges in FY 2004 MedPAR

DRG	Aged Beneficiaries	Disabled Beneficiaries	ESRD	TOTAL
496	24,439	**6,708**	20	31,167
497	37,210	**10,028**	39	47,277
498	14,766	**4,550**	1	19,317
Total Discharges	76,415	**21,286**	60	97,761
% of Total Fusion Cases	78.2%	**21.8%**	0.1%	100%

Consistent Application of Standards of Evidence

InFUSE™, Bone Morphogenetic Protein, for spinal fusions was approved by the FDA for use on July 2, 2002 and became available on the market immediately thereafter. Similar to the CHARITÉ Artificial Disc application, CMS evaluated whether or not InFUSE™ qualified as a substantial clinical improvement over the current technology, spinal fusion. Among the issues CMS considered were: does avoiding the complications associated with the iliac crest bone harvesting procedure constitute a clinical improvement; and, with the increased rate of osteoarthritis and osteoporosis in the Medicare population, is there evidence that the technology represents a substantial clinical improvement in spinal fusions among this population?

In the August 1, 2003 IPPS final rule (68 FR 45388), CMS ***approved*** InFUSE™ for add-on payments, effective for FY2004. CMS received a small series of Medicare-aged patients treated with InFUSE™ and acknowledged that there was some positive, though limited, evidence for generalized application for the Medicare population. "These results, combined with the benefits of the elimination of the need to harvest bone graft from the iliac crest (and the associated complications), lead us to conclude that InFUSE™ does meet the substantial improvement criteria."

While there are several similarities between the InFUSE™ and the CHARITÉ Artificial Disc applications, the CHARITÉ Artificial Disc provides other significant clinical improvements. In addition to eliminating the need to harvest bone graft from the iliac crest and the associated complications, CHARITÉimprovements include maintaining a more normal range of motion, restoration of disc height, potential to reduce adjacent level disease, earlier and sustained improvement in pain and function, earlier return to normal activity and improvement in quality of life.

Medicare IPPS System Provides Significant Incentive to Use Spinal Fusion Over Artificial Disc Prosthesis

CMS's current DRG assignment provides an added incentive for hospitals to favor spinal fusion over a procedure involving the CHARITE Artificial Disc. CMS proposes in FY 2006 to assign the CHARITÉ Artificial Disc (ICD-9-CM procedure code 84.65, Insertion of total spinal disc prosthesis, lumbosacral) to DRGs 499 and 500, with respective base payments of $7,139 and $4,638.

In contrast, CMS proposes to reimburse hospitals for spinal fusion cases at a significantly higher rate of $18,682 and $14,270 respectively for DRGs 497 and 498. (See Table 3).

Table 3: Payment Premium for Spinal Fusion Compared to Artificial Disc Prosthesis

DRG #	Description	Proposed FY 2006 Rate Base Payment
497	Spinal Fusion except Cervical with CC	$18,682
498	Spinal Fusion except Cervical without CC	$14,270
499	Back and Neck Procedures Except Spinal Fusion with CC (current CHARITÉ assignment)	$7,139
500	Back and Neck Procedures Except Spinal Fusion without CC (current CHARITÉ assignment)	$4,638
Payment Premium for Spinal Fusion (497 vs. 499)		**+$11,543 (162%)**
Payment Premium for Spinal Fusion (498 vs. 500)		**+$9,632 (208%)**

The payment premium that CMS proposes to offer for hospitals to use spinal fusion techniques over spinal disc prosthesis is significant (162% premium for comparable cases with CC and a 208% premium for the non-CC cases). DePuy Spine filed a new technology DRG application to address this obvious and fundamental reimbursement inequity. We recommend that CMS assign the CHARITÉ Artificial Disc to the existing spinal fusion DRGs in 497 and 498.

In contrast, the state of Maryland recently recognized this inequity and recently addressed this issue. On May 4, 2005, the Health Service Cost Review Commission (HSCRC) determined that current DRG assignment 499/500 for CHARITÉ Artificial Disc was inappropriate.

> "Though this new technology has been shown to effectively treat severe low back pain associated with disc disease, utilization has been limited in Maryland hospitals due to the financial disincentive associated with the use of this device. The case-mix weights for the DRGs to which the artificial disc cases currently group do not adequately reflect resource use for these procedures due to the very high cost of the artificial disc device."

HSCRC developed a new DRG assignment with case-mix weights to account for the additional hospital resources. The effective date of this policy is October 26, 2004, which was the FDA approval date for the CHARITÉ Artificial Disc.

Minutes from the 410th Meeting of the Health Services Cost Review Commission, May 3, 2005 can be obtained at http://www.hscrc.state.md.us/about_us/previous_minutes.html

Appendix E: HSCRC Recommendation for the Treatment of Artificial Disc Procedures

Recommendation

Based on the evidence reported above, we believe that the CHARITÉ Artificial Disc satisfies the three criteria for the new technology add-on payment or assignment to DRGs that are comparable from a clinical and cost perspective: newness, cost and substantial clinical improvement over existing technology.

As required under the Medicare statute, CMS should first consider assigning the technology to the most appropriate DRGs from both a clinical and cost standpoint. A second option would be to provide a new technology add-on payment.

We strongly recommend that CMS assign CHARITÉ Artificial Disc cases to DRGs 497 and 498. This will assure that reimbursement is equitable between two procedures that are comparable from both a clinical and cost perspective and remove reimbursement disincentives to CHARITÉ procedures. Even if CMS decides not to approve the new technology application, CMS should act in the Final Rule to remove the financial disincentives created in the current assignment of CHARITÉ Artificial Disc to DRGs 499 and 500. The agency has clear legal authority to adjust the DRG assignment for the CHARITÉ Artificial Disc in FY 2006 whether it is within or outside the context of a new technology DRG application. As clearly documented in the attached report, the CHARITÉ Artificial Disc offers a number of significant clinical advantages over spinal fusion including: eliminates the need to harvest bone graft from the iliac crest and the associated complications, maintains range of motion, restoration of disc height, potential to reduce adjacent level disease, earlier and sustained improvement in pain and function, earlier return to normal activity and improvement in quality of life. CMS is inadvertently providing a significant economic disincentive for hospitals to limit or deny patient access to the latest medical advancement for the treatment of degenerative disc disease. While the CHARITÉ Artificial Disc is not an appropriate procedure for all Medicare beneficiaries, the current payment incentives make it less likely that hospitals will provide this therapy to those disabled and elderly patients who could benefit from the therapy. We strongly encourage CMS to act in the Final Rule to remove this payment disincentive.

We thank you for the opportunity to provide comments and your consideration of this request.

Sincerely,

John R. Argiro

John R. Argiro
Director of Reimbursement
DePuy Spine

Enclosures: one original and two copies

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APPENDIX A:

Memorandum – Analysis of Charges for CHARITÉ Artificial Disc Implant, updated

Prepared by Christopher Hogan
Direct Research, LLC
June 2, 2005

Memorandum

To: Greg White, Johnson and Johnson, Inc.
From: Christopher Hogan, Direct Research, LLC
Subject: Analysis of charges for CHARITÉ Artificial Disc implant, updated.
Date: 6/2/05

This memo summarizes methods and results for the analysis of hospital charges for CHARITÉ Artificial Disc implants, using claims recorded as of 5/20/05. The following analyses are shown:

- Compare standardized charges for CHARITÉ cases to the relevant new technology threshold.
- Show that the number of CHARITÉ cases exceeds the number CMS requires for statistical precision of the estimated mean charge.
- Compare the hospitals in the CHARITÉ sample to all US hospitals, in terms of the their MedPAR charges.
- Construct "synthetic claims" for CHARITÉ cases, based on MedPAR cases clinically similar to the CHARITÉ cases, and test whether charges from these "synthetic" claims exceed the new technology threshold.

The results are as follows:

- The mean standardized charge for the 94 CHARITÉ implant cases $43,065 substantially exceeds the relevant new technology threshold $24,828 (Table 1).
- The 94 cases are more than enough to provide adequate statistical precision, based on the published CMS formula. The mean standardized charge for the CHARITÉ cases is more than nine standard errors above the threshold amount (Table 2).
- Charges from the CHARITÉ implant hospitals appear to be typical of charges from all US hospitals. Mean standardized charges for DRGs 499 and 500, from 2003 MedPAR, for these hospitals, average 5 percent (499) to 9 percent (500) higher than the mean standardized charges for these DRGs for all US hospitals (Table 3).
- The "synthetic claims gives mean charges that bracket the mean charge from the CHARITÉ sample. After selecting MedPAR cases clinically similar to the CHARITÉ cases, substituting the CHARITÉ supplies charges for the MedPAR supplies charges, and recalculating totals, the mean standardized charge on these "synthetic" claims substantially exceeds the relevant new technology threshold. (Table 4).

The remainder of this memo gives details on these four analyses.

COMPARE STANDARDIZED CHARGES FOR CHARITÉ CASES TO THE CMS NEW TECHNOLOGY THRESHOLD FOR DRG 499

- DePuy Spine provided data from recent CHARITÉ implants occurring in 37 different hospitals. The data show the hospitals' actual charges, along with hospital name and Medicare provider number. As I understand it, these were all discharges for which DePuy was able to collect the charge date. I extracted and used only those discharges that were flagged as single-level implants. There were, in addition, 26 multi-level implants not included here. Multi-level implants have much higher average charges because they involve surgery on multiple disks at once, and implantation of multiple CHARITÉ artificial disks. So, the database being used here is all single-level (single-disk) inpatient implants for which DePuy Spine could obtain charge data, and excludes 26 high-cost cases involving multiple disk implants.
- I standardized these charges using the CMS formula for charge standardization, taking wage index, COLA, disproportionate share and teaching data from the inpatient PPS 2006 Proposed Rule Impact file. A few hospitals did not appear in the Impact file. I calculated the mean charge standardization factor for all other discharges and used that mean value for those that were missing.
- The CMS grouper will place CHARITÉ cases primarily into DRG 500, and some cases will fall into DRG 499. The new technology threshold amounts are $24,828 for DRG 499 and $17,299 for DRG 500. These amounts are taken from Table 10 accompanying the 2005 inpatient PPS final rule. I used the higher DRG 499 amount in this analysis. (In theory, I could have compared the CHARITÉ charges to the weighted average of the DRG 499 and DRG 500 thresholds. In practice, the CHARITÉ mean charges substantially exceed the higher of the two threshold amounts anyway. It seemed more straightforward to compare to the more stringent, higher threshold amount for DRG 499 alone.)
- The mean standardized charge for these cases is $43,065. This is more than $18,000 above the threshold (Table 1).

Table 1: Charges and Standardized Charges for CHARITÉ Cases in Sample	
Number of Cases	94
Number of Hospitals	37
Mean Charge	$ 54,551
Mean Standardized Charge	$ 43,065
New technology threshold, DRG 499 (final rule 2005)	$ 24,828
Difference	$ 18,237

DEMONSTRATE THAT THE CHARITÉ SAMPLE SIZE IS ADEQUATE

The mean standardized charge was estimated from a sample of discharges. To satisfy the CMS criteria for a new technology application, the difference between the mean charge and the threshold must exceed a standard test of statistical significance. The mean must be at least two "standard errors" higher than the threshold amount, where the "standard error" is a statistical measure reflecting the variation of the underlying charge information and the number of observations used to calculate the mean.[1]

CMS' rules apply this "two standard errors above the mean" criterion, but they state it differently. They ask that applicants calculate the minimum number of discharges required to have that level of precision, then show that the sample has at least that many observations. The published CMS formula for the minimum number of observations is the following:

$N = (4*S*S)/(B*B)$
Where:
N = minimum number of cases required
S = standard deviation of standardized charges
B = amount by which the mean standardized charge exceeds the threshold.

Table 2 shows that the CHARITÉ sample cases have more than enough precision to meet this standard. Based on the formula, just five cases would be needed, far less than the 94 available. The number is small because the mean charge is so much higher than the threshold. (This formula is based on large-sample statistical theory, so the estimate of five observations is only approximate. Nevertheless, the correct conclusion is that very few discharges would be needed to meet the criterion.) In addition to calculate the formula, the table also shows that the mean standardized charge exceeds the threshold by more than nine standard errors. This exceeds the usual two-standard-error test of statistical significance. By either criterion, the same size is adequate.

Table 2: Adequacy of Sample Size for CHARITÉ Cases	
Number of Cases	94
Mean Standardized Charge	$ 43,065
New Technology Threshold, DRG 499 (final rule 2005)	$ 24,828
Amount by Which Mean Exceeds Threshold	$ 18,237
Standard Deviation of Standardized Charges	$ 18,736
Minimum Required N of Observations	5
Standard Error of Mean Standardized Charge	$ 1,943
N of Std Errors by Which Mean Exceeds Threshold	9.4

[1] This is equivalent to applying a standard "t test" to the difference between the mean standardized charge and the threshold, then requiring a t value of at least 2.

DEMONSTRATE THAT CHARGES FROM THE SAMPLE HOSPITALS ARE SIMILAR TO CHARGES FROM ALL HOSPITALS

The statistical test above demonstrated that the sample size has adequate precision to meet the formal CMS guidelines. Nevertheless, the results depend on the charges reported by just 37 hospitals. Unusually high or low average charges from these hospitals might affect the estimated mean charge.

In this analysis, FY 2003 MedPAR charges from the 37 CHARITÉ-reporting hospitals were compared to MedPAR charges from all hospitals. This was done for DRGs 499 and 500, the DRGs into which the CMS grouper will classify CHARITÉ cases.

Table 3 shows that mean standardized charges, from MedPAR, for these 37 hospitals, are slightly higher than the mean standardized charges for all hospitals, as calculated from MedPAR. Charges for the 37 CHARITÉ hospitals were 9 percent above the US average for DRG 499, and 5 percent above the US average for DRG 500. These differences have no material effect on the analysis. That is, even if I deflated the mean charge for the CHARITÉ discharges by (say) 10 percent, the resulting mean would still substantially exceed the new technology threshold, and the difference between the mean and the threshold would still be statistically significant.

Table 3: FY 2003 MedPAR Charges, CHARITÉ Sample Versus All Hospitals

	Standardized Charge, DRG 499	Standardized Charge, DRG 500
MedPAR 2003 Discharges from Sample Hospitals Only	$ 22,306	$ 14,116
MedPAR 2003 Discharges from All Hospitals	$ 20,460	$ 13,387
% Difference	9%	5%

SYNTHETIC CLAIMS ANALYSIS

One final suggested test is to construct "synthetic" claims and examine the average standardized charges on these claims. The process works in three steps:

- Identify MedPAR discharges that are most similar to CHARITÉ cases.
- Calculate standardized charges for these cases, separate out the amounts for supplies, and substitute the CHARITÉ average supplies charge for the actual MedPAR amounts.
- Calculate total charges combining MedPAR data for everything except supplies, with CHARITÉ data for the supplies charge.

The calculation requires an assumed rate of inflation to put the FY 2003 MedPAR charges and the FY 2005 CHARITÉ charges on a common basis. This analysis assumes a 15 percent inflation in all charges between FY 2003 and FY 2005. The CHARITÉ supplies charges were deflated by 15 percent to reduce them to a FY 2003 basis, then total charges on the "synthetic" claim were inflated by 15 percent to bring the claim up to a FY 2005 basis.

This rate of charge inflation seems unusually high but is consistent with CMS data. The usual approach for projecting the future rate of inflation is to assume that recent trends in inflation will continue. I looked at mean charges for DRGs 497 and 498, using the Before Outliers Removed (BOR) tables posted with the FY 2005 and FY 2003 inpatient final rules. Charges for the two DRGs increased an average of 15 percent. While this seems unusually large, it is actually slightly lower than the charge inflation that CMS assumed when constructing the FY 2005 outlier thresholds.

Cases clinically similar to CHARITÉ cases were pulled from the FY 2003 MedPAR proposed rule file. These were cases with principal diagnosis indicating the type of disk problems for which CHARITÉ is indicated, that were treated with lumbar spinal fusion. Formally, the cases met these two criteria:

- A principal diagnosis in this list: 722.10, 722.2, 722.5, 722.52, 722.6 , 722.7, 722.73, 756.12.
- And a procedure from this list: 81.06, 81.07, 81.08.

These cases fell almost exclusively into DRGs 497 and 498. About 5 percent of cases fell into DRG 496, a very high cost DRG that was ignored for purposes of this analysis. The analysis therefore started with FY 2003 mean standardized charges for the cases meeting the diagnosis and procedure criteria, for DRGs 497 and 498. The supplies charges were replaced with the mean CHARITÉ supplies charge (deflated from FY 2005 to FY 2003), and the resulting "synthetic" charges were inflated to the FY 2005 level.

Table 4 shows a FY 2005 mean standardized charge of roughly $46,000 to $54,000 dollars from synthetic CHARITÉ claims constructed from these cases. This is higher than the actual standardized charge of the CHARITÉ sample, and substantially higher than the new technology threshold that should apply. Thus, both the actual sample data

and the synthetic claims show that the mean standardized charge for the CHARITÉ cases exceeds the new technology threshold.

Table 4: Construction of Synthetic Claims for CHARITÉ Using Similar 2003 MedPAR Discharges

DRG	497	498
Number of discharges	7,041	5,639
A: Total Charges, Standardized, FY 2003	$50,098	$41,290
B: Med/Surg Supplies Charges, Standardized	$24,337	$22,183
C: All Other Charges, Standardized (A - B)	$25,761	$19,107
D: Charite Std. TOTAL Med/Surg Supplies Charge, FY 2005	$24,073	$24,073
E: Assumed total charge inflation, FY 2003 to FY 2005	15%	15%
F: Charite Std. Supplies Charge, deflated to 2003 (D/(1+E))	$20,933	$20,933
G: Std. Charge, Charite Synthetic Claims, FY 2003 (C+F)	$46,695	$40,040
H: Std. Charge, Charite Synthetic Claims, FY 2005 (G*(1+E))	$53,699	$46,046

The synthetic claims analysis brings up two additional points, the cost of bone harvesting, and the supplies costs in DRGs 497, 498, 499, and 500.

In theory, I would have liked to improve this synthetic claims analysis by removing the cost of the bone harvesting that is part of a traditional spinal fusion procedure. During the surgical episode, surgeons remove bone (typically from the hip) to use in the spinal fusion. No such bone harvesting is necessary with CHARITÉ. That is a clinical advantage of CHARITÉ, but means that any charges attributable to the bone harvest ought to be removed from these records.

In practice, I could not think of any reasonable way to identify such charges on MedPAR records. As such, I can only state that I believe that the bone harvest, by itself, is likely to be a minor contributor to the cost of a spinal fusion stay. As I understand it, length of stay is governed by the rate of recovery from the fusion procedure, not by healing at the site of the bone harvest, and the harvest is done in the same operating session as the fusion. I believe that even if I could isolate charges attributable to the bone harvesting step, these charges would be small and would not materially change the outcome of this analysis.

Finally, the supplies charges for DRGs 497, 498, 499 and 500 help to show, in a very clear way, why the standardized charges for the CHARITÉ cases should exceed the new technology threshold. From a payment perspective, CHARITÉ is grouped into DRGs 499 and 500. In FY 2003, those DRGs had average supplies charges of roughly $3,000 to $4,000 per case (Table 5). The CHARITÉ cases, by contrast, had a mean supplies charge that was closer to the levels shown for the spinal fusion DRGs 497 and 498. (The

table exaggerates this point somewhat by comparing FY 2003 MedPAR charges to FY 2005 CHARITÉ charges, but the point is valid nonetheless.) The Med/Surg Supplies charges for DRGs 497 and 498 are inflated due to multi-level procedures that are included in the 2003 MedPar data. To a large degree, charges for the CHARITÉ cases exceed the new technology threshold for DRGs 499 and 500 because the supplies charge for the CHARITÉ cases looks more like a spinal fusion than it does the other back and neck procedures with which CHARITÉ is grouped.

Table 5: Comparison of Supplies Charges, Four DRGs, FY 2003 MedPAR, and CHARITÉ Sample Cases, FY 2005

DRG	Mean Supplies Charge
497: SPINAL FUSION EXCEPT CERVICAL W CC	$25,169
498: SPINAL FUSION EXCEPT CERVICAL W/O CC	$21,542
499: BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC	$4,057
500: BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC	$2,827
Memo: Mean Supplies Charge, CHARITÉ cases, FY 2005	$25,538

APPENDIX B:

Final Report CHARITÉ Artificial Disc Reimbursement Analysis New Technology Add-On Payment

Prepared by Navigant Consulting, Inc.

June 13, 2005

FINAL REPORT

DePuy Spine, Inc
Charité Artificial Disc Reimbursement Analysis
New Technology Add-On Payment
June 13, 2005

Prepared By:

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Executive Summary & Findings

Summary – Navigant Consulting Inc. ("NCI") completed a comprehensive and detailed review of inpatient hospital medical claims involving the insertion of Charité, an artificial spinal disc implant designed and manufactured by DePuy Spine, a Johnson & Johnson Company ("DePuy"). Charité was approved by the FDA in October 2004. This analysis is meant to assist DePuy in its application to CMS for an enhanced Medicare hospital payment for spinal surgery involving the Charité artificial disc. Specifically, DePuy's application for a new technology add-on payment to the established Medicare DRG payment system will allow for more accurate compensation to hospitals performing Charité insertions on Medicare patients. If approved, these additional payments are available for up to the first 3 years of FDA approved use.

Findings – NCI analyzed 214 Charité claims from 62 hospitals across the United States. These 214 claims were validated as non-fusion, single-level Charité cases using a comprehensive claim validation process, which is defined in a later section. NCI's analysis considered both total and revenue code level hospital charges, billing units, length of stay statistics, and payer information. The average and median standardized total charges for a Charité case were $45,791 and $41,323, respectively. The average length of stay for a non-fusion, single-level Charité case was 2.65 days. Table 1 displays the study's key findings.

DePuy Spine - New Technology Add-On Payment Project
May 20, 2005

Table 1 - Charite Charge Analysis Findings

Total Number of Claims Collected for Analysis:	303
Total Number of Claims Used for Analysis (n):	**214**
Total Number of Hospitals used for Analysis:	62
Charge Analysis	
Average Standardized Total Charge	**$45,791.17**
Minimum Standardized Total Charge	$17,577.45
Maximum Standardized Total Charge	$155,769.05
Median Standardized Total Charge	**$41,322.80**
Average Length of Stay (days)	2.65
Payer Group Breakdown	
Commercial	66.8%
Medicare	2.8%
Medicaid	2.8%
Self Pay	3.7%
Workers Comp	21.5%
Other*	2.3%
	100%

** Includes Group Insurance, Legal-Letter of Protection and Government Insurance (Champus, TriCare, etc)*

Sample Size & Characteristics

During the data collection process, NCI received 303 Charité claims from 71 hospitals across the United States. This universe of claims was then subjected to a thorough review by the NCI team. A comprehensive validation process was applied to ensure only valid, single-level Charité claims were included in the charge analysis. The validation process is described in detail later in this report.

After validation the universe of claims included in the analysis was 214 claims (70.6% of total claims collected).These 214 claims represented discharges from 62 hospitals (87.3% of total hospitals that submitted claims). There was significant geographic variation in both the distribution of participating hospitals and in the distribution of claims. Table 2 illustrates this geographic dispersion. The majority of participating hospitals were located in the South (40%) and the Midwest (29%). In terms of actual claims, the majority

were also found in the South (44%), with the Midwest and Northeast contributing 25% and 21% of claims, respectively.

DePuy Spine - New Technology Add-On Payment Project
May 20, 2005

Table 2 - Geographic Distribution of Claims Analysis

Region*	Participating Hospitals		Valid Claims	
	Count	%	Count	%
South	25	40%	94	44%
Midwest	18	29%	54	25%
West	10	16%	20	9%
Northeast	9	15%	46	21%
Totals	**62**	**100%**	**214**	**100%**

** State location of a hospital was mapped against U.S. Census Bureau Region Tracks*

A table of detailed geographic distribution statistics has been included in the appendix of this report. Table A5 includes counts of both participating hospitals and valid claims, by state.

Data Collection Process

NCI had several meetings with DePuy staff to ensure complete understanding of Charité, its current uses, and any issues surrounding the product and related coding and billing issues. In these conversations NCI received detailed descriptions of the product, the related procedure, and the current market and reimbursement landscapes. Following these discussions NCI received a list of 125 hospitals in the U.S that perform Charité artificial disc implantations. Additionally, NCI received estimates as to the number of expected cases at each facility.

A letter was sent to the Chief Financial Officer at each hospital which provided a brief description of Charité, the purposes of the study, the required data, and the relationship between NCI and DePuy. Furthermore, the letter assured the hospital of NCI's compliance with HIPAA requirements and confidentiality of any information or data that was provided. The letter also indicated both NCI's and DePuy's willingness to sign a Business Associate Agreement ("BA") in order to receive data.

After the letter was mailed, NCI staff placed follow-up phone calls to the hospitals to answer any questions and to facilitate the data collection process. Charité claims were received both electronically and in hardcopy. Upon receipt of data, NCI staff entered the relevant data elements into an Access database. The claims were screened and reviewed in detail by the NCI team for validation purposes. The claims that were deemed valid (see next section), were flagged for inclusion in subsequent analyses.

Claim Validation Process

NCI, with assistance from DePuy, developed a multi-step approach to validating claims received during the collection process. Validated claims were then included in the analysis portion of the project. The validation process was primarily based on the application of exclusion criteria. Specifically, claims were mapped against 7 principle exclusion criteria. These are defined as follows:

1. *Spinal Fusion* – Charité cases that included a spinal fusion in the list of procedure codes were excluded from the analysis. Procedure codes that represent spinal fusions and thus were excluded are 81.00 – 81.08 and 81.30 – 81.39.

2. *Presence of Procedure Code 84.65* – Claims that did not have the procedure code 84.65 (unique to Charité cases), and could not be verified as a Charité case by the hospital, were excluded from the analysis.

3. *Multiple Occurrences of Procedure Code 84.65* – Claims that had the procedure code 84.65 listed more than once on the UB-92 were excluded from the analysis. These claims were considered possible cases where multiple Charité disks were implanted (known as multi-level Charité case). The product is not currently approved by the FDA for this purpose, and therefore claims for these cases were removed. (Note: In one case 84.65 appeared twice and the claim was included in the analysis because after further inspection the charges and billing units with consistent with other verified single-level procedures at the facility).

4. *Suspected Multi-Level Charité Cases* – Claims that were thought to represent multi-level Charité cases were excluded from the analysis. Making the distinction between single- and multi-level cases was straightforward in the majority of cases. By determining the standard implant charges and billing units for a single-level procedure for a particular hospital, NCI was able to identify cases where multiple implants were used. Furthermore, if the charge and unit information was ambiguous to the point where a distinction could not be made, the hospital was called for verification of single- or multi-level use. If the hospital did not respond the claim was excluded.

5. *Date of Service* – Claims that indicated the procedure took place prior to October 26, 2004, the date of FDA approval for the use of the implant, were excluded from the analysis.

6. *Medicare Conversion Factor* – Claims from hospitals where the Medicare Conversion Factor (used for standardizing charges) was not available and a state average Conversion Factor could not be applied, were excluded from the analysis.

7. *Duplicate Claims* – Claims that had been previously collected in an earlier DePuy analysis were excluded from the analysis so to not double count claims.

This claims validation process resulted in the inclusion of 214 claims and exclusion of 89 claims from the analysis. The total count of collected claims (prior to exclusion) equaled 303, making the charge analysis based on 70.6% collected claims.

Conclusion

The average standardized charges for the 214 claims included in this analysis were $45,791. This exceeds the CMS FY05 thresholds for DRGs 499 ($24,828) and 500 ($17,299) by $20,963 and $28,492, respectively. Therefore, Charité meets the cost thresholds established by CMS for new technology add-on payments for these DRGs.

Appendix

In addition to the main analysis of non-fusion, single-level Charité cases, NCI also completed several other sub-analyses that considered subsets of Charité cases, including Medicare cases. NCI also ran a DRG grouper on the collected claims, as well as an analysis of bed size, and has included these results in this appendix.

Medicare Cases

The following table illustrates the detailed charge analysis that was completed for the 6 Charité cases that were paid for by Medicare that were collected in NCI's original data collection process. The average standardized charge and median standardized charge for Medicare cases were $46,776 and $43,053, respectively. These charges are not dramatically different than the average and median standardized charges in the overall (all payer) analysis, which were $45,791 and $41,323, respectively. The average length of stay for these patients was 2.33 days, as compared to 2.65 days in the all payer analysis. A distinction between whether these patients were Medicare-eligible due to age or disability could not be made because the required information was excluded from the UB-92s in order to be HIPAA compliant.

DePuy Spine - New Technology Add-On Payment Project
Medicare Cases
May 20, 2005

Table A1 - Charite Charge Analysis Findings

Total Number of Claims Used for Analysis (n):	**6**
Total Number of Hospitals used for Analysis:	6
Charge Analysis	
Average Standardized Total Charge	**$46,776.19**
Minimum Standardized Total Charge	$26,753.70
Maximum Standardized Total Charge	$67,032.90
Median Standardized Total Charge	**$43,053.11**
Average Length of Stay (days)	2.33
Hospital Breakdown	# Claims
Barnes Jewish	1
Baystate Medical Center	1
Iredell Memorial Hospital	1
Sarasota Memorial Health System	1
St. John's Regional	1
St. Vincent Healthcare	1
	6

Alternative Single-Level Analysis

Navigant Consulting also performed an alternative analysis of Charité claims. In addition to the primary analysis presented in the main body of this paper in which all claims were subjected to a comprehensive validation process, NCI also performed an analysis based on a set of criteria including the exclusion of statistical outliers. In this analysis, NCI applied 4 basic exclusion criteria to the universe of collected claims (n=303). This resulted in the exclusion of:

1. claims with no 84.65 procedure code;
2. claims with multiple 84.65 procedure codes;
3. claims with a spinal fusion code; and
4. claims that had previously been collected by DePuy.

NCI performed a basic statistical analysis on the remaining 223 claims. The calculated mean charge and standard deviation were $46,568, and $21,269, respectively. Data points that fell below or above 2 standard deviations (2SDs) (claims with charges falling

outside the range ($4,030, $89,105) were removed from the analysis and the mean and median standardized charges were recalculated. This process resulted in the identification of 6 claims that fell above 2SDs (none fell below $4,696). NCI removed these six claims and re-ran the analysis. The results are illustrated in Table A2. The average and median total standardized charges for these 217 claims from 65 hospitals were $44,518 and $41,950, respectively. The majority of claims were from the Commercial and Worker's Compensation payer groups (65 and 22 percent, respectively).

DePuy Spine - New Technology Add-On Payment Project
Alternative Analysis Excluding Outliers
May 20, 2005

Table A2- Charite Charge Analysis Findings

Total Number of Claims Collected for Analysis:	303
Total Number of Claims Used for Analysis (n):	**217**
Total Number of Hospitals used for Analysis:	65
Charge Analysis	
Average Standardized Total Charge	**$44,518.14**
Minimum Standardized Total Charge	$7,561.05
Maximum Standardized Total Charge	$89,030.63
Median Standardized Total Charge	**$41,950.06**
Average Length of Stay (days)	2.67
Payer Group Breakdown	
Commercial	65.4%
Medicare	2.8%
Medicaid	2.8%
Self Pay	5.1%
Workers Comp	22.1%
Other*	1.8%
	100%

** Includes Group Insurance, Legal-Letter of Protection and Government Insurance (Champus, TriCare, etc)*

DRG Analysis (Grouper Results)

Table A3 illustrates the results of the DRG analyses performed by NCI.

DePuy Spine - New Technology Add-On Payment Project

Table A3 - DRG Analysis

Single Level Charite Claims (n=214)

DRG	#	%	Standardized Total Charges			Avg LOS
			AVG	MIN	MAX	
243	4	1.9%	$32,331	$18,728	$43,621	3.5
477	1	0.5%	$31,143	$31,143	$31,143	1.0
499	33	15.4%	$50,911	$24,357	$155,769	3.0
500	176	82.2%	$45,220	$17,577	$114,231	2.6

Facility Type & Size Analysis

In reviewing Charité claims, NCI considered and quantified the participating facilities by class, service type, and bed size. Table A4 illustrates these characteristics for the single-level analysis.

DePuy Spine - New Technology Add-On Payment Project
May 20, 2005

Table A4 - Facility Statistics for Single-Level Charite Claims Analysis

Total Number of Claims Used for Analysis (n): 214
Total Number of Hospitals used for Analysis: 62

Hospital Class	Participating Hospitals		Claims	
	Count	%	Count	%
Gov't - Hospital District	3	5%	8	4%
Gov't - State	2	3%	2	1%
Investor Owned - For Profit - Corporatior	8	13%	25	12%
Investor Owned - For Profit - Partnership	6	10%	16	7%
Not for Profit - Church Operated	8	13%	13	6%
Not for Profit - Other	33	53%	146	68%
Other	2	3%	4	2%
Totals	62	100%	214	100%

Hospital Service	Participating Hospitals		Claims	
	Count	%	Count	%
General Medical and Surgical	56	90%	197	92%
Orthopedic	1	2%	5	2%
Other	2	3%	4	2%
Other Specialty	3	5%	8	4%
Totals	62	100%	214	100%

Hospital Bed Size	Participating Hospitals		Claims	
	Count	%	Count	%
6-24	2	3%	7	3%
25-49	2	3%	12	6%
100-199	11	18%	30	14%
200-299	10	16%	39	18%
300-399	9	15%	22	10%
400-499	4	6%	8	4%
500+	22	35%	92	43%
Unknown	2	3%	4	2%
Totals	62	100%	214	100%

DePuy Spine - New Technology Add-On Payment Project

May 20, 2005

Table A5- Geographic Distribution of Single-Level Claims Analysis, By State

	No. of Hospitals	No. of Claims
Northeast		
Connecticut	1	1
Maine	0	0
Massachusetts	1	8
New Hampshire	0	0
New Jersey	1	3
New York	6	34
Pennsylvania	0	0
Rhode Island	0	0
Vermont	0	0
Midwest		
Illinois	3	13
Indiana	2	9
Iowa	2	3
Kansas	1	1
Michigan	0	0
Minnesota	2	4
Missouri	4	20
Nebraska	0	0
North Dakota	0	0
Ohio	3	3
South Dakota	0	0
Wisconsin	1	1

	No. of Hospitals	No. of Claims
South		
Alabama	0	0
Arkansas	0	0
Delaware	0	0
Florida	3	11
Georgia	4	10
Kentucky	1	2
Louisiana	1	1
Maryland	0	0
Mississippi	1	2
North Carolina	3	10
Oklahoma	2	10
South Carolina	0	0
Tennessee	0	0
Texas	9	46
Virginia	1	2
West Virginia	0	0

	No. of Hospitals	No. of Claims
West		
Alaska	1	1
Arizona	0	0
California	5	13
Colorado	2	3
Hawaii	0	0
Idaho	0	0
Montana	1	2
New Mexico	0	0
Oregon	0	0
Utah	0	0
Washington	1	1
Wyoming	0	0

	No. of Hospitals	No. of Claims
Totals	62	214

** State location of a hospital was mapped against U.S. Census Bureau Region Tracks*

Comparison of Analyses

Below is a comparison of the multiple levels, at which NCI conducted analyses, and their average/median standardized total charges. The table presents charges for all claims collected, those identified as single level claims, and those identified through the alternative analysis excluding outliers.

DePuy Spine - New Technology Add-On Payment Project
Comparison of Analyses
May 20, 2005

Table A6 - Charite Charge Analysis Findings

	All Collected Claims	Single Level Analysis	Alternative Analysis Excluding Outliers
Total Number of Claims Used for Analysis (n):	**303**	**214**	**217**
Total Number of Hospitals used for Analysis:	71	62	65
Charge Analysis			
Average Standardized Total Charge	**$51,186.55**	**$45,791.17**	**$44,518.14**
Median Standardized Total Charge	**$44,827.61**	**$41,322.80**	**$41,950.06**
Average Length of Stay (days)	2.84	2.65	2.67

Appendix 2
Comments from Surgeons

54 year old male implanted 4/6/2005
"ROM pre-op limited to 50% of normal, ROM follow-up [5/17/2005] – too early to evaluate, currently ROM up to 75% of normal. Relative to fusion, Charité allows for shorter hospital stay and easier/quicker post-op rehab."

26 year old male implanted 2/27/2003
"Excellent disc height preservation, preserved ROM"

34 year old male implanted 1/26/2005
"Post-op Charité disc patients in my practice are having less postoperative pain scales and earlier return to work than fusion patients"

Not Specific to a Particular Patient – Comment 1
"To date, I have not implanted a CHARITÉ into anyone covered by Medicare. I agree with CMS that a diagnosis of osteoporosis would potentially contraindicate use of a CHARITÉ in that particular patient, however, I do have patients that are covered by Medicare without any evidence of osteoporosis (per DEXA results) and would be helped by implantation of CHARITÉ when necessary. I also have patients covered by Medicare that are younger than 60. I do not believe that a blanket denial by Medicare would be in the best interest of the Medicare population."

Not Specific to a Particular Patient – Comment 2
"The suggestion that Medicare patients would not be appropriate for the CHARITÉ disc, due to osteoporosis, is a gross exaggeration. Certainly, I would expect the prevalence of osteoporosis to be higher in the older age group of Medicare patients. However, I see many patients >65 yo who are extremely active and do not have osteoporosis. Assuming these patients have intractable back pain due to discogenic pain, without advanced spondolytic/degenerative changes in their spine, I would expect them to benefit greatly from an ADR."

APPENDIX E:

Maryland Decision: Health Services Cost Review Commission Recommendation for the Treatment of Artificial Disc Procedures

Recommendation for the Treatment of Artificial Disc Procedures

Introduction:

The FDA approved the use of the Charite Artificial Disc on October 26, 2004, as a new treatment for degenerative disc disease. Though this new technology has been shown to effectively treat severe low back pain associated with disc disease, utilization has been limited in Maryland hospitals due to the financial disincentive associated with the use of this device. The case-mix weights for the DRGs to which the artificial disc cases currently group do not adequately reflect resource use for these procedures due to the very high cost of the artificial disc device. Hospital representatives have suggested that artificial disc cases should be re-mapped to the higher weighted spinal fusion DRGs in order to limit this financial disincentive. Upon review of the artificial disc charge data from FY 2005, staff recommends that the MD-CMS grouper be modified to create two new cells for artificial disc procedures performed between October 26, 2004 and June 30, 2005 with corresponding weights that will appropriately compensate hospitals.

Background:

The Charite Disc (manufactured by DePuy Spine, Inc. a company of Johnson & Johnson) is an artificial intervertebral disc made from two metallic endplates and a plastic movable center core that is implanted to treat pain associated with degenerative disc disease. The artificial disc replaces the diseased or damaged intervertebral disc during a surgical procedure called spinal arthoplasty. With this procedure, patients experience improvement in pain and function while maintaining flexibility in their spine. This procedure is an alternative to lumbar spinal fusion surgery, the primary treatment option for degenerative disc disease. Spinal fusion is effective in reducing pain but, unlike the Charite implant, limits the range of motion of the patient.

Clinical trials that compared artificial disc replacement to spinal fusion surgery showed that patients receiving the Charite disc implant had a shorter length of hospitalization (3.7 days versus 4.3 days) and experienced no significant differences in complications.

Economic Impact of Current DRG Mapping:

Under the current MD-CMS DRG logic, artificial disc procedures (ICD-9 Code 84.6 series – Insertion and/or revision of spinal disc) are grouped to:

	Statewide Weight
DRG 499 – Back & Neck Procedures except Spinal Fusion w/CC	1.0702
DRG 500 – Back & Neck Procedures except Spinal Fusion w/o CC	0.7107

The current mapping to these relatively low weight DRGs is problematic due to the high cost of the Charite device, listed at $11,500. Because the FDA granted approval for the use of the Charite device this year, the charges associated with this procedure were not in the base data used to establish the case-mix weights.

To illustrate the negative financial impact of the current grouping logic at hospitals that perform artificial disc procedures, St. Joseph Medical Center (SJMC) supplied staff with charge data for the procedures performed at the hospital this fiscal year. Since the Charite approval date, SJMC has experienced 10 artificial disc cases that grouped to DRG 499 with an average charge of $21,979 and 13 artificial disc cases that grouped to DRG 500 with an average charge of $21,305. Given the hospital's casemix adjusted charge per case target of $7521, cases that group to DRG 499 represent a loss of $13,930 per case and those falling into DRG 500 represent a loss of $15,960 per case for a total loss (meaning revenue above the approved target) of $346,778 on all Charite cases performed this year.

DRG Re-Mapping and Economic Impact:

Because artificial disc procedures are considered an alternative to spinal fusion procedures to treat pain associated with degenerative disc disease, staff believes that it would be appropriate to re-map the artificial disc procedures to the higher weighted spinal fusion DRGs if resource use is similar. Comments published in the Federal Register (Vol 69, No. 154) regarding the proposed DRG assignment of artificial disc procedures also suggest that the current mapping is not appropriate. Commenters stated that since artificial discs will be used for patients who would very likely be candidates for spinal fusion, the procedures should be assigned to DRGs 497 and 498. Others stated that the costs of treating patients with a spinal artificial disc are similar to patients in the spinal fusion DRGs and that operating room time is similar for both procedures.

Under the current MD-CMS DRG logic, the weights for spinal fusion procedures are:

	Statewide Weight
DRG 497 – Spinal Fusion except Cervical w/CC	3.6832
DRG 498 – Spinal Fusion except Cervical w/o CC	2.7703

Using St. Joseph Medical Center's data, if artificial disc cases are re-mapped to the spinal fusion DRGs, the hospital is overcompensated for the 23 cases that were performed this year. This suggests that the resource use for spinal fusion cases is greater than that of artificial disc procedures performed at the hospital and, therefore, re-mapping to the spinal fusion DRGs may not be appropriate. Instead of re-mapping to spinal fusion DRGs, as suggested by hospital representatives, staff believes that the MD-CMS grouper should be modified to create two new cells for artificial disc procedures with case-mix weights calculated using artificial disc data from St. Joseph Medical Center and based on the relationship between the hospital's average charge for the artifical disc procedures

and the case-mix adjusted average charge for all cases at the hospital. Artificial disc procedures that currently map to DRG 499 will be re-mapped to "Artificial Disc Procedure w/ CCs" and those that currently map to DRG 500 will be re-mapped to "Artificial Disc Procedures w/o CCs". Under this proposal, the case-mix weights for the newly established artificial disc DRGs are as follows:

	Statewide Weight
DRG – Artificial Disc Procedure w/CC	2.9223
DRG – Artificial Disc Procedure w/o CC	2.8328

Recommendation:

Commission staff recommends that the MD-CMS grouper be modified to create two new artificial disc DRG cells with case-mix weights based on current data. Under this proposal, artificial disc procedures (identified by ICD-9 Codes 84.60 – 84.69) performed between October 26, 2004 and June 30, 2005 that currently map to DRG 499 will be re-mapped to "Artificial Disc Procedure w/ CCs" with a case-mix weight of 2.9223 and those that currently map to DRG 500 will be re-mapped to "Artificial Disc Procedures w/o CCs" with a case-mix weight of 2.8328.

Retroactivity:

The effective date of this policy is October 26, 2004, which was the FDA approval date for the Charite Artificial Disc.

Long Term Strategy:

Under the APR-DRG grouper, artificial disc cases will be grouped to the appropriate DRG and severity level under APR logic.

232
(535)

June 23, 2005

JUN 24 2005

Signature

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Administrator
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Attention: CMS–1500–P
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue SW.
Washington, DC 20201

Nurs/All/Phar
Hefter
Hartstein
Lefkowitz
Truong
Ruiz

Dear Dr. McClellan:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) proposed rule announcing changes to the Hospital Inpatient Prospective Payment Systems (HIPPS) and Fiscal Year 2006 Rates that was published in the *Federal Register* on May 4, 2005. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

ASHP and its members urge CMS to restore funding for second-year, specialized pharmacy residency programs in order to allow Medicare enrollees to take advantage of the benefits of patient care that can only be provided by clinical pharmacy specialists. This is an urgent public health issue as more Medicare beneficiaries make use of an increasing number of high-risk medication therapies. CMS has – and should make use of -- the authority it has to make a simple change to its current policy. In the preamble to the final rule on 2006 HIPPS rates, CMS must acknowledge that second-year, specialized pharmacy residency programs have met the "industry norm" test established in 2003, instruct hospitals to submit reasonable cost, pass-through charges, and provide communication to the fiscal intermediaries to approve payment.

In a May 19, 2003, proposed rule on payment rates under the HIPPS, CMS made potentially devastating changes to the way the costs of all pharmacy residency programs would be reimbursed. CMS proposed that, beginning on October 1, 2003, these residency programs would no longer be reimbursed on a pass-through, reasonable cost basis, but only as normal operating costs covered by the HIPPS rate. ASHP was vigorously opposed to this change, and met with CMS staff who wrote the proposed rule to discuss the issue. Additionally, numerous hospital administrators, pharmacists, and physicians sent comments to CMS that explained the importance of continued funding of pharmacy residency programs. We appreciate CMS's responsiveness to ASHP and our members concerns by at least partially reversing its position.

In the HIPPS final rule, issued on August 1, 2003, CMS determined that it would continue to reimburse providers on a reasonable cost, pass-through basis for general pharmacy practice residencies (first-year residencies) but would not continue pass-through funding for second-year specialized pharmacy residencies. CMS stated in the 2003 final rule:

> Second-year residencies would *not* qualify for reasonable cost pass-through payment because ... it is not currently the ''industry norm'' to require completion of these programs before beginning work in these specialties. If we find in the future that it has become the ''industry norm'' for hospitals to require second-year pharmacy residencies, we may allow the hospitals operating those programs to be reimbursed for the costs of those programs on a reasonable cost basis.

"Industry norm" was defined by CMS "to mean that more than 50 percent of hospitals in a random, statistically valid sample require the completion of a particular training program before an individual may be employed in a specialty."

In response, ASHP conducted such a survey in early 2004, the results of which demonstrate that second-year pharmacy residencies are indeed the industry norm. We submitted the survey results during the comment period for the May 18, 2004, proposed rule on the HIPPS rates for FY 2005. There was no specific response from CMS to our submission in the final rule issued on August 11, 2004.

ASHP resubmitted the 2004 survey data in March of this year, prior to the agency issuing the proposed rule for 2006 HIPPS rates. To briefly reiterate those data, 82% of health care institutions prefer to fill clinical pharmacy specialist positions with specialized residency-trained pharmacists. Fifteen percent of all respondents said they absolutely require a specialized residency and would hold a position open until a candidate with the residency training were found. Sixty-seven percent of those surveyed said they would fill a pharmacy clinical specialist position with a pharmacist who lacked the specialized residency training only if they were unable to find a candidate who had completed such a residency. ASHP believes that these data represent an industry norm in a profession confronting chronic personnel shortages and rapid change.

As a supplement to the 2004 survey data submitted in March of this year, we attached a summary of information compiled from the Personnel Placement Service (PPS) recruitment effort that took place at ASHP's Midyear Clinical Meeting in Orlando, Florida, in December 2004. That information mirrors the data in the survey. When ASHP staff met with Herb Kuhn and staff from CMS's Hospital and Ambulatory Policy Group in May of this year to discuss the residency funding issue, Mr. Kuhn noted that the PPS review validated the survey results.

One question that was raised during our May meeting with CMS staff was why ASHP's 2004 survey covered hospitals with more than 200 beds, while the "industry norm" standard that the agency set in its August 1, 2003, final rule seems to require a sampling of hospitals with at least 100 beds.

In developing the 2004 survey, ASHP concluded that hospitals with 200 or more beds would be most likely to employ clinical pharmacy specialists and respond to the survey. Smaller hospitals have relatively few pharmacists on staff, and they must, by necessity, act as generalists rather than focus all of their attention in one area of specialization. When CMS defined its "industry norm" standard in the August 1, 2003, final rule, the agency recognized that "due to the unique staffing circumstances faced by many smaller hospitals, inclusion of small hospitals in the sample would introduce factors that are not typically representative of the industry as a whole and would skew the results inappropriately. In such cases, we would consider excluding hospitals with less than 100 beds." Using this same rationale of the "unique staffing circumstances" of hospitals with fewer than 200 beds – that they would be unlikely to hire clinical pharmacy specialists –we confined our original survey to hospitals with over 200 beds.

However, to address CMS's question from the May meeting, and to confirm that our own assumptions were correct, ASHP recently sent the same survey to hospital directors of pharmacy in our data base who list their bed size between 100-199 (survey period: June 8-20, 2005). A copy of that survey is attached. Seventeen percent responded to the survey (17/99). Of these respondents, six had clinical positions in specialties where there is corresponding specialized pharmacy residency training. Sixty-seven percent of these institutions desired specialized residency trained individuals for their specialist positions. Thirty-eight percent said they would fill a clinical specialist position with a pharmacist who lacked the specialized residency training only if they were unable to find a candidate who had completed such training. As we initially assumed, fewer of these small hospitals have clinical specialists. However, the response from those who hire pharmacy specialists is similar to the larger hospitals in desiring specialized residency trained individuals to fill specialist positions. Also attached is a chart comparing the different hospital size groups' responses to our survey. That chart demonstrates the trend toward more utilization of specialty-trained pharmacists in larger institutions.

It is difficult to understand how, on one hand, CMS can recognize the importance of clinical pharmacists to patient care, yet on the other refuse to restore the funding that will ensure continued availability of such specialists. In the proposed rule on Conditions for Coverage for End Stage Renal Disease (ESRD) Facilities that the agency issued on February 4, 2005, CMS

suggested that hospital pharmacists could play an important role on multidisciplinary teams within dialysis facilities because "there are a number of publications that describe the contributions of pharmacists to the improved care of various patient populations while simultaneously reducing medication-related costs." Without the availability of appropriately trained pharmacists, these cost savings and improved patient outcomes will not be achieved.

CMS's current policy of not reimbursing hospitals for second-year, specialized residency programs is truly disastrous for the future of pharmacy residencies and continued patient safety and quality of care. There has already been a reduction in the number of institutions providing specialized residency training and those planning future specialized residency programs because of lack of federal funding. This will be devastating in terms of maintaining quality health care for Medicare beneficiaries and other patients in acute care settings, as hospitals are still facing a workforce shortage of qualified pharmacists. The impact of the current CMS policy will be a reduction in the number of qualified clinical pharmacists and pharmacy practice leaders needed to ensure appropriate management of high-risk medication therapy in hospitals.

CMS will be receiving numerous comment letters from members of ASHP, other pharmacy organizations, and others urging CMS to restore funding for second-year, specialized pharmacy residency programs. Many of these letters will provide you with personal accounts of how specialized residency training has improved a pharmacist's ability to ensure improved outcomes for Medicare beneficiaries and other high-risk patients. There are also some consistent themes that run through these comment letters:

- Pharmacy directors will validate the survey data ASHP provided to CMS, noting that they require specialty-trained pharmacists for specialty positions and how, as employers, they depend on specialty-trained pharmacists to provide quality care to patients on high-risk drug therapies.
- Directors of pharmacy residency programs will tell you how pharmacists in specialized residency programs contribute to and enhance the care given to patients.
- Current practicing clinical pharmacists will tell you how it will become increasingly important for patients with complex medical conditions to have access to the expertise of specialty-trained pharmacists, particularly those who have trained in specialties that are important to Medicare beneficiaries, such as geriatrics, oncology, infectious diseases, and critical care.
- Pharmacists currently completing specialized residency programs will tell you that their job search experience is consistent with the survey data ASHP provided to CMS.

- Pharmacy faculty, many of whom have additional responsibilities to maintain clinical practice at affiliated institutions, will tell you how their training in specialized residency programs enhance patient care and develop future pharmacy leadership.
- Physicians will note how they interact with and rely on clinical pharmacy specialists as members of interdisciplinary health care teams to manage the medication therapy of severely ill patients.
- Many will tell you that the amount of federal funding needed today and in the future to support specialized pharmacy residency programs is infinitesimal compared to the impact that *lack* of funding will have on specialized patient care.

Enclosed with these comments is a petition, signed by 551* attendees at ASHP's Summer Meeting that was held in Boston June 11-15, 2005, urging CMS to restore funding for second-year, specialized pharmacy residency programs. The signers of the petition, from throughout the United States and holding all levels of positions in a wide range of practice settings, recognize the importance of specialty-trained pharmacists for the future of our nation's health care.

ASHP is disappointed that CMS did not take into consideration for its May 4 proposed rule the survey data and other information that we provided on March 14, 2005, to demonstrate that specialized pharmacy residency programs met the agency's "industry norm" standard. Continued lack of funding for specialized pharmacy residency programs will have a detrimental impact on patient care for Medicare beneficiaries in the inpatient setting. Hospitals and health systems increasingly rely on the expertise of pharmacists trained in specialized clinical fields to work in collaboration with other members of the health care team to improve patient outcomes.

ASHP is confident that the survey data provided to the agency meets the test that CMS established in the August 1, 2003, HIPPS final rule. Specifically, it is the "industry norm" for the majority of hospitals to require completion of a second-year, specialized pharmacy residency program before hiring pharmacists to fill specialized clinical pharmacist positions. In the upcoming final rule for 2006 HIPPS rates, we urge CMS to acknowledge that we have met the test, instruct hospitals to submit reasonable cost, pass-through charges, and provide communication to the fiscal intermediaries to approve payment.

For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. For more than 40 of those years,

* Six of the signatures are duplicates, and have been highlighted as such.

ASHP has been the sole accrediting body for postgraduate residency programs in pharmacy in the United States. We appreciate the opportunity to present comments on this important patient care issue. If you have any questions regarding our comments, please contact me either by telephone at 301-664-8702, or by e-mail at gstein@ashp.org.

Sincerely,

Gary C. Stein, Ph.D.
Director of Federal Regulatory Affairs

Attachments

cc: Herb B. Kuhn
Elizabeth Richter

Results Summary

Show All Pages and Questions

Export... View De

Filter Results

To analyze a subset of your data, you can create one or more filters.

Edit Filter... **Total:** 25 **Visible:** 17

Share Results

Your results can be shared with others, without giving access to your account.

Configure... **Status:** Enabled **Reports:** Summary and Detail

1. Specialists Positions Survey – Directors/Bedsize 100-199

1. Does your health system include a hospital?

	Response Percent	Response Total
Yes	100%	17
No	0%	0
Total Respondents		17
(filtered out)		8
(skipped this question)		0

2. American Society of Health-System Pharmacists

2. Do you have any Clinical Pharmacy Specialists* at your facility?

	Response Percent	Response Total
Yes	40%	6
No	60%	9
Total Respondents		15
(filtered out)		7
(skipped this question)		3

3. Pharmacy Specialist Positions

3. For each specialty below, please indicate how many specialists you currently have at your facility. (Do not include specialized residents.)

NOTE:

For each specialty with no staff, please skip the item to indicate "none."

	1	2	3	4	5 or more	Response Total
Critical Care	**100% (2)**	0% (0)	0% (0)	0% (0)	0% (0)	**2**
Drug Information	**100% (1)**	0% (0)	0% (0)	0% (0)	0% (0)	**1**
Geriatric	**100% (2)**	0% (0)	0% (0)	0% (0)	0% (0)	**2**
Infectious Diseases	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Internal Medicine	**100% (1)**	0% (0)	0% (0)	0% (0)	0% (0)	**1**
Nuclear	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Nutrition Support	**100% (2)**	0% (0)	0% (0)	0% (0)	0% (0)	**2**
Oncology	**100% (2)**	0% (0)	0% (0)	0% (0)	0% (0)	**2**
Pediatric	**100% (2)**	0% (0)	0% (0)	0% (0)	0% (0)	**2**
Pharmacotherapy	**100% (1)**	0% (0)	0% (0)	0% (0)	0% (0)	**1**
Primary Care	0% (0)	0% (0)	0% (0)	**100% (1)**	0% (0)	**1**
Psychiatric	**100% (1)**	0% (0)	0% (0)	0% (0)	0% (0)	**1**
All other specialists	0% (0)	**100% (1)**	0% (0)	0% (0)	0% (0)	**1**
					Total Respondents	**6**
					(filtered out)	**2**
					(skipped this question)	**17**

4. If "all other specialists" applied to you, please list the area of specialties and the number of specialists in each area.

View	**Total Respondents**	**1**
	(filtered out)	**2**
	(skipped this question)	**22**

4. Specialist Positions

5. *There are 12 areas* where specialized residency training is available.* When your facility is recruiting for a position in one of these areas, which of the following statements apply:

	Response Percent	Response Total
Do not have specialists in any of these 12 areas	25%	2
Require a specialized residency and keep positions open until we find a qualified candidate with a specialized residency	12.5%	1
Prefer a specialized residency but will fill positions with pharmacists who do not have a specialized residency, if we are	**37.5%**	**3**

unable to find a candidate with a specialized residency		
Do not consider a specialized residency a significant criteria for hire	25%	2
Total Respondents		**8**
(filtered out)		**3**
(skipped this question)		**14**

5. Specialist Positions

6. Please indicate the top TWO reasons that you feel that your facility may not always be able to find a candidate with a specialized residency?

	Response Percent	Response Total
Geographic location of our facility	**100%**	**3**
Inadequate supply of candidates with a specialized residency in the marketplace	66.7%	2
Lack of a pharmacy school affiliation/faculty appointment at our facility	33.3%	1
Salary/benefits our facility can offer	0%	0
Competition with other more prestigious facilities	0%	0
Other (please specify)	0%	0
Total Respondents		**3**
(filtered out)		**0**
(skipped this question)		**22**

7. When you CANNOT find a candidate with a specialized residency, what other qualifications would you consider as substitutes for the preferred residency? (Please indicate all that apply.)

	Response Percent	Response Total
A pharmacy practice residency	**100%**	**3**
Experience in the specialized area	**100%**	**3**
Board certification (BPS)	**100%**	**3**
Completion of a traineeship program*	33.3%	1
Other (please specify)	0%	0
Total Respondents		**3**
(filtered out)		**0**
(skipped this question)		**22**

6. Specialist Positions

8. What other qualifications do you look for when recruiting for a specialist position. (Please indicate all that apply.)

View

	Response Percent	Response Total
A pharmacy practice residency	33.3%	1
Experience in the specialized area	**66.7%**	**2**
Board certification (BPS)	0%	0
Completion of a traineeship program*	0%	0
Other (please specify)	33.3%	1
Total Respondents		**3**
(filtered out)		**1**
(skipped this question)		**21**

7. Specialist Positions

9. How many years of experience in the specialized area do you generally require?

	Response Percent	Response Total
1 year	**100%**	**1**
2 years	0%	0
3 years	0%	0
4 years	0%	0
5 years	0%	0
More than 5 years	0%	0
Total Respondents		**1**
(filtered out)		**0**
(skipped this question)		**24**

8. Specialist Positions

10. How many years of experience in the specialized area do you generally require when a candidate does not have a specialized residency?

	Response Percent	Response Total
1 year	0%	0
2 years	**100%**	**3**
3 years	0%	0
4 years	0%	0
5 years	0%	0
More than 5 years	0%	0

Total Respondents	**3**
(filtered out)	**0**
(skipped this question)	**22**

9. Specialist Positions

11. Do you require any of your specialists to be board certified?

	Response Percent	Response Total
Yes	16.7%	1
No	**83.3%**	**5**
Total Respondents		**6**
(filtered out)		**1**
(skipped this question)		**18**

10. Board Certification

12. Which board certified areas do you require for your specialists? (Please select all that apply.)

	Response Percent	Response Total
Pharmacotherapy	0%	0
Pharmacotherapy with added qualifications in Infectious Diseases	0%	0
Pharmacotherapy with added qualifications in Cardiology	0%	0
Nutrition Support	0%	0
Oncology	**100%**	**1**
Psychiatric	0%	0
Geriatrics	0%	0
Toxicology	0%	0
Other (please specify)	0%	0
Total Respondents		**1**
(filtered out)		**0**
(skipped this question)		**24**

11. Specialist Positions

13. Please rate your level of agreement with the following statements with "1" meaning strongly disagree to a "5" meaning strongly agree.

	Strongly Disagree				Strongly Agree	Response

	1	2	3	4	5	Average
My organization finds it difficult to fill our specialist pharmacy positions.	0% (0)	0% (0)	33% (2)	**50% (3)**	17% (1)	**3.83**
My organization has had to compromise on its preferences to fill specialist pharmacy positions.	0% (0)	17% (1)	33% (2)	**50% (3)**	0% (0)	**3.33**
The loss of Medicare pass-through funding for specialized residencies will make it more difficult to recruit specialized residency trained pharmacists at my organization in the future.	0% (0)	0% (0)	33% (2)	**50% (3)**	17% (1)	**3.83**

Total Respondents	**6**
(filtered out)	**0**
(skipped this question)	**19**

14. In the past three years, what is the longest period of time you have left a specialist position open, while trying to find a qualified candidate?

	Response Percent	Response Total
Not hired a specialist in the past 3 years	**33.3%**	**2**
1-3 months	0%	0
3-6 months	0%	0
6-9 months	**33.3%**	**2**
9-12months	0%	0
1-2 years	16.7%	1
2-3 years	16.7%	1
More than 3 years	0%	0
Total Respondents		**6**
(filtered out)		**0**
(skipped this question)		**19**

12. Resident Training

15. Do you have accredited residency training programs at your facility for *pharmacy practice residencies*?

	Response Percent	Response Total
Yes	5.9%	1
No	**94.1%**	**16**
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

16. Do you have accredited residency training programs at your facility for *specialized residencies*?

	Response Percent	Response Total
Yes	0%	0
No	**100%**	**17**
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

13. Resident Training

17. Please rate your level of agreement with the following statements on the impact you think the elimination of Medicare pass-through funding for specialized residency programs will have on your organization, with "1" meaning strongly disagree and "5" meaning strongly agree.

	Strongly Disagree 1	2	3	4	Strongly Agree 5	Response Total
Curtail further development of residency programs in specialized areas	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Reduce the current number of residency programs in specialized areas	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Curtail future increases in the number of specialized residency positions	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Reduce the current number of specialized residency positions	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
Eliminate the specialized residency program	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	**0**
					Total Respondents	**0**
					(filtered out)	**0**
					(skipped this question)	**25**

14. American Society of Health-System Pharmacists

18. Please indicate the ownership of your hospital.

	Response Percent	Response Total
For profit	11.8%	2
Not for profit	**76.5%**	**13**
View Other (please specify)	11.8%	2
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

19. How many licensed beds are available at your hospital?

	Response Percent	Response Total
Less than 100 beds	0%	0
100-199 beds	**100%**	**17**
200 - 299 beds	0%	0
300 - 399 beds	0%	0
400-499 beds	0%	0
500 beds or more	0%	0
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

20. Which description below BEST describes your hospital?

	Response Percent	Response Total
Academic/University Medical Center	0%	0
Armed Forces	0%	0
Children's Specialty	5.9%	1
Community (with academic affiliations)	**47.1%**	**8**
Community (without academic affiliations)	35.3%	6
Disproportionate Share	0%	0
Oncology Specialty	0%	0
Public Health Service/ Indian Health Service	0%	0
Prison System	0%	0
Psychiatric Focus (state or county mental health facility)	0%	0
Veterans Administration	5.9%	1
Other (please specify)	5.9%	1
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

View

21. Is your hospital affiliated with a medical school?

	Response Percent	Response Total
Yes	23.5%	4

No	**76.5%**	**13**
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

22. Is the pharmacy department affiliated with a pharmacy school?

	Response Percent	Response Total
Yes	47.1%	8
No	**52.9%**	**9**
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

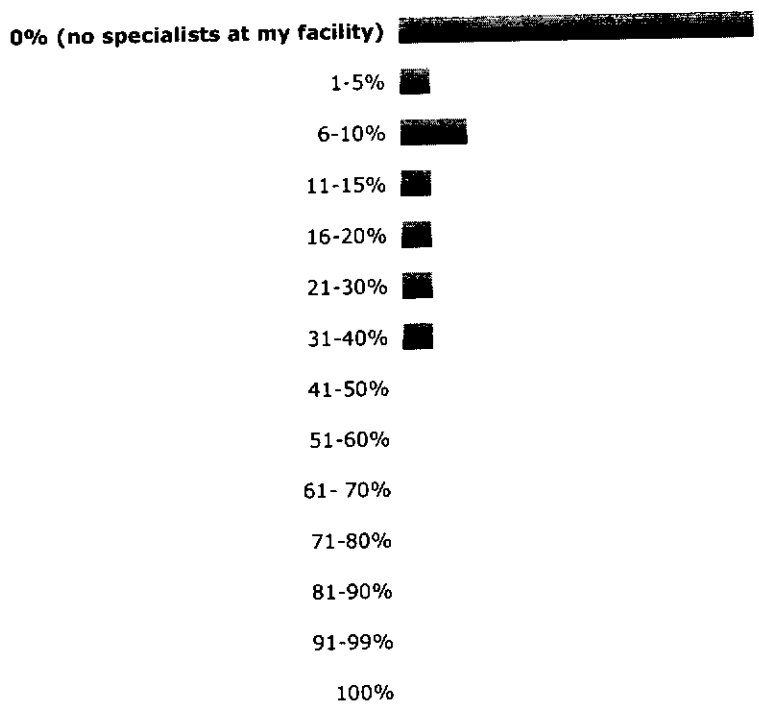
23. Do you have college of pharmacy faculty members who practice at your hospital?

	Response Percent	Response Total
Yes	11.8%	2
No	**88.2%**	**15**
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

24. How many total FTE pharmacist positions* are currently within your budget?

	Response Percent	Response Total
1-2 positions	11.8%	2
3-5 positions	29.4%	5
6-10 positions	**41.2%**	**7**
11-20 positions	17.6%	3
21-30 positions	0%	0
31-50 positions	0%	0
51-100 positions	0%	0
More than 100 positions	0%	0
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

25. What percentage of total FTE pharmacist positions (from above) are specialist positions?



	Response Percent	Response Total
0% (no specialists at my facility)	**58.8%**	**10**
1-5%	5.9%	1
6-10%	11.8%	2
11-15%	5.9%	1
16-20%	5.9%	1
21-30%	5.9%	1
31-40%	5.9%	1
41-50%	0%	0
51-60%	0%	0
61- 70%	0%	0
71-80%	0%	0
81-90%	0%	0
91-99%	0%	0
100%	0%	0
Total Respondents		**17**
(filtered out)		**4**
(skipped this question)		**4**

15. Thank You!

26. Please use the space below for any general comments you would like to add related to the development of specialized positions or recruitment and training of these individuals:

View **Total Respondents**	**5**
(filtered out)	**0**
(skipped this question)	**20**

Comparison of responses to the ASHP surveys regarding hiring practices for clinical pharmacy specialists, sorted by bed size

(The original survey was conducted in the Spring 2004 of hospitals 200 or more beds. An additional survey was conducted of smaller hospitals with 100 – 199 beds in June 2005)

Bed Size of the Hospital	100 – 199 Beds 2005 survey	< 400 Beds 2004 survey	> 400 Beds 2004 survey
# respondents (%= response rate for bed size group)	17 (17%)	123 (25%)	146 (39%)
# with specialist positions, in areas where specialized residency training exists	6 (35%)	83 (63%)	127 (86%)
Looking for specialized residency trained individuals to fill clinical specialist positions, in the areas where specialized residency training exists	67%	80%	94%
Prefer a specialized residency trained pharmacist but will fill positions with pharmacists who do not have a specialized residency, if they are unable to find a candidate with specialized residency training	38%	63%	69%
Agree they have had to compromise their hiring, due to difficulty recruiting	50%	37%	40%
Thought the difficulty in finding specialized residency trained candidates was due to an inadequate supply of these individuals	67%	72%	78%
Thought the difficulty in finding specialized residency trained candidates was due to the geographic location of their facility	100%	40%	37%
% of sites that have had to wait at least 2-3 years to hire individuals with specialized residency training	17%	4%	9%
Offer pharmacy practice residency training at their site	6% (1)	21% (25)	67% (97)
Offer specialized residency training at their site	0%	8% (10)	31% (44)
Typical # of Full Time Equivalent Pharmacists in their budget.	6- 10	11-20	21-30, or more

Petition to Restore Federal Funding for Specialized Pharmacy Residency Programs

June 2005

Mark B. McClellan, M.D, Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1500-P
Hubert H. Humphrey Building – Room 443-G
200 Independence Avenue, SW
Washington, DC 20201

American Society of Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

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

The undersigned persons petition the Centers for Medicare & Medicaid Services (CMS) to restore reasonable-cost, pass-through Medicare funding for specialized (second-year) pharmacy residency programs.

In 2004, and again in 2005, the American Society of Health-System Pharmacists (ASHP) sent survey data to CMS to confirm that specialized residency programs meet the "industry norm" test that CMS created: that "more than 50 percent of hospitals in a random, statistically valid sample require the completion of a particular training program before an individual may be employed in a specialty."

Comment letters that CMS has already received and will receive by the June 24, 2005, comment deadline in response to the May 4, 2005, proposed rule emphasize the following:

- Pharmacy directors will validate the survey data ASHP provided to CMS, telling you that they require specialty-trained pharmacists for specialty positions and how, as employers, they depend on specialty-trained pharmacists to provide quality care to patients on high-risk drug therapies.
- Directors of pharmacy residency programs will tell you how pharmacists in specialized residency programs contribute to and enhance the care given to patients.
- Current practicing clinical pharmacists will tell you how it will become increasingly important for patients with complex medical conditions to have access to the expertise of specialty-trained pharmacists, particularly those who have trained in specialties that are important to Medicare beneficiaries, such as geriatrics, oncology, infectious diseases, and critical care.
- Pharmacists currently completing specialized residency programs will tell you that their job search experience is consistent with the survey data ASHP provided to CMS.

Restoration of funding for specialized residency programs by CMS will lead to the increased ability of hospital pharmacists to ensure the safe and effective use of medications by high-risk Medicare beneficiaries. We therefore, petition CMS to restore this funding.

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

	Signature	Print Name	Address	Affiliation (Institution)	Position
1		Mark Woods	4401 Wornall Road Kansas City, MO 64111	Saint Luke's Hospital	Clinical Coordinator
2		Jill Martin	513 Missouri Ave Cincinnati, OH 45226	Univ. of Cincinnati	Assoc. Professor
3		BL Black	4070 Pennhurst Dr Marietta GA 30062	ASHP	Director
4		Edward Stemley	316 Breezway Bend LN League City, TX 77573	Harris County Hospital District	DIRECTOR
5		Scott Mark	2502 Matterhorn Drive Wexford PA 15090	University of Pittsburgh Medical Center	Director
6		Sara J White	550 ORtega B123 MT VIEW CA 94404	—	—
7		CARL W. GROVE	PO BOX 970 Sanford, ME 04073	PARKVIEW Adventist med'l ctr	Director
8			95 Concord St Wakefield, MA 01880	Lahey Clinic	Operations Mgr
9		DOUG STICKWELL	110 KAY DR MIDDLETOWN OH 45042	MIDDLETOWN REGIONAL	STAFF RPh
10		Robert Main	2921 Laurel Woods Blvd Stow OH 44224	CARDINAL Health	V.P.

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

	Signature	Print Name	Address	Affiliation (Institution)	Position
(11)		JAMES STEFANADES	DURHAM, NC	DUKE UNIV.	OUTPATIENT PHARMACY
(12)		Teri Bair	6031 Lyndon Houston TX		of Counsel
(13)		BRUCE PLESSOW	63 Bronridge Dr NY 14623	NYSCHP	Pres
(14)		DonLynx	7240 ForestAve, Hammond, IN	ICHP	Member
(15)	K. Rajanna	Kottamasu Rajanna	7991 Elm Leaf Dr		Member
(16)	Michelle Kraus	Michelle Kraus	3221 McKelvey Rd. Ste 30	MedAssets	Director
(17)		Frank Briggs	1009 Brookwood Dr Morgantown WV 26508	WVU Hospitals	Assistant Director
(18)		Lourdes M Cuellar	6655 DeMoss Dr Houston, Tx 77074	TIRR	Director
(19)		Theresa M. Wann	217 Window Ave Medford OR 97504	PMH	Lead pharmacist
(20)		KATHLEEN PANLICK	46277 CORDOBA DR. Novi, MI 48374	William Beaumont Hospital	Director

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Charles Jagtman JR	6627 Milne Blvd New Orleans, LA 70124	Univ. of LA at Monroe	Associate Professor
	Laura Wachter	6859 Happy Heart Ln Columbia, MD 21045	Johns Hopkins Hospital	Pharmacist
	ERIC HOLA	36 MUD POND RD. BLAIRSTOWN, NJ 07825	ST. BARNABAS MED CTR.	DIRECTOR
	Robert Mowry	26 Dorothy Rd.	Quincy Med. CENTER	DIRECTOR
	Charles E. Myers	6832 Westcott Drive Richmond VA 23225	ASHP	VP
	DENNIS WILLIAMS	Beaux HALLCB 7360 UNC	UNC	Faculty
	[illegible]	5805 Upvalley Run Austin, TX 78731	UT	Assistant Dean Professor
	Ray Anthony	8125 Solomon Seal Manlius, NY 13104	UY	Director of Phy
	Renee Neely	615 E 70th St KC MO 64131	Liberty Hospital	Clinical Coordinator
	Kathryn Schwartz	1500 Maryst N Maplewood MN 55119	Allina Medical Clinic	pharmacy manager

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Kevin Colgan	1098 Belter Dr. Wheaton, IL 60187	ERT-Q	Vice President
	Marcia Gutfeld	136 Chestnut Hill S. Williamsville NY 14221	McKesson Med Management	RPh, RVP
	JAMES WALLACE	1320 W 4th St Davenport IA 52804	TRINITY HC	DIR RPH
	Stasia Blank	5000 CHEVELLE DR. BILLINGS, MT 59106	DEACONESS BILLINGS CLINIC	CLINICAL COORDINATOR
	Phillip "Justin" Boyd	8908 Copper Oaks Lane Fort Smith, AR 72903	St. Edward Mercy	Section Manager- Pharmacy Operations
	Max L. Hunt Jr.	245 Candlelight Cove Coppell, TX 75019	Novation	Sr. Director, Pharmacy
	Rick Knudson	2210 14th Pl. N. Clear Lake, IA 50428	Premier	Pharmacy Consultant
	Jack Brown	Po Box 1154 Grantham NH	Dartmouth	Clinical Specialist
	Traci Metting	5617 Westwood Ln The Colony, TX 75056	Broadlawn	Director, Clinical Pharm
	Jim Garvelt	4131 Plum Tree St. Wichita, KS 67226	Wesley Medical Center	Manager, Clinical Services

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	STEVEN SHEAFFER	16 BROOKSIDE RD WALLINGFORD PA 19086	PHILA COLLEGE OF PHARMACY	ASSOC. PROFESSOR
	Jean Scholtz	1620 Jennifer LN Blue Bell, PA 19422	Phila College of Pharmacy	Assoc Prof
	Gwendolyn Grell	1309 Fairfield St Morgantown, WV 26505	West Virginia Univ. Hosp	Asst Dir
	DON MCKAIG	369 Hillsdale Rd Richmond, RI 02892	RI Hospital	Staff RPh
	Toby CLARK	11 MAGAZINE CHARLESTON, SC	MUSC	clinical assoc prof
	Tom Brenner	P.O. Box 248 MT WOLF, PA	PSHP	Director
	[illegible]	SCA OSC AIR MORRISTOWN	ASHP	STATE RPh
	DARRYL RICH	4669 Rossmoor Ln Roseville CA	~~ASHP~~ JCAHO	FIELD REP
	DAVID MANCAN	88 EAST NEWTON ST BOSTON, Ma 02118	ASHP	STERILE PRODUCTS SUPERVISOR
	Carla B. Frye	3214 Fox Ridge Ct Woodridge, IL 60517	EPI-Q	Clinical Res. Scientist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
51	Tina Hatzopoulos	900 Greenwood St Evanston IL 60201	Childrens' Memorial Hosp	~~Administrator~~ Pharmacy
52	Jeanette Murphy	42 whitney st Westbury NY 11590	Haymarket Media	Editor
53	Joyce E. Broyles	3792 Oakley Ave Memphis TN 38111	Methodist Healthcare	Coord, Ed / Train
54	Yarisi Valles	5710 Hoover Blvd Tampa, FL	AHC	PIC.

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Diane Miller	815 N. Washington Lansing MI 48906	MPA	Assoc. Exec Director
	Joseph A. Oddis	6519 Rockhurst Rd Bethesda MD 20817		Retired
	FRANK SAYA	1409 Red Bluff Ct San Dimas, Ca. 91773	CSHC	MANAGER
	Jill Haug	23424 Summerstream Pl. Dulles, VA 20166	ASHP	DIRECTOR
	R. CHARLENE GREEN	TELFORD, PA	ASHP, ASPEN	DIRECTOR
Carol J. Rollins	Carol J. Rollins	1621 E. Lester Tucson AZ, 85719	ASHP, ASPEN	Clinical pharmacist
	Sandra L Chase	7884 Kenwood Dr SE Ada, MI 49301	ASHP, ACCP, APhA Jackson Health	Clinical Pharmacist
	Hannah Vanderpool	8665 Tower Dr. Laurel, MD 20723	ASHP	Pharmacist
	David Chen	1108 Windmill Lane SS MD 20905	ASHP	Pharmacist
	Scott E. Townshend	167 So. Mineral St Keyser, WV 26726	ASHP	Asst. Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Steven R. Abel	Steven R. Abel	13892 Stonemill Cir. Carmel, IN 46032	Wishard Health Services	Clinical Manager
Greg Bedenkop	Gregory S. Bedenkop	9364 Briarhurst Dr. Dallas, TX 75243	Broadlane, Inc.	Vice President Clinical Pharmacy & Dx Svcs
Joan Zaleski	Joan Zaleski	418 Paderewski Ave Perth Amboy NJ 08861	Raritan Bay Medical Center	Staff Pharmacist
[illegible]	Marilu Hunt	7201 N Univ Dr Tamarac	Univ Hosp	Director
Sylvia Thomley	Sylvia Thomley	2141 Commonwealth Ave Madison WI 53726	Univ of Wisconsin Hosp	Manager
Y Williams	Yolanda Williams	1265 Union Ave Memphis, TN 38104	Methodist University Hospital	Pharmacy Practice Management Resident
Alex Gernoulis	ALEX GERNOULIS	BEVERLY HOSP BEVERLY MA 01915		R.Ph.
Paul F. Davern	PAUL F. DAVERN	60 DIANE DRIVE SOUTH WINDSOR, CT.	SAINT FRANCIS HOSPITAL HARTFORD, CT.	MEDICATION SAFETY OFFICER
L Jones	Lawrence Jones	800 Spruce Street Phila, PA 19007	Pennsylvania Hospital	Director
Maureen Cauley	Maureen Cauley	Stanford Hosp. Clinic 300 Pasteur Dr. H0301 Stanford, CA 94305	→	Residency Director

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
[signature]	Fred S. Friedman	73-11 210th Street Bayside NY	MT Sinai	Assoc. Director
[signature]	LEONARD GRASCHITZ	78 FORSYTHIA LANE JERICHO NY 11753	BROOKDALE	ASSOC. DIRECTOR
[signature]	Al Patterson	300 Longwood Ave Boston MA 02115	Childrens Hosp. MC Boston	Director
[signature]	Anne Lesko	3333 Burnet Ave Cincinnati, OH 45229	Cincinnati Children's Hosp	Clinical Dir
[signature]	John Van Eeckhout	6803 W 64th St Shawnee Mission KS	CHCA	VP Clinical
[signature]	Tyffani Wingfield	4200 KAYWOOD DRIVE #8 Mount Rainier, MD 20712	ASHP	Exec. Comm. Assoc
[signature]	Donna Soflin	1510 Liberty Drive Lexington, NE	Tri-County Hospital	Director of Pharm
[signature]	Barbara Smutney	501 N. Elam Ave. Greensboro NC 27403	Wesley Long Community Hospital	Staff RPh IV Admix Coor.
[signature]	ARTHUR DALL	82 South St Waltham MA 02453	CAPS/Boston	DIRECTOR
[signature]	Heather Ipema	414 S. Scoville Oak Park, IL 60302	UIC College of Pharmacy	Student

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Steven R. Ross	150 Cherokee Tr. Knoxville TN	Univ. of Tennessee Med. Ctr	Sr. VP
John P. Santell	JOHN P. SANTELL	108 LITTLE QUARRY RD GAITHERSBURG, MD	U.S. PHARMACOPEIA	DIRECTOR, ED PROGRAM INITIATIVES
James Baker	James Baker	5901 NW ~~Kansas~~ 103rd St. Kansas City MO 64154	~~H-S~~ Cardinal Health	Nat. Dir of Prof. Services
Stephen A. Day	Stephen DAY	2249 N KACHINA MESA, AZ 85203	BANNER BAYWOOD Medical Center	Director of Pharmacy
James Grant	James GRANT	241 Forsgate Dr JAMESBURG NJ 08831	Pharmacy Times Journal	Publisher
Nicki Bohl	Nicki Bohl	10 East 31st Street Kearney, NE 68847	Good Sam. Hospital	Director
Richard Faris	Richard FARIS	2020 Heather Cove Memphis, TN 38119	methodist university hosp.	Director.
Ross Thompson	ROSS THOMPSON	663 E. 7th Street #1 South Boston, MA 02127	McKesson Medication Management	Health System Director
John Redwanski	JOHN REDWANSKI	356 walt whitman Newport News VA 23606	Hampton University	DI specialist
Paul Bosle	PAUL BOSLE	1361 Buckingham East Mount Pleasant SC	Medical Univ of SC	Director

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Betty Dong	BETTY DONG	UC School of Pharmacy 521 Parnassus Ave C452	SF CA 94143-0622	Professor Clin Pharm
Barbara Ly	BARBARA IRBY	MASS General Hospital Pharmacy Dept. 55 Fruit St Boston MA 02114	MASS. General Hospital	Residency Director
Kurt Slifka	Kurt Slifka	10411 Barnview ct Dayton, Oh 45458	CMH Regional Health System	Clinical Pharmacist
Jim Knight	Jim Knight	952 Century Oak Nashville TN.	Vanderbilt University	Director
Paul Kraehling	Paul KRAEHLING	630 Yennecott DR Southold, N.Y. 11971	Pharm Assist Associates Inc	Exec V-P
Lynnae Mahaney	Lynnae Mahaney	7200 Stonewood Ct Middleton WI 53562	VA Hospital	Chief of Pharmacy
Mary Kolgan	Mary K Colgan	1098 Belden Dr Wheaton, Il 60187		
William H Puckett	WILLIAM H. PUCKETT	9850 PINEDALE DR. ORLANDO, FL 32836	HOSPITAL PHARMACY CONSULTANT	MANAGER
Wayne Russell	WAYNE RUSSELL	7910 Plum Creek Dr. Gaithersburg MD 20879	Premier Inc	Senior Director
Patricia C Kienle	Patricia C. Kienle	106 Elmwood Dr Luflin PA 18702	Cardinal Health	Operations Director

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Edward Ma	1425 S. Main St Walnut Creek, CA 94595	Kaiser Hospital	Director
Lori Tsukiji	LORI TSUKIJI	KAISER FOUNDATION HOSPITAL 2025 MORSE AVENUE SACRAMENTO, CA 95825	KAISER HOSPITAL	INPATIENT PHARMACY DIRECTOR
	JANE TENNIS	Healthcare Consultants 6209 Mid Rivers Mall Dr. #142 St Charles Mo 63304		Consultants Educator.
	ALBERT HELMERI	1E BALDORIA DR CHADDS FORD, PA 19317	CHRISTIANA CARE HEALTH SERVICES	DIRECTOR.
	Mark Isopi	30110 Bentley Livonia, MI 48154	Pfizer Inc	CEC (Clinical Pharm)
GEORGE REID	GEORGE REID	101 E Wood St SPARTANBURG SC 29303	SPARTANBURG REG HEALTH SYS	DoP
	Nick Genovese	311 Cardinal Dr Hollidaysburg PA	Hollidaysburg PA	DCP
	Norberto A Alberto	Spoleen Clinton Place Massapequa, NY 11758	VBHC	A DoP.
	MARY BURKHARDT	5414 Cliff #201 Ypsilanti MI	US Dept of Veterans Aff	Program mgr
	DOUGLAS SCHECKELHOFF	10540 HUNTERS WAY LAUREL, MD 20723	ASHP	DIRECTOR

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
A J Westbrook	Audrey Westbrook	2228 S. Central Ave Flagler Beach, FL.	Florida Hospital	Clinical Coordinator
[illegible]	Grant Bray	370 Rendezvous Dr Lafayette CO 80026	Denver Health medical Center	Manager Clinical Pharm Services.
Jeffry A Reitz	Jeffrey Reitz	70 Lake Tahoe Circle Bear, DE 19701	ChristianaCare Health System	Clinical Specialist.
Eugene R Ciemiewicz	Eugene R. Ciemiewicz	337 Jessica Dr Middletown DE 19709	Christiana Care Health System	Pharmacy Supervisor
[illegible]	Eric Weber	4238 E. Catalina Dr Phoenix AZ 85018	Cecil T Hogan VA Medical Center	Clinical Specialist
duplicate [illegible]	Phillip Justin Ford	8908 Copper Oaks Ln Fort Smith, AR 72903	St. Edward Mercy	Section Manager - Operations
John P Swenson	John P. Swenson	3407 22nd Way NE Olympia, WA - 98506		
Karren Crowson	Karren Crowson	1282 Castlegate Blvd Huntsville, Al 35801	Cardinal Health	Professional Assoc.
[illegible]	Erica Killingsworth	1357 E Regatta St Boise ID 83706	Catholic Health Initiatives	Manager Pharmacy Services
David D. Allen	David D. Allen	59 St. Andrews Dr. Amarillo TX 79124	Texas Tech School of Pharmacy	Associate Dean

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Robert Ignoffo	ROBERT IGNOFFO	1377 Grand Ave San Rafael Ca	Calif. Soc. H P	President
Claudia Foutz	Claudia Foutz	725 30th St, Sacramento, Ca	CA Society of Healthsystem Pharm	EVP
Anthony Au	Anthony Au	412 Winter St. Philadelphia Pa	ASHP PSHP	Student
Debra Feinberg	Debra B. Feinberg	76 Eldox Rd Delmar, NY 12054	NYSCHP	ED
Stephanie Peshek	Stephanie C Peshek	525 E. Market St. Akron, OH 44309	OSHP	President
Linda Gore Martin	Linda Gore Martin	PO Box 241 Laramie WY 82073	Wyoming Society of Health-System Pharmacy	Secretary-Treasurer
Robert M. Parsons	ROBERT M. PARSONS	50 GREENWOOD CIR. MARIETTA, OH 45750	OHIO SOC. OF HEALTH-SYSTEM PHARMACISTS	EXEC. VICE PRESIDENT
John A Armistead	John A Armistead	104 Foxborough Nicholasville KY 40356	Kentucky SHP	President Elect
Erin Kinsella	Erin Kinsella	3389 clearview AVE Columbus OH 43221	New Practitioners Forum	Vice Chair
Carolyn K. Boardman	Carolyn Boardman	209 Yaqui St. Sierra Vista, AZ	RW Bliss Army Health Center	Chief Pharmacy Service

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
[signature]	Deborah L Burgun	710 Harvard Lane Newark DE 19711	CCHS	
[signature]	James D Cathey	8633 Meadow Green Dr Cordova TN 38016	St Jude	
[signature]	Ricardo Nannini	310-B Winans West Point NY	KACH	Ch c I
[signature]	Karen L. Kier	1487 TR 41 Ada, OH 45810	ONU	Pharmacist.
duplicate [signature]	Tom Bremer	P.O. Box 248 Mt. Wolf PA	PSHP	Rx
[signature]	Deborah J. Tapley	145 West Circle Dr Lexington, SC 29072	Palmetto Health	Director Rx
[signature]	Tad A. Gomez	3631 Pebble Beach Dr. Martinez, GA 30907	MCG Health System	Director
[signature]	Phil Ayers	279 Red [illegible] Circle Ridgeland, MS 3915[illegible]	Baptist Health Syst	Clinical Specialist
[signature]	Rebecca Finley	145 W. Rose Valley Rd Rose Valley, PA 19086	Meniscus Educ Fdn	President
[signature]	Cheryl Aiken	2000 Sunset Lake Rd Dummerston, VT	VSHP (Vermont)	Secretary

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Paul F. Davis	6225 US Hwy 290E Austin, TX 78723	TCHD SHD	Executive Director
	Bob G. Crews	1357 E. Regatta St. Boise, ID 83706	IDAHO	Executive Director
	Rhonda B. McManus	1328 Cardinal Dr. West Columbia SC 29169	SC	President
Baeteena M. Black	Baeteena M. Black	123 Carnousti Franklin, TN 37069	TN. Society of Health-System Pharmacists	Executive Director
Jeanne R Ezell	Jeanne R. Ezell	1116 Hitch Rd Maryville TN 37804	Blount Memorial Hospital	Director of Pharmacy
Kim Phan	Kim Phan	713 Woodlyn cinnaminson, NJ 08077	USP/PCP	student
Dennis Moon	Dennis F Moon	4000 Batesville Blvd Batesville, AR 72501	Arkansas	President Elect
Maria Spencer	Maria Spencer	1201 Braddock Pl #503 Alexandria VA 22314	ASHP	Govt Affairs Dir
	Scott Knoer	12727 Mankato St NE, Blaine, MN 55449	Univ Minnesota Med Ctr.	Director
	Stephen Kessler	3417 Sw 2nd Ave Cape Coral FL 33914	Lee Memorial Health System	Pharmacy Manager

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Patricia Knowles	Patricia Knowles	619 Fieldstone Way Evans, GA 30809	Medical College of GA Health System	Pharmacist
Deborah Mangum	Deborah Mangum	118 Sigman Place Martinez, GA. 30907	University Hospital	Asst. Director
	JOHN PASTOR	6824 RIDGEVIEW DR EDINA MN 55439	MINNESOTA SOCIETY OF HEALTH-SYSTEM PHARMACISTS	PRESIDENT
Phil Saucedo	PHIL T. SAUCEDO	2705 Nakomis NE Albuquerque NM 87112	New Mexico Society of H-S Phar	EX Director
Lisa Gunther Lum	Lisa Gunther Lum	1686 Via Palermo Montebello CA 90640	California	Treasurer, Delegate
Randy Kuiper	Randy Kuiper	3328 Eagle Ct Great Falls, MT 59404	Montana	Delegate
Abigail Strawbery	Abigail Strawbery	5115 West Lane Waldorf, MD 20601	MD	Delegate
	Megan Mc Murray	1105 Spring St #510 Seattle, WA 98104	Harborview Medical Center, WA	Delegate
Ronald M Barnes	RONALD M BARNES	6025 Coventry Cir Alpharetta, GA 30004	Saint Joseph's Hospital - Atlanta	Pharmacist
	JAMES STEVENSON	16766 OLD BEDFORD RD. NORTHVILLE, MI 48167	UNIVERSITY OF MICHIGAN	DIRECTOR OF PHARMACY - DELEGATE

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Deborah R. Saine	Deborah R. Saine	63 Wellington Cir Lebanon, NH 03766	Dartmouth Hitchcock Medical Center	Pharmacy Mgr, Medication Safety
Nicole Allcock	Nicole Allcock	2720 S. Highland #135 Lombard, IL 60148	The Univ of Chicago	Clinical Pharmacist MICU
Scott A Meyers	Scott A Meyers	2925 Southbridge Rd Rockford IL 61114	Illinois Council of Health-System Pharmacists	Executive Director
Sara J White (duplicate)	Sara J White	550 ORtega B123 MT VIEW CA 94040	—	Past Pres
Dianna Borowski	Dianna Borowski	913 E. Beryl Ave Phoenix AZ 85020	Arizona	Chair, Academy Delegate
Lynn Belcher	Lynn Belcher	105 Belton Rd St. Helens, Or 97051	Oregon	Clinical Spec. Delegate
Vivian Rexrode	Vivian Rexrode	12141 Red Stream Columbia MD 21044	MD	MD Delegate
Kathleen D. Donley, RPh	Kathleen D. Donley	7695 Olde Eight Hudson, OH 44236	Akron General Medical Center	Delegate
Larry Clark	Larry Clark	1602 Hitchrack Rd Bailey, CO 80421	Exemplyhealthcare	Sr Director of Pt Support Svcs Delegate
David Blanchard	DAVID BLANCHARD	392 Hugick RD Richfield Spg, NY 13439	FAXTON-ST. LUKES Utica, NY	Delegate

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Kent Fleming	6963 W. Mahoning Dr.	Banner Health System	Pharmacy Compliance Officer
	Leslie Thomas	529 N Sycamore Gardner KS	Rensen Mem Hosp	Pharm Director
	Nancy Hedrick	6525 New Sharon Rd	Duke	pharm mgr
	Mike Schulte	6525 New Sharon Rd	Duke	Clinical Pharmacist
	MARC SUMMERFIELD	1333 S.D AHCA	VHUC	Director
	Alicia Boyce	Bourbonnais IL 60902 3249 So Oak Park Ave	McNeal Hospital	Manager
	Melissa Rice	2 Rehabilitation Way Woburn, MA 01801	Health South	Pharmacy Supervisor
	ALLEN FANN	405 East 21st St Suite Atlantic, Iowa	CCMH	Pharmacy Director
	GINA WOH	11307 Manley Dr Bowie MD	WAH	Staff Pharmacist
Michele Biccardi	Michele Biccardi	10 Holly Drive E. Hampton, CT	Midstate Medical center	Pharmacy Clinical Coordinator

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
[signature]	Jerry Brown	164 Camp Parkmor Rd. Phenix City, AL	East Alabama Medical Center	Pharmacy Manag…
[signature]	Karen Loudon	863 Highland Dr. Roanoke VA	Carilion Health Sys.	Manager, D…
[signature]	Eric Bethmann	1600 Rock Mtn Rd Pinebrook NJ 07027	AmerisourceBergen	IT
[signature]	Michael DeBisschop	1522 East A St Casper WY 82601	University of Wyoming	Professor
[signature]	Richard Smith	898 Genoa Way San Marcos, CA 92078	Pfizer	Clinical Educatio… Consult…
[signature]	Joseph Medicis	750 East Adams Street Syracuse NY	Upstate Medical	Ass. Dir…
[signature]	Leanne Lai	3200 S. Univ. Dr. Ft. Laud. FL 33328	Nova Southeastern University	Professor Program…
[signature]	Michele Schillerstrom	2918 Eaton Rd Eaton NY 13334	Chenango Memorial Hosp.	Director Pharm…
[signature]	Susan M. Wilks	831 Hartrey Av Evanston, IL 60202	ENH	Assist… Direct…
[signature]	David Tsang	5101 S. Willow Springs Rd La Grange IL 60525	La Grange Mem Hosp	Direc… Pharm…

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	John Hertig	207 Quincy St. W. Lafayette, IN	Purdue University	Student
	Arnold Solomon	PO BOX 1504 Edwards Co 81632	Vail Valley Med Center	Director
William Gouveia	W A Gouveia	87 Douglas Rd Belmont, MA 02478	NEMC	Director
Kuldip Patel	Kuldip Patel	1202 Longhunter Ct. Nashville, TN 37217	HCA Centennial Med Ctr.	Asst. Director
	Ronald A. Hoffman, Pharm D	1720 Woodgrove Ct Wildwood MO 63038	MEDASSETS	VP, Pharmacy
	Doug DeJong	9208 W 117th Terrace Overland Park KS 66210	Saint Luke's of KC	Director
	Jeannere Striarse	73 David St. Locust Valley NY 11560	Stony Brook University Hospital	Director
	Jennifer Ford	11700 metric Blvd #324 Austin, TX 78758	University of Texas @ Austin	student
	Dean Parry	245 Ash St Danville PA 17821	Geisinger Medical Center	Director
	Jacqueline Oh	41 Roosevelt Place Somerville NJ 08876	Rutgers University	Faculty

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
John Kusmierz	JOHN KUSMIERZ	34583 HIDDEN PINE DR.	Henry Ford Bi-County Hosp	Dir. of Pharm
[illegible]	Ranjani Varadarajan	128 Miller Hall. Auburn, AL.	Auburn University	graduate Research Asst.
Jessica O'Donnell	Jessica O'Donnell	58 Old Readingsburg Rd. Califon NJ 07830	Ernest Mario School of Pharmacy	student
[illegible]	Pete Campanells	2116 Contreras Rd NE Rio Rancho	University of New Mexico	Dir of Ops
[illegible]	Rose Babbitt	1918 Ravine Cross Garland, TX	Parkland Hosp	Assoc Dir
[illegible]	Luke Mansfield	11078 S Appleview Dr. Brookston, IN 47923	Purdue	Student
John W Collins Jr	JOHN COLLINS	5137 COUNTRY CLUB HIGH RIDGE MO	ST. LOUIS UNIVERSITY HOSP	DIRECTOR
Camille Sabbey	Camille Sabbey	108 Chestnut St. Southbridge, MA	Scripps Green Hospital	Director
Yu Wen Chiu	Yu-Wen Chiu	Taipei Taiwan	Tri-Service General Hosp	Pharmacist
Andrea McAllister	Andrea McAllister	4127 Shiloh Rd. Corinth, MS	Magnolia Regional Health Center	Pharmacist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Joseph J. Canzdica	2480 Stonybrook W Aucondla IL 60087	Dept of Veterans affairs	Associate Chief Consultant
	Robert J. Stoneburner	4544 Mayfield Ave Chesapeake, VA 23321	Bon Secours Maryview Med. Ctr.	Local System Dir. of Pharmacy
	Richard H. Ensign	1414 Hill St Kaysville, UT 84037	University of Utah	Adjunct Faculty
	Gerald E. Meyer	216 W Brookhaven Rd Wallingford Pa 19086	Thomas Jefferson University Hospital	Assistant Director, Pharmacy
	Kelly Ison	526 Monticello, Blvd Norfolk, VA 23505	Chesapeake General Hospital	Director of Pharmacy
	Michelle Dusing	25 Sunnymeder Dr. Ft. Mitchell, Ky 41017	Health Alliance	Director Clinical Pharm
	Alan Lodder	12126 Bluff View Dr Sandy, UT 84092	Alta View Hospital	DOP
	Amina George	5858 W. 87th St. 3B Burbank, IL 60459	UIC College of Pharmacy	student
	Nisha Mathew	122 W. Aldridge Lane Round Lake, IL 60073	UIC College of Pharmacy	Student.
	Eric Kreick	123 Stratford Place Shrewsbury, N.C. 28144	Rowan Regional Medical Ctr.	Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Joseph O'Day	Joseph O'Day	67 Appleton St Salem, MA	Faulkner Hospital	Director
Clare Spencer	Clara Spencer	230 Avenham Roanoke Va. 24014	Carilion Health System	Director Contracting
[illegible]	Daniel Good	509 Lonesome Prairie Haslet TX 76052	Baylor	Director
Carl J Possidente	CARL POSSIDENTE	BOX 1021 JERICHO CTR, VT 05465	Pfizer	CEC
Rena Coll	Rena Coll	1101 NW 23rd Ct Coral Springs, FL	FSHP	Admin affairs Council
Don B Kupper	Don Kupper	530 South Jackson Louisville, Ky 40014	Univ Hosp. KSHP?	Admin Director
Sumathi Rao	SUMATHI RAO	2001 Medical Parkway Annapolis, MD	Anne Arundel Medical Center	Pharmacist
[illegible]	LEIGH BRIDGE-DUNGAN	2073 Co Hwy 10 Laurens NY 13796	BASSETT HEALTHCARE	DIRECTOR
Ronald K Tong	RONALD K. TONG	1326 Elsona Ct Sunnyvale CA 94087	O'Connor Hosp	Staff
Barbara Tong	Barbara Tong	"	Good Samaritan Hosp	Senior Pharmacist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Rawley Guerrero	Rawley Guerrero	291 Hodencamp Rd #46 Thousand Oaks, CA 91360	Amgen	Sr Manager Marketing
[illegible]	James Dorvuch	4324 Ariel Ct Naperville Ill 60564	Sch - Arch.	Director Medical Affairs
[illegible]	MIN THAN	1724 AVENUE W BKLYN, NY 11229	Newark Beth. Med	Director.
[illegible]	ROBERT ROSENOW	14935 ASHLEY DR. TIGARD, OR 97224	PACIFIC UNIVERSITY	DEAN
Robert Fink	ROBERT FINK	2405 DEERBOURNE BRENTWOOD, TN 37027	COMMUNITY HEALTH SYSTEMS	CORPORATE DIRECTOR
[illegible]	DUNIVE SMMON	Mona Kgn 7, Jamaica	University Hospital of The West Indies	DIRECTOR
Collie L. Forrester	COLLIE FORRESTER	PHARMACY DEPT 1000 WATERMAN WAY TAVARES FL 32778	FLORIDA HOSP WATERMAN	DIRECTOR
Jack Udell	Jack Udell	104 Rocky Circle Carl Junction, MO 64834	St. John's RMC Joplin, MO	Director
Jeffrey J Weber	Jeffrey J. Weber	5700 W. Yankee Lake Rd Denton NE 68339	Bryan LGH Medical Center	Manager
Bill Stephenson	BILL STEPHENSON	1431 Lakeshore Drive ANNISTON AL 36207	Retired	Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Tony LEUNG	1446 W. OLIVE CHICAGO ILL 60660	LaGrange Hosp.	Pharmacy Manager
Uma Thyagarajan	UMA THYAGARAJAN	124 SPRING RIDGE DRIVE	UT AUSTIN	STUDENT
	JOE GERBER	9 Eagle Drive Rumsees NJ 08551	S-a. Pharmacy	Sr. Dir.
	Chris Woodruff	6726 Barbage Landing Cir Suffolk, VA 23435	Mary Immaculate Hosp	Pharmacy Manager
	Margaret Gordon	6654 Universal Las Vegas NV 89142	VA Southern Nevada HCS	Assoc Chief, Pharmacy
	Michele Danish	10 Owings Stone Rd Barrington RI 02806	St Joseph Health Services	Clinical Manager.
	William G. Yount	3513 Quail Run Cape Girardeau MO	St. Francis Medical Center	Director of Pharmacy
	Grant Peterson	2021 W. Farwell Chicago IL 60626	Baxter Healthcare Corporation	Senior Marketing Manager.
	Jim Stephens	407 S 12th Windsor, CO 80550	Platte Valley med Center	Director of Pharm
	Jeri Odom	120 South 9th St Oakdale CA 95361	Dept of ARMY	Clinical Pharmacist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Paul J. Barbour	Paul J. Barbour	830 Chalkstone Ave Providence, RI 02908	Providence VAMC	Director Pharm
Thuy Maranto	Thuy Maranto	10101 Ridgegate Pkwy Lone Tree, CO 80124	Sky Ridge Med Ctr	Pharm Spvr
Paul D. Wittmer	Paul D. Wittmer	1644 7th Avenue SE Rochester, MN 55904	Mayo Med. Ctr	Coordinator Cont Imp.
[illegible]	David L Pearson	2501 West 36th Ave Kennewick, WA 99337	Kadlec Medical Center	Pharmacy Director
[illegible]	E.J. Haughey	230 Fern Ave Collingswood NJ.	[illegible]	Pharmacy Director
Bruce Scott	Bruce Scott	13150 Flamingo Ct. Apple Valley MN 55124	McKesson medication management	COO
T. A. Martin	Timothy A. Martin	11473 April Sound Dr. Northport, AL 35475	DCH	Pharmacy Director
[illegible]	Ike Mohsen	9805 Woodington Dr Potomac MD 20854	NIH	Info Speci
Robert J. Cluxton Jr	Robert J. Cluxton	10627 Indian Woods Dr Cincinnati OH 45242	Univ. Cinti	Faculty
Denis Hamilton	Denis Hamilton	1812 Forest Park Ct Jeff City, MO	CRMC	Dir of Rx

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Annette Bird	Annette Bird	125 E John Carpenter Fwy Irving TX 75062	Novation	Manager
Carol S	Carol Schneiderman	2800 E. Ajo Way Tucson, AZ 85713	UPH Hospital	Director
Venessa Price	Venessa Price	13805 NW 22nd Pl Sunrise FL 33323	Pfizer, Inc.	CEC
Anita Chu	Anita Chy	44 Binney St Boston MA 02115	DFCI	Pharmacist
Nicole Speredelozzi	Nicole Speredelozzi	15 Glide St. Dorchester, MA 02112	BWH	Student
Antoinette Oyinlola ANTOINETTE OLUSUEMA	ANTOINETTE ORUWOLA	69 WAVERLY AVE BROOKLYN, NY 11205	NY METHODIST HOSPITAL	STAFF PHARMACIST
Lisa McDevitt	Lisa McDevitt	1243 Beacon St, #8 Brookline, MA 02446	Mass College of Pharmacy	Faculty
Mirna Castro	Mirna Castro	101 Hamilton St Dorch 02125 MA	Milton Hosp	2 Ph Staff
Susan Lasell	Susan Lasell	1200 El Camino Real SSF	Kaiser SSF	IP Director
Anke Wolcott-Fliteholl	[illegible]	University Hosp. Pharm	UNM 2-	Pharmacist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	HASEWINKLE, William C.	5437 A SEAY CT Ft. POLK LA 71459	US ARMY Bayne-Jones Hospital Ft. Polk	Director
	Jialynn Wang	5600 Fishers Lane HFD-42 17B17 Rockville, MD 20857	USPHS	Pharmacist
	Harvey MALDOW	13 LINDSAY DRIVE MORGANVILLE NJ 07751	A2	Director Professional Affairs
	JAMES E. KNOBBEN	11608 SEA ISLAND COURT SILVER SPRING, MD 20905	USPHS	Drug Information
	Sandra F. Durley	20429 Attica Rd Olympia Fields, IL 60461	University of Illinois @ Chicago	Associate Director
	Jesse William Caprioto	513 W Coronado Rd Phoenix AZ 85003	Banner Good Samaritan Medical Center	Manager
	RONALD L. COSSE	401 W. GREENLAWN AVE FLORENCE/LANSING, MI 48910	Ingham Regional Med Ctr	Director of Pharmacy
	Catherine Klein	4285 Stoneleigh Rd Bloomfield Hills, MI 48302	ASHP Advantage	Project Mgr.
	Kasey Thompson	5625 Pier Dr. Rockville, MD 20851	ASHP	Director
	Daniel Degnan	14701 Shadow Lakes Dr Carmel, IN 46032	Community Health Network - Indy	Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Atif Rahim	277 Park Ave, NY	JPMorgan	Analyst.
	Daniel Laster	500 N. Indiana Ave Winslow, AZ 86047	Winslow Indian Healthcare Ctr.	Staff Pharmacist
	C.R. TALLEY	8606 HEMPSTEAD AVE ~~DENVER~~, MD	ASHP	Asst. V.P.
	D Toussignant	6233 Georgetown Rd New Market MD	ASHP	Retired
	James A. Jorgensen	8612 S. Alta Cove Drive Sandy, UT 84093	University of Utah	Chief Pharmacy Officer
	Brian M. Meyer	18037 O'Hara Cir Olney MD 20832	A.S.H.P	Director Govt Affairs
	Steve Newb	8710 Master Link Ct [illegible] TX	ASHP	Project Consultant
	Burt Finkelstein	8608 Villa La Jolla, Dr. La Jolla, CA 92037	~~ASHP~~ CARDINAL HEALTH	Manager
	Patti Vance	~~#~~ 1 Medical Park ~~1000 Miller Cove Dr~~	Saline Memorial Hosp	Dir.
	Lisa A Wendt	5710 Crofoot Hill Constableville NY 13325	Natural Standard	Rotation Students

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Nicole Ybarra	Leesville LA 71446 130 Anderson Dr	BJACH	Pharm Tech
	Dorothea Rudul	Mass. College of Pharmacy ←	179 Longwood Ave Boston, MA	Assoc. Professor
	MICHAEL NYAME-MIREKU	1701 N. GEORGE MASON DR. ARLINGTON VA 22205	UHC	CLINICAL COORDINATOR
	Aki K Sirjam	9627 Rosehill Dr Bethesda, MD 20817	Suburban	Clinical Pharm
	Annette Rivera	Hos Auxilios 988 Calle Cuarto San Juan PR 00921	San Juan City Hospital	Pharmacy Director
	MARY (Ann Hand)	10001 Franklin Sq. Balto. MD 21236	Novation Premier	Sales Admin
	Iris Shenkman	1 Watermill Place Arlington, MA 02476	Children's Hospital Boston, Emerson Hospital, Concord	Pharmacist
	JOHN GENTRY	400 South 23RD St RICHMOND, IN	REID HOSPITAL RICHMOND, IN	PHARMACIST
	Madelyn Marciniak	86 Cambridge Dr Grayslake, IL. 60030	Midwestern Regional Medical Center	Pharmacist
	Carol Wolfe	4301 Massachusetts Ave, NW #7009 Washington, DC 20016	ASHP	Publisher

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Dan Dougherty	2865 Cattle Trace Semmes, AL 36575		
	Patricia Palmieri	9418 Monmouth Margate NJ 08402		
	Linda Stuckey	3400 Spruce St, Basement Silverstein Philadelphia, PA 19118	Hospital of the U of Penn	Pharmacy Practice Resident
	Mercedes F. Urgelles	2038 SW 138 ct Mia FL 33175	Palmetto General Hospital	Clin Coord.
	Margarita Nieves	13176 SW 29th St Miramar FL 33027	Palmetto General Hospital	Clinical Pharmacist
	Teresa Tronerud	171 Hartness Rd Sutton MA 01590	UMass Clinton Hospital	Director of Pharmacy
	Cathie F Braun	22031 250th Pl SE Maple Valley WA 98038	St Francis Hospital Federal Way	Internal medicine Specialist
	RYM BENHAMADI	151 S. Point DRIVE # 108 Dorchester MA 02125	Analysis Group	Associate
	John X Toth	125 Brick Kiln Place Cheshire CT 06410	Yale New Haven Health System	VP Ops Mgr
	Sanchali Basu	1314 E. Walnut St. Washington, IN 47501	Daviess Community Hospital	Pharmacy Manager

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Paul L. Jeffrey	PAUL JEFFREY	15 MINUTEMAN RD HINGHAM MA 02043	MASS. MEDICAID	PHARMACY DIRECTOR
Ronald L Brockemeier	Ronald L. Brockemeier	5015 Tacoma Ave NE TACOMA WA 7847[illegible]	Franciscan Health System	Pharmacy Director
Arlynn Manasse	Arlynn Manasse	107 56th Court Downers Grove IL 60516	Natl. Assoc. of Ped. Nurse Practitioners	Pediatric Nurse Practitioner
Ben Dickinson	BEN DICKINSON	1601 N. 6th St Philad. PA 19106	Hospice Pharmacia	CLINICAL PHARMACIST
Paul B Davis	Paul B Davis	8605 Spectrum Dr McKinney Texas	RX	VP
Amanda C Chuk	Amanda Chuk	3903 City Avenue, Apt C412 Philadelphia PA 19131	Hospital of the University of Pennsylvania	Pharmacy Practice/ Critical Care Specialty Resident
John Dorjee	John Dorjee	ERMC 160 Allen St Rutland VT 05701	Rutland Regional Medical Ctr	Clinical Pharmacist
Deborah Gentry	Deborah Gentry	1431 Virginia Ave. Connersville IN 47331	Fayette Memorial Hospital	Clinical Pharmacist
Bethany Wells	Bethany Wells	8 Valleypicle Court Germantown, MD 20874	ASHP Foundation	Manager, Marketing & Communications
Kirk Starr	Kirk Starr	1924 SW 28th St Topeka, KS 66614	St. Francis Health Center	Operations Coordinator

Applicant

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
		University Hospital-WI-Ky	UHWI Ky	Ky Tech
	LANCE Richard	NWTHS	NWTHS	CLINICAL
	Robert L. Masick	CTCA	MEMC	Director
	DEBRA M. LAFond	750 WASHINGTON ST TUFTS-NEMC	NEMC	Reimb Mgr
	Carrie Coseboom	18 TOURMALINE LN AUBURN, ME 04210	CMMC	Clinical Coordinator
	Michael Thorp	Billerica, MA	Pharm Consult	Engineer
	William Darko	VMV 750 East Adams St Syracuse NY	UMVH	Clinical
	Michelle MacDonald	3510 Fairlands Drive Richardson, Texas	Presbyterian Hospital of Dallas	Manager
	SAIRA RAO	601 Burroughs Mill Court Cherry Hill, NJ 08002	HUP	Resident
	Tara Besich	1608 Burroughs Mill Cir Cherry Hill, NJ 08002	HUP	Resident

(3 K)

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Amy Olin	Amy Olin	11062 Harding Rd. Kensington, MD 20723	ASHP	Director, Education
Colleen O'Malley	Colleen O'Malley	5809 Edson Lane Rockville MD	ASHP	Director, Industry Relations
[illegible]	TOM CANN	50 PORTSMOUTH STRATHAM, NH	NSHP	DIRECTOR PHARMACY
[illegible]	Robert Semple	4917 Cypress Preserve PL FT MYERS FL	ASHP	COO
[illegible]	William D. Tousey	7480 Twin Eagle Lane Ft. Myers, FL 33912	ASHP	VP
[illegible]	Jennifer Askew	715 Orange St Wilmington NC 28401	ASHP	Forum chair & Delegate
[illegible]	Stanley Mcallister	706 Main St P.O Box 10 W. Boylston MA 01583	ASHP	ONCOLOGY PHARMACIST
[illegible]	ROBERT MILLER	18329 LINCOLNSHIRE SAN DIEGO, CA	ASHP	System Director of Pharmacy
[illegible]	RALPH F. MASTRIANO	16 SUNNYBROOK LN CANTON, MA 02021	MASS EYE + EAR INFIRMARY	DOP
[illegible]	Jennifer Davis	1924 I Johnson Ferry Rd Atlanta, GA 30319	ASHP	Manager

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Kenneth A. Kesler	7500 S. 91st St Lincoln NE 68526	Nebraska Heart Institute	Dir. of Pharmacy
	PAUL ABRAMOWITZ	385 KNOWLING DR Coralville, Iowa 52241	Univ of Iowa Hospitals & Clinics	Director of Pharmacy
	TINA LOVE	5504 W. Greythorn DR Muncie, IN 47304	Ball Memorial Hospital	Director of Pharmacy
	Thomas Thielke	2963 Woods Edge Way Madison, WI 53711	University of Wisconsin Hospitals and Clinics	VP Professional and Support Services
	Carol Woodward	2045 Lakeside Estates Morgantown, WV 26508	West Virginia University Hospitals, Inc.	Director of Pharmacy
	Panda Moyers	2435 Shetland Way Monument CO 80132	Memorial Hosp Colorado Springs	Clinical Coord/Residency Dirat
	James C McAllister III	111 Rhododendron Ct Chapel Hill NC 27517	UNC Hospitals	Director of Pharmacy
	RICHARD J. MUELLER	1555 S. Layton Blvd Milwaukee, WI 53215	Community Care Organization	Clinical Pharmacy Supervisor
	David A. Kvancz	17945 Lyon Lane Strongsville, Ohio 44149	The Cleveland Clinic	Chief Pharmacy Officer
	Linda Y. Radke	320 Seitz Drive Salina, KS 67401	Salina Regional Health Center	Clinical Coordinator

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
[signature]	J. Kelly Martin	6775 Weaker Glass Lane, Gig Harbor WA 98335	Franciscan Health System	Pharmacy Manager
[signature]	Terry Audley	224 Willow Court Hartland WI	Community Memorial Hosp.	Clinical Supervisor
[signature]	Stanley Cormack	1924 Hillcrest Drive Paragould, AR	Arkansas Methodist Medical Ctr	Director of Pharmacy
[signature]	MARIA KOTTA-ROKOZ	5 Hank's Way Att. MA 02703	Mass. College of Pharmacy + HS	Academia
[signature]	CRAIG A COOPER	3724 WILLOWGLEN CT WASHINGTON MI 48094	WM BEAUMONT HOSP - TROY	DIRECTOR OF PHARMACY
[signature]	J. David Kotcher	PO Box 608 Silver City NM	Sierra Medical Ctr El Paso TX	Staff Pharm
[signature]	Michael D. Novario	505 Wellesley Dr. Normal, IL 61761	OSF St. Joseph Med Ctr Bloomington IL	Director of Pharmacy
[signature]	Connie R Peterson	3252 S. Common Rd Madison WI	UWHC	Assistant Director of Pharmacy
[signature]	Sudol, Lidia	PO Box 1531 Ranchos de Taos, NM	Holy Cross Hosp	Pharmacy Manager
[signature]	Mitchell Sobel	94 Old Short Hills Rd Livingston NJ 07039	SAINT BARNABAS Med CTR	Asst Director Phcy.

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	James R Rinehart	4110 S. 48th St Lincoln, NE 68506	Bryan LGH Medical Center	Director of Pharmacy
Cinta Brennan	Cynthia Brennan	16720 15th Ave NW Shoreline WA 98177	Harborview Med Center	Asst Director Pharmacy
Stephen Allen	Stephen Allen	7513 Old Chapel Bowie, MD 20715	Am. Soc. H-S Pharmacists Research & Educ. Foundation	Executive Vice President
	Christene Jolowsky	4402 Livingston Dr Eagan MN 55123	United Hosp St Paul MN	Director of Pharmacy
Erika Thomas	Erika Thomas	12039 Coldstream Dr. Potomac, MD 20854	ASHP Advantage	Project Manager.
Judith Walter	JUDITH WALTER	7122 Coed Spring Ct. Alexandria, VA 22306	ASHP	director, Educational Services
Rose Laffoon	Rose Laffoon	781 Pleasant View Madisonville	ASHP	Pharmacist
Anne Policastri	ANNE POLICASTRI	803 Poplar street MURRAY, KY	Murray Calloway County Hospital	Vice President Professional Services
	DENNIS ACKERMAN	8 ELIZABETH DR MERRIMACK NH 03054	DARTMOUTH HITCHCOCK	MANAGER
Olga DeTorres	Olga DeTorres	7707 Broadway Ave #18A San Antonio, TX 78209	Methodist Hospital	Clinical Manager

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Joseph A. Melucci	6267 Harrisburg-Georgesville Rd Grove City, OH 43123	Mount Carmel West Columbus, OH	Pharmacy Director
	Phoebe Li	154 Images Circle Milpitas CA 95035	Santa Clara Valley Med Center	Assist Director
	THOMAS SAITO	17100 WARNER FOUNTAIN VALLEY CA 92708	FOUNTAIN VALLEY REGIONAL HOSP	DOP
	PAUL T. CONLON	94 WILLIAMS HILL ROAD TOWNSEND, MA 01469	MASACHUSETTS NEUROLOGICAL	DOP
	MELISSA BLUM	3213 FOXHALL NW WASHINGTON, DC 20016	STUDENT @ the University of IOWA	STUDENT
	Kathy Vertrees	1301 Mesa Rd Colo Spgs, CO 80904	Memorial Hosp Colo Spgs, CO	RPh
	Leigh Anne Scott	13011 W. 128th Terrace Overland Park KS 66213	University of Kansas	Asst. Director
	Beth S. Williams	6067 Old Orchard Rd Kernersville, NC 27284	Wake Forest Univ Baptist MC	Director
	SUSAN A. CANTRELL	12121 BETTS LN. RALEIGH, NC 27614	HSHP	Sr. Director
	HENRI R. MANASSE, JR	10118 VANDERBILT CIRCLE ROCKVILLE, MD 20852	ASHP	EVP/CEO

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	SATHUR REHMAN	89-79 Queen village NY 11427	Lenox Hill Hospital	Manager Pharmacy Operations
	CYNTHIA LACIVITA	12301 Glen Mill Rd Potomac, MD 20854	A.S.H.P.	Director of Clinical Stds + Quality
	MARK Thomas	103 Lakeview Drive Aledo TX 76008	Cook Childrens Medical Center	Director Pharmacy
	John Pearn	699 Bement Av SI NY 10310	Staten Isl Univ Hosp	ASSO Dir pharm
	Michael Erwin	5031 William St. Omaha, NE 68106	Neb. Med. Center	Staff Pharm.
	SUSAN KLEPPIN	2 WATERFORD CIR MADISON WI 53719	UW HOSPITAL AND CLINICS	DEPUTY DIRECTOR
	Colleen Johnson	61 Cherry St Glens Falls, NY 12801	ASHP	Clinical Staff Pharmacist
	Daniel Scott	13011 W. 128th terr. Overland Park KS 66213	Olathe Medical Center	staff Pharmacist
	Martin Glasgo	139 Leslie Ct Advance, NC 27006	North Carolina Baptist Hospital	Assistant Director
	DOMINIC ALTIERI	419 N. Kenmore St. Arlington VA 22201	ASHP	Mgr.

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Jeffrey Lanning	711 6th St South St. Petersburg, FL	Bayfront Medical Ctr	Director of Pharmacy
Minh-Thu Dennen	Minh-Thu Dennen	1069 Rutledge Place Pleasanton, CA 94566	Washington Hospital	Director of Pharmacy
	Kim Ludington	1135 Harbor River Cove Memphis, TN	Methodist University	PharmD
	KEITH STRECKENBACH	7 N PINCKNEY ST MADISON, WI 53703	PharmacyOneSource	CEO
	JOE MASTERS	1515 Chestnut Forrest City AR 72335	Critenden Mem Hosp	PRP Pharmacist
	James E. Dice	508 Dissosteele Ct. Chesapeake, VA 23320	Children's Hospital of The King's Daughters	Director of Pharmacy
Frances Zalewski	FRANCES ZALEWSKI	18843 CANDLELIGHT STREET ROSEVILLE, MI 48066-1221	ST. JOHN OAKLAND HOSPITAL MADISON HGTS, MI	DIRECTOR OF PHARMACY
	CASIMIR ZALEWSKI	18843 Candlelight Roseville, Mich 48066-121	Fluermerica	
Maryanne Davis	Maryanne Davis	5 Woodmint Place Malta, NY 12020	Saratoga Care	Director of Pharmacy
William A. Zellmer	William A. Zellmer	5516 Roosevelt St Bethesda, MD 20817	ASHP	Dep. EVP

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Michael Schlesselman	Michael Schlesselman	23 S. Edgewood Rd Niantic, CT 06357	L+M Hospital	Director of Pharm
Roland A Patty	Roland A. Patty	1300 S Coulter Amarillo, Tx 79106	Texas Tech School of Pharmacy	Chair, Dept of Pharmacy Practice
R A Grasso	R. GRASSO	60631 1965 Rayner Dr Calumet IL	US NAVY	DIR of PHARM
David Zilz	David Zilz	Iola, WI 54945 N11311 Mud Lake Rd	UW Health	Consultant
Mary L. Brubaker	Mary L. Brubaker	2500 N. Rose St Flagstaff, Az 86004	NorthCountry CHC	Director
Shara Steenbergen	Shara Steenbergen	71 Prospect Ave Hudson Ny	Columbia Memorial	Director
Mickie Hunter	Mickie Hunter	181 West Meadow Dr Vail, CO 81657	Vail Valley Medical Center	Educator (Pharmacy)
James M. Hetherington	James M. Hetherington	5442 Haverhill Dr Dublin, OH 43017	CARDINAL HEALTH	VP, Clin. Affairs
Bernadette G. Ellegood	Bernadette G. Ellegood	175 E 96 St #8L NY NY 10128	Mount Sinai Med Center	Asst Director
Barries Leung	BARRIES LEUNG	2320 ORMOND BLVD. DESTREHAN LA 70047	TOURO INFIRMARY	ASSISTANT DIRECTOR

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Andrew Donnelly	Andrew Donnelly	1740 W. Taylor St. Chicago, IL 60612	University of Illinois	Director
Cathy Ayers	Cathy Ayers	JSUMC – 1945 State Rt 33 Neptune, NJ 07754	Meridian Health	Pharmacy Director
Kristie Gholson	KRISTIE GHOLSON	2526 Summertree Dr. Belden. MS 38826	North Miss. Medical Center	Asst. Director
Marie Tanzosh	Marie Tanzosh	4603 Stonehenge Rd Edison, NJ 08820	Raritan Bay Medical center Perth Amboy, NJ	Staff RPh
Cheryl Krenga	Cheryl Krenga	22 East. Craig St. Basking Ridge NJ 07920	St. Lukes-Bethlehem PA	Director
Bruce Daniels	Bruce Daniels	P.O Box 6193, Maine	China Village Maine General Med Ctr	Manager
Ellen Williams	Ellen Williams	Dept. of Pharmacy Mission Hospitals 509 Biltmore Ave Asheville NC 28803	Mission Hospitals	Director
Joy Cho	Joy Cho	153 Northwood Drive Spring field. PA. 19064	Mercy Hospital of Philadelphia	Director
Maureen M. Carty	MAUREEN A MCCARTHY	P.O. BOX 484 STORRS, CT	DAY KIMBALL HOSPITAL	DIRECTOR
R David Anderson	R. DAVID ANDERSON	6 PELHAM GREENE, WEST WAYNESBORO, VA 22980	AUGUSTA MEDICAL CENTER Fishersville VA	STAFF PHARMACIST

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Bona Benjamin	BONA BENJAMIN	8606 Hempstead Ave Bethesda, MD 20817	NIH	QA
MD	[illegible]	436 Cambridge Drive Marietta, Ga	MCG	MD
[signature]	Doug Schoonover	3604 VISTA DRIVE NAMPA, ID 83686	~~ISHP~~ St. Alphonsus and Idaho Sec. Hosp	SPM/Member ISHP
Donald R Olsen	DONALD ROSMEN	606 OZARK TRAIL MADISON, WI 53705	EPIC	PHARMACIST ADVISOR
Hyun Gailland	Hyun Gailland	157 Shapstead Lane Gaithersburg, MD 20878	PRBH	Director
E. Wilhelms	E. Wilhelms	45 N. Broad St. Ridgewood NJ	Ridgewood med. media	Editor
D Kelley	D. Kelley-Halvorsen	"	"	"
Earl Sampson	EARL F. SAMPSON	6565 FANNIN DBI-09 HOU. TX 77030	The Methodist Hosp.	manager
Janette Monzingo	Janette Monzingo	10918 Elm Avenue Kansas City, MO 64154	Saint Lukes Health System	Resource Manager
[signature]	Ira Silver	5349 NW 117th Ave Coral Springs, FL 33076	West Boca Med Ctr.	Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Brad Blackwell	400 Beale St #1101 San Francisco CA 94105	Omnicell	Manager
	Steve Nourse	111 Maple Ridge Dr Boone NC 28607	Watauga Med Center	Pharm Dir.
	Julie Nelson	9536 Kelowna Cove Austin Tx 78759	Law Offices of Julie Nelson	Owner
	Shirley Reitz	2907 Cedar Ave S Renton, WA 98055	Group Health Cooperative	Assoc. Dir.
	Agatha L. Nolen	304 Pinnacle Pl. Nashville, TN 37221	Centennial Med Ctr.	Dir.
	Michael Oszko	9211 Greenway Ln Lenexa KS 66215	Univ. of Kansas	Assoc. Professor
	Frank P. Bosnowski	57-63 80th St Middle Village NY 11379	Montefiore Med Center Bx NY	Director
	Michael R. Wilk	2305 Old Ky 144 Owensboro Ky 42303	Owensboro Medical Health System	Director.
	Stephen Eckel	1 Bamboo Lane Chapel Hill, NC 27517	UNC Hospitals	Asst. Director
	John Clark	1611 NW 12th Ave Miami, FL 33136	Jackson Memorial Hosp	Director Resi Dir

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Helen Calmes	5330 Camp St New Orleans	LSHP	Treasurer
	Michael Cockerham	5705 Aragon Dr Shreveport, LA 71129	LSHP	President
	MARIANNE [illegible]	2320 Blackhawk Rd [illegible]	ICHP	[illegible]
	MaryLouise Degenhart	Chicago, IL 60604 2948 S. Keeley St.	ASHP	Contract Surveyor
	MARJORIE AHILLIER	436 CAMBRIDGE WAY MARTINEZ, GA 30907	MCG MEDICAL COLLEGE GEORGIA HEALTH SYSTEM	PHARMACIST MED SAFETY
	ANDREA ROBINSON	3935 FORRAND Dr ATLANTA, GA 30319	ST JOSEPH'S HOSPITAL OF ATLANTA	CLINICAL COORDINATOR
	Tommy I Manning	12514 Merlin Ave BATON ROUGE LA 70816	LSHP	PAST President Pharmacist
Duplicate	Doug Schoonover	3604 VISTA Dr Pingree ID 83262	IDSHP	president
	Keven Thompson	3604 N Albemarle St Arl, VA 22207	BCBSA	Acct Exec
	Helga Brake	1N311 Pagworth St Wheaton, IL 60187	UHC	Project Mgr

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Danielle M Patrick	932 Golden Meadows Ct. Trenton, OH 45067	University of Cincinnati	Student Forum Exec. Committee
	Adam W. Brothers	1740 NE 80th St #307 Seattle, WA 98115	University of Washington	Student Forum Executive Committee
	REMA THYAGARAJAN	124 Spring Ridge Dr. Murphy, TX 75094	Univ. of Texas at Austin	SFEC
	Karl F. Gumpper	3790 Angelton Ct. Burtonsville, MD 20866	Children's National Medical Center DC	Director of Pharmacy.
	Dayna Quinones	506 Asuncion St San Juan, PR 00920	University of Puerto Rico	Clinical Specialist.
	Edward Li	84 West South Street, SLC Rm 334B Wilkes-Barre PA 18766	Wilkes University	Assistant Professor.
	Harold N. Godwin	10112 West 98th Street Overland Park, KS 66212	Univ. of Kansas	Professor
	Paul Driver	2423 Seaport Dr Lewiston, Idaho	St Joseph Reg Med Ctr	Clinical Pharmacist
	Marianne F. Ivey	2187 Grandon Rd Cincinnati OH 45229	The Health Alliance of Gtr Cincinnati	Director of Pharmacy
	PEDRO J. LECCA	Howard University Washington, D.C	Howard University	Dean

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
William L. Greene	William L. Greene	1316 Riverwind Cove Memphis, TN	Methodist Healthcare	Director - Clinical Pharmacy
SUSAN S. FISH	SUSAN FISH	18 White St Arlington MA	Boston University	Assoc Dir. Office of Clinical Research
Leila R. Mahassel	Leila R. Mohassel	80 Prospect Ave, Hackensack, NJ 0769	Hackensack University Medical Center / Rutgers University	Clinical assistant Professor / clinical pharmacist
Susan Goodin	Susan GOODIN	195 Little Albany Street New Brunswick, NJ	Robert Wood Johnson Medical School	Director, Div. of Pharmaceutical Sciences
James A. Trovato	JAMES A. TROVATO	5 FOXWAY TERRACE BALTIMORE MD 21286	UNIVERSITY OF MARYLAND	FACULTY
	Michael D. Katz	445 E. Dietzel St Tucson AZ 85701	University of Arizona University medical ctr	Associate Prof/ Clinical Pharmacist
MBilleter	Marianne Billeter	909 Lafayette St. #7 New Orleans, LA 70113	Ochsner Clinic Foundation	Clinical specialists
	Rita Jew	3 Walnut Grove Road Hillsborough NJ 08844	The Children's Hospital of Philadelphia	Clinical Manager
	Philip J. Schneider	15112 W. 86th St Lenexa, KS 66219	Olathe Medical Center	Director of Pharmacy
Mary Ann Klietherres	Mary Ann Klietherres	160 Kenmore Elmhurst, IL 60126	University of Illinois at Chicago	Manager of MTMS

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	William McConaghie	1600 Rockland Rd Wilmington, DE	Nemours, A. I. duPont for Children	Director
	Fred Maloon	8303 Dodge St - Pharm Omaha NE 68114	Methodist Hospital	Director.
	Lisandra Perez	HC-08 Box 50801 Humacao, PR 00659	VAMC	Clinical Pharmacist.
	Rosario (Rose) Lazzaro	74 South Street Cresskill, NJ 07626	Holy Name Hospital HNH	Director of Pharmacy
	Anne Morstad	4700 E 21st St Sioux Falls, SD 57110	Avera McKennan Hospital	Staff Pharmacist
	Joseph Botticelli	W145 N6237 Auburn Ct Menomonee Falls WI 53051	Covenant HealthCare System	System Director
	Josh Aukes	~~4333~~ 1720 S. University Fargo ND 58103	~~SCI Hospital~~ - Fargo	
	Daniel M. Ashby	403 Marlow Rd Baltimore, MD 21218	Johns Hopkins Hospital	Director of Pharmacy
	Ernest Anderson	489 Copeland St Brockton MA 02301	Lahey Clinic Hospital	Director of Pharmacy
	Dale E English II	1241 Tivoli Court Miamisburg, OH 45342	Ohio Northern University	Assistant Director of Experiential Education

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Stephen Dedrick	4416 Turnberry Circle Durham NC 27712	Duke Hospital	Director of Pharmacy
	Bonnie Senst	550 Osborne Ave Fridley, MN 55442	Mercy + Unity Hospitals	Director of Pharmacy
	William N. Kelly	2463 Bay Berry Dr Clearwater, FL 33763	William N. Kelly Consulting	President
	Paul Cliff Cutt	4 Walton Ct St. Charles MO 63301	MedAssets	Pharm. Contract Director
	Teresa Miller	14 Punk West Ct, Sacramento, CA 9583	CA Dept. of Hlth Services	Pharmacist Consultant
	Bonnie Kirschenbaum	PO Box 8322 Breckenridge CO 80424	Healthcare Consultant	
	Risa Rahm	101 N. Monroe St. Ste 302 Tallahassee, FL 32309	HCA	Division DOP
	Diane Fox	302 Darby Trails Sugar Land TX 77479	Healix Infusion Therapy	Director of Pharmacy
	Janet A. Silvester	112 Claiborne Cir Troy, VA 22974	Martha Jefferson Hospital	Director of Pharmacy
	Ferzin Kaufman	Drexel Hill, PA 19026 721 Morgan Ave	CAE/ PSHP	System Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Carol Aldred	CHRCL ALDRED	537 ROSEBUD N LOMBARD, ILL 60148	Good Samaritan Advocate ~~Downers Grove~~	Director PROJ LEADER
Sandi Mitchell	SANDI MITCHELL	1503 CHIVALRY CT ROSEDALE MD 2037	JOHNS HOPKINS	INFORMATICS
Mary C. Bingham	MARY BINGHAM	4808 Mowland Ln #510 Bethesda, MD 20814	SHADY GROVE ADVENTIST HOSP	Pediatric Clinical Specialist
David Tjhio	DAVID TJHIO	2654 N. CALIFORNIA CHICAGO, IL 60647	CERNER CORP.	PHARMACY SOLUTION CONSULTANT
Peter H. Vlasses	PETER H. VLASSES	358 GRANDVIEW AVE. GLEN ELLYN, IL 60137	ACPE	Pharmacy accreditor
Michael J. Rouse	MICHAEL J. ROUSE	1701 MAPLE LANE WHEATON, IL. 60187	ACPE	ASSISTANT EXECUTIVE DIRECTOR
Marv Feldman	MARV FELDMAN	18 Sumner St Canton, MA 02021	Premier, Inc.	SENIOR DIRECTOR, MEDICATION MANAGMT
Richard Sobkowiak	RICHARD SOBKOWIAK	1900 SPRING ROAD OAKBROOK, IL 60523	ADVOCATE	CONTRACT MANAGER
Donald Robbins	DONALD ROBBINS	1508 LOST CREEK DR. ASHTON MD. 20861	ADVENTIST HEALTHCARE	DOPS
Jamie Marshall	Jamie Marshall	3815 Highland Avenue Downers Grove. IL 60515	Advocate	OR Pharmacist

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Wayne Bohenek	Wayne Bohenek	615 Elsinor Place Cincinnati, OH, 45202	Catholic Healthcare Partners	Vice President
Judith Ronshagen	Judith Ronshagen	15 Autumn Lane Londonderry NH 03053	Elliot Hosp Manchester NH	Systems Coordinator
Stan Kent	STAN KENT	263 ADLER DR. LIBERTYVILLE, IL. 60048	EVANSTON HOSPITAL	AVP
Mark Kaplan	Mark Kaplan	55 Fruit St Boston, MA 02114	Mass General Hosp.	Pharmacy Specialist
duplicate ~~Cynthia Lynch~~	~~ANTONIETTE ORTIZ~~	69 WAVERLY AVE ~~BROOKLYN, NY 11205~~	NY METHODIST ~~HOSPITAL~~	STAFF PHARMACIST
JoAnn Ely	JoAnn Ely	27090 FLAMINGO DR. BONITA SPRINGS FL 34135	Cleveland Clinic FL Hosp.	DIR. Z Pharm
James P Gould	James P Gould	975 Road 6 Schuyler, NE 68661	Columbus Community Hosp	VP Operations
William A. Mills	William A. Mills	3675 Foxana Drive Iowa City, IA 52245	University of Iowa, Iowa City, IA	Professor Adjunct Faculty
~~David J Warner~~	David J Warner	6721 N 51 St Omaha NE 68152	Univ of Nebraska Medical Ctr	Pharmacist

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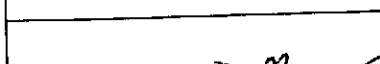
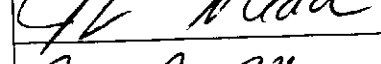
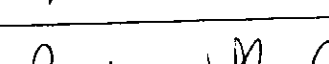
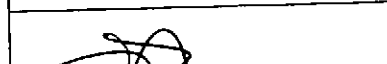
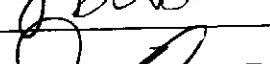
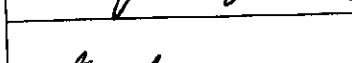
BLB - MMA 2555 K

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Douglas E Miller	5792 Revington Dr Norcross, GA	Grady Health System	Vice President & Chief of Pharmacy
	Jennifer Reddan	14314 Delany Dr Noblesville IN 46060	Clarian Health Partners	Mgr, Drug Use Policy
	MARY ANN ELLIS	6 Crestview Drive Exeter NH	Exeter Hosp	ONC Pharm Coor.
	BARBARA POE	4807 SOUTH LAKE DR NORMAN, OKLA	NORMAN REG HOSP	DIR OF PHARM
	JEFF BOVE	6919 MIAMIWOODS LOVELAND, OH 45140	BAYER	NATL ACCT.
	TAMMY BRATTON	1050 FEDERALES TRL IRVING TX 75063	AMGEN	RML
	Chris Sedlmayer	3041 Stonehedge DR NE Rochester MN 55905	Mayo Clinic	PIC
	Jennifer Blasl	524 Graeten Street Birmingham, MI 48009	Amgen	RML
	JOE ZAGOZEN	702 WILLINGHAM SAGINAW, MI 48603	BS PHARMACY	RPh
	Barbara Ramos	103 Canterbury Road White Plains, NY 10607	Westchester Medical Center	Director of Pharmacy

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	ABDUL LATIF SHEIKH	AKUH. KARACHI.	AKU	DIRECTOR
Linda O'Brien	Linda O'Brien	United Community Hosp 631 N. Broad St. Ext Glove City, PA 16127	UCH	Director

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Alton Candra	2304 Ripplewater Dr Atlanta GA 30316	Grady H.S.	IDP Pharmacy Supervisor
	William Dager	2315 Stockton Sacramento, CA. 95817	U.C. DAVIS	Pharmacist Specialist
	Paul Kroch	438 West Wilson #4 Madison. WI 53703	UWHC	Admin Resident
	Thomas Kissling	101 Glenthistle Rd. Madison WI 53705	UWHC	Admin Resident
	JACK TEMPLE	1521 Golfview Rd. Unit G Madison, WI 53704	UWHC	Admin Resident
	Jennifer Tryon	7410 Timber Lake Trail #106 MADISON, WI 53719	UWHC	ADMIN Resident.
	WAYNE CONRAD	10042 Wimbledon Ct Cincinnati, OH	University of Cincinnati	College Faculty
	Scott McCreadie	B2D301 1500 E. Medical Ct. Ann Arbor, MI 48109-0008	University of Michigan	Residency Director - Informatics

American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
Ellen Wilcox	Ellen Wilcox	13039 Glen Mill Rd Rockville MD 20850	ASHP	
Kathy Biesecker	Kathy Biesecker	19688 Greggsville Rd., Purcellville, VA 20132	ASHP	
Aretha Hankinson	Aretha Hankinson	9926 Walker House Rd Apt 1 Montgomery Village MD 20886	ASHP	
Joan Buckley	JOAN Buckley	277 CREST DR TARRYTOWN NY 10591	Pharmacy Practice News	
Bruce Buckley	Bruce Buckley	277 Crest Dr. Tarrytown NY 10591	Pharmacy Practice News	
Kathleen Cantwell	Kathleen Cantwell	1451 N. Scott St. Arlington, VA 22209	ASHP	

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American Society of Health-System Pharmacists Petition to Centers for Medicare & Medicaid Services to restore funding for specialized pharmacy residency programs under the Hospital Inpatient Prospective Payment System; CMS-1500-P

Signature	Print Name	Address	Affiliation (Institution)	Position
	Kavish Chandhari	1102 North High Point Rd #4 Madison, WI 53717	Wisconsin (UW)	Resident
	Gary C. Stein	1760 Cobblestone Dr. Harrisonburg, VA 22801	ASHP	Gov. Affairs

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Transfers

Hefter
Hartstein
Walz
Hart

June 24, 2005

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

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

Dear Dr. McClellan:

On behalf of the Washington State Hospital Association, representing about 100 hospitals in the State of Washington, we are writing to provide comments on the fiscal year 2006 inpatient prospective payment system proposed rule.

We are particularly concerned about the proposed expansion of the post-acute care transfer policy and the loss in payments for our members due to this expansion. CMS is proposing to expand the definition of transfers from 30 DRGs to 231 DRGs. These "transfers" are cases where the patient had a length of stay less than the average and received some post acute care. By proposing to classify these cases now as transfers, CMS is proposing to reduce the amount it pays hospitals to care for these patients from the full DRG payment to a per-diem payment based on the length of stay.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient prospective payment system is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

300 Elliott Avenue West
Suite 300
Seattle, WA 98119-4118
Phone 206-216-2500
Fax 206-283-6122
e-mail: leog@wsha.org

We find this proposed policy especially troublesome because Washington hospitals are relatively efficient with short lengths of stay. Our hospitals will be hurt more than the average hospital, since more cases in Washington will fall below the average length of stay. In Washington, this new policy will mean a loss of $19 million in Medicare payments per year.

We urge you to reconsider this proposal. Our hospitals cannot continue to function effectively without adequate and appropriate Medicare payments.

Sincerely,

Leo Greenawalt

Leo Greenawalt
President and CEO

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SpH
MedPAC

Hefler
Hartstein
Romano
Treitel

AMERICAN SURGICAL HOSPITAL ASSOCIATION

PO Box 23220, San Diego, CA 92193
Phone: 858-490-8085; Fax: 858-490-9016
Email: info@surgicalhospital.org Web: www.surgicalhospital.org

June 23, 2004

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

Re: Specialty Hospitals
MedPAC Recommendations

Dear Dr. McClellan:

The American Surgical Hospital Association is the national trade association for physician owned acute care hospitals that specialize in the delivery of elective surgical services and other types of specialized care. We are responding to the discussion of the definition of a hospital in the proposed rule on the inpatient prospective payment system published on May 4, 2005. We will also comment on CMS' actions with regard to the recommendations of the Medicare Payment Advisory Commission (MedPAC) relating to specialty hospitals.

SPECIALTY HOSPITALS

Medicare law, regulations, and provider manuals define a hospital as "an institution which is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons..." The discussion in the proposed rule suggests that specialty hospitals "may be primarily engaged in furnishing services to outpatients, and thus might not meet the definition of a hospital".

Failure to meet the requirements for the definition of a hospital could lead to revocation of the facility's Medicare provider number, which could have serious consequences for

the institution, including loss of Medicare inpatient revenue, as well as contracts for inpatient services with private health plans. In some states, loss of Medicare certification would also result in revocation of the hospital's state license.

It is difficult to determine exactly what CMS is looking for in this discussion. While it raises the threat against specialty hospitals, it provides no particulars for public comment. For example, the key issue is the way that CMS determines the meaning of "primarily engaged in providing inpatient services." Yet the agency does not propose a standard that the public can react to or comment on. Certainly this issue is too important to be left to informal processes like manual instructions. We believe this vagueness undermines any legal effect that this discussion may have. We recommend that there be a separate proposed rule, with specific issues raised, on the definition of what Medicare considers a hospital. We also note that CMS did not evaluate the impact of a change in policy, even though it would have a significant impact on affected hospitals.

While the discussion in the proposed rule is titled "Definition of a Hospital in Connection with Specialty Hospitals", Medicare law defining "hospital" does not differentiate the kind of hospital except to exclude psychiatric facilities from the definition. While the MMA 2003 defined specialty hospital for purposes of the now expired 18 month moratorium, it did not alter the definition of "hospital" in terms of participation in Medicare. We do not believe that there is a definition of "specialty hospital" which can be applied to participation in Medicare, which is the thrust of the text in the proposed rule. There is no legal basis for Medicare to set one set of participation standards for "traditional" hospitals and another for "specialty" hospitals. Therefore, the review of participation criteria should apply to all hospitals. Specialty hospitals are almost always licensed by the state as acute care hospitals. We believe that this fact also argues for a review of the definition as it applies to every hospital.

We believe that the law requires the application of one test for determining the participation of any hospital, other than psychiatric facilities, and that is the measurement of inpatient services. However, the law and regulations offer no guidance on the application of this 40-year-old definition to the hospitals of the 21st century. We do not believe that very many hospitals, whether specialty or general hospitals of any kind, and whether or not they have physician investors, would pass a strict reading of the statute. This leads to the inevitable conclusion that today's hospitals no longer qualify to participate in Medicare because the nature of the services they provide has changed so dramatically.

In 1965 virtually all hospital services, particularly surgical, were provided on an inpatient basis. In 2005, the reverse is true. In absolute numbers, hospitals provide far more outpatient services that they do inpatient. Medicare data and information from the American Hospital Association suggest that the ratio of outpatient to inpatient services is approximately four to one. On average 80% of all surgery performed in this country is now done on an outpatient basis. Since the entire thrust of healthcare is to move patients to the least expensive setting, and for hospitals to limit their services to those things they can do best, we question the point of this entire discussion.

A literal reading of the statute and regulations would deny almost every hospital the opportunity to participate in Medicare since virtually no facility provides primarily inpatient services if the measure is the number of patient encounters. We do not believe it is the intent of CMS to exclude all hospitals from Medicare. Some other test must then be devised to satisfy the statute and the current circumstances of medical care delivery. However, the rulemaking is silent on what the test might be.

Data from CMS and AHA do show that on average hospitals earn far more from their inpatient surgery than from their outpatient care. It is estimated that the average hospital earns at least 60% of its total revenue from inpatient surgery. For specialty hospitals, that number is lower, approaching 50% in most cases. That situation does not occur evenly across all hospitals, however. Many small community and rural hospitals do not have the same dollar volume of inpatient service as their larger, more urbanized cousins. This circumstance argues against using a dollar figure or ratio to determine whether or not a hospital meets the Medicare definition. The unintended consequences of such a move would certainly draw the attention of the hospital industry, Medicare beneficiaries and Congress.

For the same reasons, the use of average daily census or number of beds will not suffice as a basis for determining whether or not a hospital meets the Medicare definition. There is simply too much variation among hospitals across the country. According to AHA data, in 2002 there were 321 hospitals in the 6-24 bed size category. Only 26 were investor owned. Most were rural hospitals. They had an average daily census of fewer than 6 patients.

In the same year, 931 hospitals were classified in the 25-49 bed range. Investors owned 107 of these facilities. The average daily census was just over 15 patients. More than 700 were in rural areas. It appears that use of number of inpatient beds or average daily census as the basis for determining if a hospital qualifies for Medicare may disadvantage small and rural hospitals.

According to the American Hospital Association, the smaller hospitals, 6-24 beds, reported 161,716 inpatient admissions in 2002, compared with 5,929,797 outpatient visits. In the next category, 25-49 beds, 1,062,147 inpatient admissions were counted in 2002. These facilities reported 29,726,357 outpatient visits.

This relationship does not dramatically change as the size of the hospital increases. This AHA data amply demonstrate that the hospital of the 21st Century is not "primarily engaged in the provision of inpatient services".

There is a very good reason that Medicare has been flexible in its interpretation of the term "hospital" and that is the dynamic nature of the hospital sector. Today's hospital would barely be recognized by an administrator or physician who practiced in the pre Medicare period. The discussion in the proposed rule fails to take these changes into account.

Medicare has relied on state licensing as the fundamental determinant of what facility can be considered a hospital. Using the flexibility available to the state to respond to the unique circumstances of its own situation and needs has allowed Medicare to keep up with the changing hospital sector. For the federal government to attempt to usurp this role and override the effect of state law and regulation only means that CMS will have to struggle with the reality that virtually no hospital, by any standard, qualifies for Medicare under a strict reading of the statute.

The Association believes that CMS should abandon this attempt to discriminate against specialty hospitals. The agency already has authority to withdraw a Medicare number from a facility that no longer meets Medicare standards, including whether or not it sees hospital inpatients. There is no evidence presented that this authority is no longer sufficient. In the absence of such evidence, we fail to understand why a new stance on the issue is required.

We also do not understand why CMS would want to exclude specialized hospitals from the program. According to its own study of specialty hospitals, the morbidity and mortality levels are superior to those found in general hospitals. We presume that CMS would want to increase the quality of healthcare for its beneficiaries, especially when it is not costing the agency more money to achieve these improved results.

The CMS study also demonstrates high levels of patient satisfaction with specialty hospitals. Why would the agency want to take an action to deny beneficiaries a choice they find more satisfactory?

Reliance on state licensing as the basic standard has allowed the agency to adapt to the changing nature of hospitals over the life of the program. We believe that CMS should use the state's grant of a hospital license as the basic evidence of qualification for Medicare. Any national standard will only create unintended consequences for hospitals and their patients. At the very least, the agency should issue a separate rulemaking in which it poses some specifics for public comment. As previously noted, this is too important an issue to be left to informal processes, like provider manual revisions.

Although not discussed in the proposed rule, CMS has announced that it will revise payments to ambulatory surgery centers (ASCs) to assure that the current discrepancies do not create an incentive for ASCs to convert to hospitals only for reimbursement reasons. We welcome an effort to create a more logical ASC payment system, one that is related to the current hospital outpatient reimbursement structure.

MEDPAC RECOMMENDATIONS

One outcome of the MedPAC study of specialty hospitals was identification of DRGs that were "more profitable" than others. In other words, some DRGs paid more than the cost of care provided, and some DRGs paid less. These discrepancies create the potential that hospitals might select their Medicare admissions with payment rates in

mind, perhaps discriminating against certain patients. At the very least, the variation in value forced hospitals to use higher paying DRGs to subsidize the care provided in lower paying DRGs.

It should come as no surprise that a payment system that has been in place more than 20 years now has some anomalies in it. Whether or not one accepts the arguments about incentives that have been raised as a result of these distortions, it does make sense to try to make sure that the inpatient prospective payment system reimburses for the cost of care as accurately as possible. We believe that the MedPAC recommendations go a long way to achieving that goal and would greatly reduce the need for hospitals to use cross subsidies to sustain services that are today underreimbursed.

The American Surgical Hospital Association has supported the MedPAC recommendations, and we are pleased that CMS is actively working to implement them. We believe that their adoption will go a long way to establishing an even basis for fair competition among hospitals. Further action addressing issues in the specialty hospital debate will not, we believe, be necessary if CMS adopts these payment changes promptly.

While we support an appropriate phase in of the new rates, we urge CMS to act with dispatch to implement these important revisions.

The American Surgical Hospital Association appreciates the opportunity to comment on these important issues. We look forward to a continued and constructive dialogue with CMS on specialty hospitals.

Sincerely,

James Grant

James Grant
President

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320 Ellis Street, Mountain View, CA 94043
tel: 650.938.2100 fax: 650.938.2700
www.concentric-medical.com

Concentric Medical

DRG/Gen (strokes)

Hafter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 22, 2005

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

Attn: CMS-1500-P

Dear Dr. McClellan:

Concentric Medical, Inc. appreciates the opportunity to comment on the Proposed Rule for the Hospital Inpatient Prospective Payment Systems and Fiscal-Year 2006 Rates (CMS-1500-P). Concentric Medical, Inc. is a medical device company committed to opening the pathway to stroke treatment. We are the first company to bring a surgical device to the healthcare arena that assists with the removal of occlusive blood clots from patients experiencing an ischemic stroke. The Merci® Retrieval System is used during a mechanical thrombectomy surgical procedure to remove the clot and restore blood flow. It offers hope to ischemic stroke patients with no other options. We appreciate the Centers for Medicare and Medicaid Services (CMS) addressing the current inadequacy of the DRG reimbursement rates for our nation's hospitals that care for stroke patients.

***

RE: Reclassifications - Stroke DRG

I: Issue

In the Proposed Rule for the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, the Centers for Medicare and Medicaid Services (CMS) has decided to continue to pay for ischemic stroke patients treated with drug-related therapy under medical DRGs 14 and 15, respectively. CMS made this decision due to the small number of cases that it was able to identify in its MedPAR database using ICD-9 code 99.10, even though the cases that it did identify where drug-related therapy was administered in the form of a thrombolytic agent were more expensive ($16,000 and $10,000 higher, respectively) than stroke patients who did not receive a drug-based, medical therapy.

By only using ICD-9 procedure code 99.10 as the identifier for stroke cases that have received a medical therapy, specifically infusion of a thrombolytic agent, the CMS analysis of its MedPAR data is too narrow. Furthermore, stroke patients that receive a surgical intervention (mechanical thrombectomy) are also more expensive cases and

these cases should also be reviewed as part of this data analysis, as well as those cases where the patient receives combination therapy.

Access for Medicare beneficiaries to the recent advances in stroke treatment needs to be supported by the creation of a set of new DRGs, medical and surgical, that are flexible enough to capture all stroke cases where an intervention is performed, having rates assigned which reflect the higher average standardized charges that CMS has already identified in the MedPAR data and will continue to identify by implementing the recommended additional data analysis.

II: Recommendations

Concentric commends CMS for addressing the inadequacy of current reimbursement rates to hospitals for the care they provide to ischemic stroke patients. Inadequate reimbursement rates are causing less hospitals to take advantage of the benefits of reperfusion and IV drug therapy and of surgical interventions where indicated. Advancing the standard of care for ischemic stroke patients from a "wait and see" approach to an aggressive interventional approach would improve patient outcomes and minimize the impact on our nation's rehabilitation system to care for patients with long term neurological deficits and disabilities.

Therefore, we recommend that CMS take the proposed first step in recognizing the increased hospital costs associated with acute stroke stays by creating a new medical DRG for ischemic stroke patients that are treated with drug-based reperfusion therapies. However, at the same time, CMS should also commit to creating a surgical DRG for ischemic stroke patients who are treated with surgical-based interventions.

Concentric, in partnership with the appropriate medical specialty societies and professional coders, will be submitting an application for the September 29-30, 2005 meeting of the ICD-9-CM Coordination and Maintenance Committee with several options for the committee to consider regarding ICD-9 procedure coding for the surgical interventions, intracranial endovascular mechanical thrombectomy, performed to repair the arteries by removal of occlusive blood clots that are causing an obstruction, and therefore causing the ischemic stroke. We believe that the current lack of systematic procedure coding, that affects DRG assignment, for both medical and surgical interventions is negatively impacting reimbursement rates to hospitals for stroke cases and is also hindering CMS in its ability to identify these cases in its MedPAR data for assignment of appropriate payment. Depending on the outcome of the Committee's meeting, any new or revised ICD-9-CM procedure codes would need to be factored into the DRG structure for FY 2007.

Given that every year in the United States, about 700,000 individuals suffer a stroke of which 88 percent are ischemic in nature, we believe that the incidence within the Medicare population of those treated with a medical or surgical intervention is much greater than the 2,448 cases that CMS identified in the MedPAR database using ICD-9 procedure code 99.10 as the search criteria. We recognize the complexities presented in basing a potential DRG assignment change on an analysis using an ICD-9-CM code that does currently affect DRG assignment, and thus is most likely under reported. Therefore, we recommend that CMS expand its data analysis, particularly if DRG changes are not implemented this year for stroke. Using the following ICD-9 diagnosis

and procedure code combinations to identify stroke cases in the MedPAR data may increase the scope of CMS' analysis.

Medical Interventions (IV tPA and IA tPA):

ICD-9 Diagnosis Codes:

430
433 – 433.91
434 – 434.91
435.8
435.9
436
437.0
437.1

ICD-9 Procedure Codes:

88.41 + 99.10
42.23+88.41+88.72+99.10
38.93+99.10
42.23+88.41+88.72
88.41+99.10+39.50
88.41+88.42
88.72+99.07+99.04+88.41+38.93+42.23
88.41+88.42+88.72+42.23
99.29+39.50
38.93+88.41+96.72+96.04

Surgical Interventions (mechanical thrombectomy):

ICD-9 diagnosis codes:

430
433 – 433.91
434 – 434.91
435.8
435.9
436
437.0
437.1

ICD-9 Procedure Codes:

88.41+38.02
88.41+39.72
88.41+39.50
39.50+39.72+39.90+88.41+96.71
99.19+88.41+38.93+39.79
00.61+00.64+39.79+88.41+96.04+96.72+99.19

This expanded analysis will give CMS a more complete picture regarding the standardized charges of ischemic stroke patients and the financial deficits that hospitals are absorbing when caring for these patients.

III. Supporting Information

Statistics Regarding the Incidence of Stroke:

Every year in the United States, about 700,000 individuals suffer from a new or recurrent stroke of which 88 percent are ischemic in nature. Stroke is the third leading cause of death in the United States with a mortality rate of 7.6% at 30 days. Someone in the United States suffers a stroke every 45 seconds; every 3.1 minutes an American dies from stroke. Stroke is the leading cause of long-term disability. A person's risk of having a stroke doubles every decade after the age of 55 years old. The annual economic cost of incidence of strokes is about $51 billion in direct medical costs, plus indirect costs including losses in productivity *(U.S. Centers for Disease Control and American Heart Association/American Stroke Association, Heart Disease and Stroke Statistics - 2004 Update).*

The Cost to a Hospital of Treating a Stroke Patient:

The data from the following three hospitals are a representative sample from those facilities that routinely treat ischemic stroke patients – one is a community hospital in the eastern United States, one is a non-profit hospital, teaching hospital located in the Midwest, and one is a major academic medical center on the west coast. At each hospital, patients are treated using all means, including IV thrombolysis, IA thrombolysis and mechanical embolectomy.

At The Stroke Center at Hartford Hospital, they treat approximately 500 acute ischemic stroke cases annually. The majority (72%) of these cases involve Medicare beneficiaries. A subset of this population includes resource-intensive cases such as those involving thrombolytic therapy where a reperfusion agent is used (eg, tissue plasminogen activator, tPa). The average costs per case are about $20,400 whereas the average DRG reimbursement is only $9,566.

At St. Lukes' Hospital located in Kansas City, MO, approximately 68 percent of the acute ischemic stroke cases treated involve Medicare beneficiaries. As mentioned above, St. Lukes' Hospital treats patients by all means. Typically, the average adjusted total cost per case to treat an ischemic stroke patient with IV thrombolysis is $10,473 whereas the average DRG reimbursement is only $6,073 per case. For IA thrombolysis, the average adjusted cost per case is $19,048 whereas the average DRG reimbursement is only $10,621. For mechanical embolectomy, a surgical procedure, the average adjusted total cost per case is $ 21,618.90 whereas the average DRG reimbursement is only $17,576.90.

At UCLA Medical Center located in Los Angeles, CA, approximately 48 percent of the acute ischemic stroke cases treated involve Medicare beneficiaries. As mentioned above, UCLA Medical Center treats patients by all means. Typically, the average adjusted total cost per case to treat an ischemic stroke patient with IV thrombolysis is $25,030 whereas the average DRG reimbursement is only $17,294 per case. For IA thrombolysis, the average adjusted cost per case is $34,486 whereas the average DRG reimbursement is only $ 19,263. For mechanical embolectomy, a surgical procedure, the average adjusted total cost per case is $ 36,711 whereas the average DRG reimbursement is only $22,138.

As you can see, all of these hospitals suffer economic losses from treating these very sick individuals who have experienced an ischemic stroke.

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Concentric Medical, Inc. appreciates the opportunity to provide comments on this proposed rule and requests that that CMS take the proposed first step in recognizing the increased hospital costs associated with acute stroke stays by creating a new medical DRG for ischemic stroke patients that are treated with drug-based therapies. However, at the same time, Concentric Medical, Inc urges CMS to commit to creating a surgical DRG for ischemic stroke patients who are treated with surgical-based interventions. If Concentric Medical can provide CMS with additional information regarding this matter, please do not hesitate to contact myself or Lisa Zindel at 650-938-2100 or email at GCurtis@concentric-medical.com or LZindel@concentric-medical.com.

Sincerely,

Gary Curtis
President and CEO