NT 286

TREITEL
WALZ
HEFTER
HARTSTEIN

CMS-1500-P-573

Submitter : Dr. Kelly Will

Date: 06/22/2005

Organization : Dr. Kelly Will

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-573-Attach-1.RTF

Attachment 573

NORTH TEXAS PAIN MANAGEMENT ASSOCIATES, P.A.

General, Pediatric, & Oncologic Pain Medicine

Board Certified in Anesthesiology, Pain Medicine
*Board Certified in Internal Medicine**

KENNETH L. REED, M.D.*
KELLY R. WILL, M.D.

June 22, 2005

RE: Hospital Reimbursement for Rechargeable Spinal cord stimulators

Dears Sirs:

I am an anesthesiologist in Dallas, Texas and my practice is limited to the management of chronic pain. I have been in private practice in Dallas since 1989. I am writing in regards to the hospital reimbursement for rechargeable spinal cord stimulator systems. These are a major clinical improvement in the management of chronic pain. In the past, patients who had implantable systems had to look forward to frequent outpatient procedures to replace or revise their stimulators and batteries. Often, patients would tell me they were using the device infrequently, even though they had good relief, in order to conserve the battery and avoid or postpone a replacement. The rechargeable systems will result in a reduction in the number of surgeries to replace the depleted batteries. It will also improve patient compliance and enable them to experience the full benefit of neurostimulation.

These new technologies are totally different from the older radiofrequency spinal cord stimulator. These are devices that have the power source outside the body and have to be worn by the patient at all times in order to use the device. The adhesives involved often cause skin reactions and over time, many patients end up just "living with the pain" rather than use the device due to the side effects, even though neurostimulation gave them good relief. The new rechargeable systems are an implanted internal power device (like a "pain pacemaker") that can be recharged every 3-6 weeks at home in a short time.

In short, I believe it is critical that hospitals receive adequate reimbursement for these devices so our patients have the best options available for treatment of debilitating chronic pain.

Sincerely,

Kelly Will, M.D.

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CAH/Redoc 287

CMS-1500-P-574

COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

Submitter : Mr. Eric Nickeson **Date:** 06/22/2005

Organization : Parkview Health System, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-574-Attach-1.DOC

CMS-1500-P-574-Attach-2.DOC

Attachment 574

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: **Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates – Page 23466 of Federal Register/ Vol. 70, No. 85/ Wednesday, May 4, 2005/Proposed Rules**

To Whom It May Concern:

Thank you for providing an opportunity for input into the proposed changes to the Hospital Inpatient Payment Systems. Specifically, we are writing to express concern with the proposed regulation changes that impact necessary provider Critical Access Hospital (CAH) relocations and the continued CAH designation under the Medicare program.

In order to maintain CAH status, the proposed rules limit replacement facilities from being built further than 250 yards from the existing hospital under section (d)(1). This section also refers to construction being undertaken on "land owned by the CAH prior to December 8, 2003." We are unsure of the possible interpretation by CMS of this phrase due to the fact that our CAH did not become certified until February 1, 2005. To add further complexity to the effect of this proposed rule, our organization purchased the CAH on May 1, 2005 from the previous owner.

Furthermore, section (d)(2) of the proposed regulation would be impossible for our CAH to meet as it did not qualify as a CAH until February 1, 2005 and, therefore, there can be no documentation that the CAH's "plans to rebuild in the relocated area were undertaken prior to December 8, 2003."

It is our understanding that the intent of CAH designation is to provide hospital services to rural populations under a payment system that provides the necessary financial resources to provide care to these communities. Establishing an arbitrary date from which replacement facility plans would have had to be developed prevents improvement of service delivery to the community in newly acquired facilities.

Parkview Health recently purchased LaGrange Community Hospital (Hospital), a CAH in northern Indiana that qualified under the necessary provider rules. The facility is in extremely poor physical condition and is badly in need of replacement. The location of the current facility is also undesirable from an access perspective. Obviously, plans for replacement of the facility could not possibly have been developed prior to December 8, 2003. The age and physical condition of the facility will eventually become more costly to the Medicare program in terms of maintenance and repairs. At some point in the near future, the structural integrity and potential safety concerns relating to the current Hospital facility will no longer be able to be repaired or maintained.

The future outlook for the Hospital is dim without continuation of the necessary provider CAH designation. If the Hospital were to go out of business or reach a point where the age of physical plant and ability to render safe, efficient, high-quality care were adversely affected, then local physicians would relocate out of the area to practice medicine, further reducing Medicare recipients' access to quality health care in LaGrange County.

The reduction in Medicare income from operations of a relocated Hospital, assuming the Hospital would fall back into the PPS pool of providers, would eventually lead to financial difficulties as well. The return on investment of a newly constructed rural facility, absent the CAH status, is not financially attractive.

Replacement of the Hospital on its current site (or within 250 yards of the current site) is not the most economical option at this time. The construction of a replacement facility on the current site would necessitate tearing down portions of the current facility while simultaneously putting up the new structure. This would lead to disruptions in the care given to patients as they would need to be moved from the current building to the new building in phases. This could negatively affect the quality of care received by Medicare beneficiaries during the phase-in period. The alternative of renovation on the current location would likely cost the CAH program more money over the long-term.

Medicare recipients should have access to health care within a reasonable distance of their home. There are no other alternatives for hospital care in LaGrange County. The deteriorating condition of the Hospital necessitates a replacement facility in order to ensure Medicare recipients' continued access to care. We do not believe that the alternative of elderly Medicare recipients being forced to travel long distances for primary/secondary hospital care or, for tertiary care, 50 to 60 miles to regional urban hospitals is consistent with the goals of the Medicare program. If the Hospital were to reduce its services or close, then Medicare recipients' access to care would be diminished.

Also to be considered is the fact that there is a significant Amish population in LaGrange County, about 10,000 people. The reduced access issue for the Amish is very real as they do not typically use automobiles or motorized vehicles for transportation and, in the event of closure of the only hospital in LaGrange County, a journey to the next nearest facility could be potentially life threatening.

A replacement facility will enable improved access and quality of care delivery to the nearly 38,000 residents of LaGrange County, Indiana serving the entire county with one hundred percent (100%) of the existing staff.

On behalf of the LaGrange County, Indiana community, we urge you to reconsider the proposed regulation restricting critical access hospital replacement facilities and the potential disruption this may cause to Medicare beneficiaries in LaGrange County.

We would be happy to provide additional information regarding this issue if requested. Thank you for your earnest consideration of this request.

Respectfully submitted,

Eric E. Nickeson, Parkview Health Director – Reimbursement/Charging

COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

Submitter :

Organization : **QHR**

Category : **Health Care Industry**

CHH/RELOC

Date: **06/22/2005**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-577-Attach-1.DOC

QHR Attachment 577

QUORUM HEALTH RESOURCES

105 Continental Place Brentwood, Tennessee 37027 615.371.7979

June 22, 2005

Centers for Medicare & Medicaid Services

Department of Health and Human Services
Attention: CMS-1500-P
Box 8011
Baltimore, Maryland 21244-1850

Subject: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates: Proposed Rule, Comment Period

File Code: CMS–1500-P

We are providing these comments and questions to the Department of Health and Human Services for consideration in accordance with instructions published in the May 4, 2005, Federal Register. Our questions and comments regarding the proposed regulations affecting Critical Access Hospitals as published on pages 23450 to 23453 of the May 4, 2005, Federal Register. In addition, we are taking this opportunity to comment and ask additional questions for purposes of obtaining clarification of current policies regarding Critical Access Hospital bed counts, observation room services, combined billing, and ancillary services provided by hospital personnel in a critical access hospital. These particular issues have developed during the past year and a half and are being raised since we have seen different interpretations from State agencies and fiscal intermediaries.

QHR is the leading provider of hospital professional management services in the United States. We provide professional management and consulting support services to over 200 not-for-profit acute care hospitals in the United States. We provide management services to a vast majority of the hospitals located in rural communities with populations ranging from 5,000 to 30,000 residents. Rural health issues and policies developed and implemented by Health and Human Services have significant impact upon our affiliated hospitals and the communities they serve on a daily basis.

Within our client base are approximately 70 hospitals that are Medicare designated Critical Access Hospitals or will be by December 31, 2005. Most of these hospitals obtained CAH designation prior to January 1, 2005. Approximately 20 are currently in the process of obtaining CAH designation. These hospitals are now able to qualify for CAH designation due to the revision of the CAH bed count limitation to 25 on January 1, 2004.

Since establishment of the Critical Access Hospital program, QHR managed and affiliated CAHs have been able to continue providing access to care for Medicare population. CAHs have been able to improve operating margins, purchase modern equipment, and improve overall access and quality of services to their communities. The Critical Access Hospital program has been an exceptional program and has helped improve patient access to care in rural to a level not seen since the Hill Burton program. We would be saddened to see this wonderful program curtailed and many of these hospitals eventually close or return to pre-CAH financial status due to inability to meet specific CMS regulations.

BACKGROUND INFORMATION AND COMMENTARY

Medicare initiated the Medicare Limited Service Hospital (Critical Access Hospital) program with passage of the Balanced Budget Act of 1997. An initial criterion for a hospital to participate in the Limited Service Hospital Program was a bed count of 15 and patients had to be discharged or transferred within 96 hours of admission. Subsequently, the Beneficiary Improvement Act of 1999 revised the 96 hours discharge criteria to an average length of stay of four. This was a significant change and allowed numerous hospitals to enter the program.

The Medicare Modernization Act of 2003 further enhanced the ability of acute care hospitals to participate in the program. In particular, CAHs were allowed to operate and maintain 25 acute care beds and also operate a 10 bed psychiatric unit and a 10 bed rehabilitation unit. Industry wide, these changes have allowed more hospital to review the potential to become CAHs without reducing services to Medicare beneficiaries.

For example, a hospital within the QHR system had actively reviewed becoming CAHs prior to MMA changes but also operated inpatient psychiatric units. These hospitals would have converted to CAH status but did not want to close the psychiatric units and cease providing inpatient psychiatric care to their communities.

These changes were made to enhance the accessibility to healthcare for the Medicare beneficiaries in rural areas of the country. QHR is concerned the proposed regulations are not implementing the legislation but making additional rules not intended by the legislation.

Congressional Intent

Similar to other "special providers" and status granted by the Medicare program, the overall intent of creating the CAH program was to ensure Medicare beneficiary access to health care services. For example, the Medicare program created Rural Health Clinic and Federally Qualified Health Centers to promote health care services in underserved areas. Hospitals subject to the prospective payment system can obtain Sole Community Hospital or Medicare Dependent Hospital designations if they meet specific criteria, and in turn qualify for enhanced Medicare payments. This ensures a hospital's financial viability and ability to provide health care services. As such, the CAH program follows a long Medicare program public policy to ensure access to patient care by equalizing payments between rural and urban hospitals.

From a financial and reimbursement perspective, PPS methodology is a volume driven payment methodology. Higher Medicare volumes equate to higher Medicare reimbursements and ensure that the hospital recovers fixed type operating costs: minimum staffing, equipment and plant costs, administrative operating type costs such as billing, collections, and management. In short, higher volumes yield lower fixed costs per case, and improved operating margins and cash flow. In rural settings however, the ability of hospitals to generate patient volumes sufficient to recover fixed overhead costs is limited. Rural communities have a lower population number thus limiting the ability of some rural facilities to generate sufficient volumes to survive under a PPS payment methodology.

BBA transition to PPS for all services provided by rural hospitals created additional financial strain on rural hospitals. Small rural hospitals had no choice but convert to CAH in order to survive financially. Congressional intent, to ensure continual access to patient care in rural communities has been very well served since the Balanced Budget Act of 1997 created the Critical Access Hospital program.

MMA of 2003: Necessary Provider Designation

The ability of the individual States' Departments of Rural Health to designate a hospital as a necessary provider of health services will expire on December 31, 2005. MMA of 2003 contained a statue revoking the ability of State Departments of Rural Health to designate a hospital as a necessary provider of health services. Effective January 1, 2006, a hospital that decides to become a CAH will have to meet federal location requirements of being 35 miles or more away from another hospital and be located in a rural area.

CMS has further clarified that the hospital must actually have already gone through the Medicare certification process and obtained a CAH provider number by December 31, 2005. Hospitals deemed necessary providers by the State in the State Rural Health Plan and are not certified as CAHs on December 31, 2005, cannot obtain a necessary provider designation and thus CAH status at some future date.

MMA also contained language grandfathering certified CAHs. If a hospital is a certified CAH as of December 31, 2005, then such status will continue. Reimbursements will continue to be on a cost basis.

After December 31, 2005, very few hospitals will obtain CAH designation since most hospitals meeting the 35-mile criterion have already obtained CAH. Such hospitals either converted to CAH or obtain significant Medicare reimbursement enhancements as Sole Community Hospitals or Medicare Dependent Hospitals or generate sufficient patient volumes to remain financially viable under the Medicare prospective payment system.

Replacement Facilities

Due to CAH designation and improved Medicare program payments, many CAHs are now considering remodeling or totally replacing their physical plants. Due to historically poor performance, many rural hospitals have not been able to access capital for plant and property improvements. Most CAHs are in old facilities, with many dating to the Hill Burton program. The signs of years of wear and tear are obvious to many facilities and their communities.

In addition, most facilities were designed and built long before the emphasis on healthcare shifted to outpatient-based delivery models from inpatient care. These hospital buildings are inherently inefficient.

Capital financing has become readily available to CAHs due to improved operating performance. For the first time in years, small rural hospitals, CAHs, are moving forward with facility replacement projects and accessing capital via the bond markets, other financing sources and obtaining local tax support to finance replacement facilities. These developments will provide the community with a modern facility, improve patient safety, patient access to inpatient and outpatient care, patient satisfaction while improving the efficiency and cost effectiveness of the hospital.

The United States Department of Urban Development has developed an expedited loan guarantee process specifically for CAHs (HUD 242 Program). It is known that a number of CAHs have obtained HUD loan guarantees in the past few years. In fact, QHR manages one facility that has already obtained a HUD loan guarantee and just recently opened their new facility and 2 other

CAHs that are actively pursuing a HUD loan guarantee. QHR has multiple CAH clients that are in the initial process of financing and planning facility replacement projects and identifying most affordable financing vehicle.

The United States Department of Agriculture (USDA) has also been actively promoting and making either direct loans or loan guarantees to CAHs. QHR manages one facility that just recently qualified for an USDA loan guarantee and anticipates breaking ground on new facility within the next 30 days. Numerous other CAHs are considering USDA program as a viable financing vehicle.

General Policy Questions

Are the proposed regulations in concurrence with Congressional intent to allow State designated necessary providers to be grandfathered as necessary providers effective January 1, 2006?

The Congressional intent to grandfather Critical Access Hospitals would not be served by the regulations as proposed. Under the proposed regulations will only allow a Critical Access Hospital the ability to replace the physical facility if such development plans were under significant progress as of December 6, 2003, or the CAH built either on the same site or with 250 yards of current facility on land adjacent to and owned by the CAH on or before December 6, 2003. As such, all CAHs that do not meet these stringent guidelines must remain in current location or, if they relocate, lose necessary provider designation, critical access hospital designation, and cost based reimbursement.

Under these proposed regulations, CAHs that are in significant need of facility replacement may eventually be forced to close the hospital. As the building continues to deteriorate, patient safety will eventually become an acute issue. At this point in time the CAH will be forced to close for patient safety concerns. State licensure and certification regulations will take effect and the hospital will be forced to close, or the community and hospital will have to seek out purchasers of the hospital facility.

Under these proposed regulations, building a new facility will be impossible for this particular group of hospitals. As proposed, a CAH that relocates and does not meet 35-mile distance requirement will become an acute care hospital subject to the prospective payment system. The hospitals would suffer a significant reimbursement reduction from the Medicare program by moving into a new facility and converting back to a PPS payment methodology will prevent

them relocating and constructing and relocating to a new facility since they will not be able to survive the underlying reduction in profitability and cash flow. The ability to obtain financing from USDA, HUD, or other third party financing sources will evaporate since all these entities require certain levels of profitability and cash flow.

Effectively, the CAHs that need replacement facilities are in a Catch 22: stay on same location and eventually have to close due to building safety concerns, or go through very expensive and time and cost prohibitive renovation projects, or relocate and become a hospital subject to PPS and suffer a large reduction in Medicare payments. This final option is really not an option at all since CAH's revenue base is so small that the reduction in Medicare payments will make any form of new facility unaffordable.

Under these proposed regulations, a large number of these hospitals may eventually close, eliminating access to patient care in numerous rural communities. In some of these communities, local healthcare will not exist or at minimal be reduced in future years.

It would not be Congress' intent to force small rural communities to close their CAHs due to facility issues and inability to replace facility when the MMA of 2003 grandfathered existing CAHs. Instead, we believe the intent was to effectively grandfather all such CAHs for the foreseeable future and prevent existing acute care hospitals from becoming Critical Access Hospitals after December 31, 2005.

It should be pointed out, that MedPAC recently estimated that CAHs cost the federal government approximately $1,000,000 per year per hospital. QHR's internal information and results of various studies in the past 5 years indicates that this is a reasonable amount on average. Our studies have indicated that the reimbursement benefits CAHs enjoy from cost based reimbursement over prospective payment system reimbursements range from $250,000 per year to approximately $1,000,000 per year. During the past 6 months, studies conducted on hospitals with 25 acute care beds have indicated that the reimbursement benefit is higher ranging from $600,000 to $2,000,000 per year. The additional reimbursements are crucial to small rural hospitals.

The typical CAH in the QHR system have net revenues from all payors of less than $20,000,000 per year and operating margins of less then $500,000 per year. If the financial benefit is removed, CAHs would be losing money each year and be unable to obtain financing for a new facility or possibly not even able to service existing debt. The proposed regulations will have the direct effect of causing reduced access to patient care for Medicare beneficiaries residing in the very communities the Critical Access Hospital program was created to assist.

Will the proposed regulations promote cost savings to the Medicare Program in future years and encourage CAHs to make cost effective decisions when considering renovation projects or replacement facilities?

CAHs within 35 miles of another hospital will be forced to renovate existing plants and facilities on current sites. As discussed above, very few, if any, CAHs will be able to absorb the financial loss of losing CAH status, let alone afford the financing and depreciation costs of a new facility. As such, CAHs will have to spend capital funds on current facilities to remain open, stay in compliance with fire and safety codes, ensure patient safety, provide modern medical technology, and ensure long-term patient access to care to patients in their communities.

Often, renovation and improvement of existing aging facilities are as expensive as totally replacing a facility. At 2 QHR managed facilities, facility master plans and engineering and building renovation estimates have approximated or exceeded the costs of replacing the entire facility. The studies are attached for your reference and were compiled and prepared by a subsidiary corporation of QHR: American Health Facilities Development, LLC.(AHFD). AHFD provides construction management and master facility planning services throughout the United States.

Many CAHs were built 40 to 50 years ago as primarily inpatient facilities well before the modern advances in medical technology and treatment. Outpatient services have grown tremendously throughout the United States the past 15 years proving to be effective and much more cost efficient then inpatient care and surgery. This trend will likely continue on into the future as fewer invasive procedures are performed. Facilities built and constructed over 30 years ago are ill suited to provide these services and very expensive to totally renovate.

Major renovation projects can take years to complete. As one section of the hospital is renovated, services must be relocated to another part of the hospital facility. When that area requires renovation, services for that area must be moved elsewhere. Patient access is interrupted, and additional steps have to be taken to ensure patient safety. For an extended period while renovations are taking place, certain services may be limited or not available. Medicare patients would have to travel further distances to obtain healthcare services during the time a hospital would be renovating its existing facility. In effect, the proposed regulations will do the exact opposite of the Congressional intent and CMS standing policy: to ensure Medicare patient access to care.

Piece meal renovations over a number of years are even more inefficient and costly. Replace the roofing system one year, replace the plumbing and HVAC system the following, renovate the

patient rooms the following, expand a wing the following year, add a floor 4 years from now, remove a wall over in another area, and add a few hundred square feet. Many CAHs will be forced to go about renovating facilities in piecemeal fashion.

The cost to the Medicare program is higher in the long term with major building renovations and piece meal facility renovations versus complete facility replacement in a number of areas:

1. Additional costs of building renovation will be reflected in higher depreciation costs on the annual Medicare cost report.

2. Cost of financing will be higher since CAHs may have to resort to piece meal financing approaches at higher interest rates than a single debt issuance.

3. Staffing costs in antiquated facilities are higher than modern facilities due to plant layout and design. The level and type of services offered have expanded significantly the past 20 years, requiring higher levels of patient throughput and a more coordinated approach to patient care. Staffing cannot be optimized and minimized since nurses and other personnel cannot staff or support multiple areas of the hospital. This issue is particularly crucial for smaller hospitals.

4. Maintenance and repair costs increase with the age of a physical plant.

5. Utility expenses such as heating and air conditioning costs are always higher in old hospital facilities than new facilities due to improvements in building and insulation materials.

6. Costs of materials and labor will and always have increased over time. A renovation project taking a 3-5 year period of time to complete will be more costly simply because labor material costs will increase by 3-5% per year. A new facility can be constructed and placed into service within 18 months of construction start up. As such, construction and renovation occurring after 18 months will result in increased costs of materials and labor and likewise costs to the Medicare program.

Comment: Departure from Historical Payment Policy (Is CMS following historical certification and payment policies?)

The proposed regulations are a departure from the historical CMS payment policies in a number of instances. We believe part of this issue is due to the manner in which "certification" as a CAH inherently affects a CAHs reimbursement. Hospitals that have converted to CAH have done so due to the increased reimbursement that results from cost based reimbursement methodology versus a PPS payment methodology. Congressional intent was to provide higher payments to CAHs to ensure their financial survival. We have found no evidence or statements in the Congressional record to indicate that Congress intended to curtail or limit a CAHs ability to modernize or replace existing facilities.

CMS has always treated "certification" issues separately and distinctly from "new providers for payment purposes".

The proposed regulations appear to depart from historical CMS policies and guidelines granted to hospitals by Congress to improve payments to such providers or provide exception payments. We have compiled several examples illustrating historical policy to separate building, relocation and certification issues from underlying payment issues.

Example 1
If a Sole Community Hospital relocates its site, the Sole Community Designation is not automatically reviewed by CMS. Current policy is that the SCH is required to inform CMS if the new location places them within the statutory 25 mileage criteria. Relocating a SCH within 25 miles of another acute care hospital would then trigger a loss in SCH designation for payment purposes.

However, we are unaware of any instance whereby a Sole Community Hospital has relocated the physical facility and then lost Sole Community Hospital Status for payment purposes. We assume, and are requesting commentary and confirmation, based on the proposed regulations for CAHs, that CMS would follow the same methodology: determine whether the hospital has ceased to operate as an ongoing entity and, if so, the hospital would have to go through a survey and obtain a new provider number. Likewise, the SCH would have to reapply for SCH status and would not be paid under previous provider's hospital-specific payment amount. The hospital would qualify for capital cost pass through reimbursement under 42 CFR Section 412.324(b) as a new provider. Any sub providers would also be resurveyed and treated as new providers with the Medicare program for payment purposes.

Example 2
Inpatient PPS exempt units, inpatient psychiatric units, and rehabilitation units are required to notify CMS Regional Offices when such units expand or relocate within the hospital, add additional beds, or relocate to other areas on the main hospital campus. However, CMS historically has not automatically scheduled a survey nor allowed adjustments to TEFRA rates or treated the units/hospitals as new providers. With expansion and relocation of exempt units, these units were not permitted to obtain new TEFRA rates, nor qualify for any other special payments that exempt units qualified for during first year of operations. CMS historical policy has always been that facility relocation or expansion did not trigger a change in base year rates or resetting of such rates or treatment of the provider as a "new provider".

Example 3
Skilled Nursing Facilities, when subject to the per diem reimbursement limitations before 1998, were granted a "new provider" exemption from the per diem limitations for the first three years the Skilled Nursing Facility of operation. CMS did not recognize a new exemption period if the SNF relocated, expanded, or was purchased by another provider. Generally, policy has been that it the SNF relocates but is treating the same general patient population and providing similar services, the SNF was not a "new provider" and therefore did not qualify for the 3-year exemption from the per diem cap limitations.

Example 4
Change in hospital ownership transactions are reviewed from a "certification" standpoint separate and distinct from "payment" issues. The Provider Reimbursement Manual discusses notification requirements and generally has held that a change in ownership resulting in issuance of a tie-in notice or new provider number will not automatically result in changes to Medicare payments. Generally, the new provider will still enjoy payment benefits or "status" as the previous provider had and valuation of assets will not be allowed automatically. Such determination is made separately from the provider number and assignment of the Medicare participation agreement.

Example 5
When the Medicare inpatient PPS system was implemented in the early 80's, hospitals could qualify for an adjustment/revision to their hospital specific payment amount under extraordinary circumstances. If the hospital incurred substantial changes in operating costs from their base period beyond their control or if the hospital was a new provider, the hospital specific payment rate could be adjusted from the base period amount. In a number of PRRB cases and HCFA Administrative decisions, the Secretary held that construction of a new facility did not constitute a new provider nor did it justify revising the hospitals specific payment amount.

In each example above, CMS has historically separated certification issues from underlying payment issues. CMS historical policy has been that facility replacement, expansion or

renovation did not create a "new provider'. CMS historical policy also determined the original provider had not ceased operations causing the need for a new provider number, new participation agreement or assignment of an existing participation agreement. Instead, CMS and the Secretary have based new provider status on basis of patients being served and level of services provided in the new or expanded hospital. Previously, if the "expanded", new facility or beds of the facility are serving the same patient population and generally providing the like services, then a "new provider" did not exist.

The proposed regulations should be revised to reflect this underlying historical payment and certification policy.

Determination should be made on whether relocating a facility will significantly and materially alter the patient population being served and assuring a "new provider" is not being created with a new facility. After affirmative confirming these items, the "necessary provider" designation granted by the State should be applied to the existing CAH provider number and the new building. Having the "necessary provider" designation follow the provider number and participation agreement will be exactly the same as historical payment policy, the same way the policy was established for TEFRA rates, exemptions from caps, relief from cost limitations.

This approach will be in concurrence with long standing Medicare payment and certification policies and satisfy Congressional intent to grandfather the necessary provider designation.

The proposed policy stating that any new CAH facility that is more then 250 yards away from the current facility or the facility did not have development plans significantly completed by December 8, 2003 has ceased operations as a hospital and is now a "new provider" is contrary to historical CMS policies.

Specific Questions and Issues Regarding the Proposed Regulations

Question

Does CMS through State survey agencies have legal and statutory authority to revoke a providers certification upon relocating to another location .If so, what is the statutory authority, regulatory references or and manual references to support such a certification issue.

Comments

We believe CMS has right to review certification of any provider for purposes of managing the Medicare program and ensuring integrity of the Medicare program. CMS also reserves the right to conduct surveys on providers whenever they wish in order to ensure a facility is meeting and complying with Medicare conditions of participation requirements. To clarify CMS should at this time develop clear regulations to address when a provider's certification will be reviewed and under what circumstances. We recommend these regulations be developed for all providers that participate in the Medicare program.

Question

Can CMS review a CAHs "necessary provider" designation after December 31, 2005 and effectively revoke such designation on basis that the original provider no longer exists.

Comments

The statute is clear. CAHs that are certified as such on January 1, 2006 are grand-fathered as necessary providers. It is understood however, that CMS has a responsibility to manage the Medicare program and is obligated issue interpretive regulations. However, public health policy would be better served if revocation of a necessary provider designation should resides with the state agencies provided such designations.

The statue reads:

(2) STATE DESIGNATION OF FACILITIES._

(B) CRITERIA FOR DESINGATION AS CRITICAL ACCESS HOSPITAL- A State may designate a facility as a critical access hospital if the facility –

(II) Is certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area:

The statute is clear. If a CAH is certified by the State as being a critical access hospital, then the hospital is a CAH. The statue does not propose that CAHs must remain on same site and relocation of physical plant would negate their necessary provider designation.

CMS has partially justified the proposed regulations on the basis that the necessary provider designations throughout the United States were common in that all were based upon the provider's location. CMS notes on page 23452, paragraph 1:

"Each State's criteria are different, but the criteria share certain similarities and all define a necessary provider related to facilities location"

CMS further justifies the proposed regulation by noting that a CAH that relocates to another location may not be serving the same patients in the same area as when the original necessary provider status was granted by the State. CMS notes on page 23452:

"We have interpreted "services to residents in the area" to mean that the necessary provider designation does not automatically follow the provider if the facility relocates to a different location because it is no longer furnishing "services to patients" in the area determined to need a necessary provider."

CMS should come to some form of process for reviewing the necessary provider designation for relocated facilities. Medicare program integrity could be jeopardized without guiding regulations. For example, if CMS did not review the necessary provider designation, unscrupulous individuals could become very creative in relocating CAHs to the detriment of local communities and other competing hospitals for individual profit. However, this determination should be made on a hospital-by-hospital basis and rest in the hands of the state's departments of rural health since they are more familiar with the local rural health issues and needs than the Regional or Central CMS offices.

CMS should be applauded for developing regulations defining when a CAH has relocated or ceased business as a CAH at one location. These regulations are necessary to protect the Medicare program. However, CMS should avoid strict guidelines such as miles or the "250" yards criterion in the proposed regulations. Instead CMS or preferably state's departments of rural health should rely upon CAHs primary market areas, historical policies on new providers as discussed above and other readily available parameters. Generally, if the new location is in the hospital's primary market area and primary roads exist for providing ease of access from the old

location, the hospital medical staff will not change, then patient access will not be severely hindered and a relocated CAH will still be serving the same "area".

Hospitals improve patient access to the facility when choosing a new hospital location. This is particularly true of CAHs since many plants are so old, community population bases may have moved, State and / or Federal Highways may have been built within the past 20 years that now make the current location difficult to access. Many CAHs are often located in town centers where access is only by city streets and the site is land locked and surrounded by residences. Though such locations may serve the residents of a particular neighborhood very well, other patients in surrounding areas are not so well served. In many cases, these CAHs would be unable to build replacement facilities on their existing site without closing and demolishing all or part of the existing facility temporarily because there is not enough space on which to build. This would obviously have a negative effect on the CAH's ability to meet their community's health care needs.

CAHs are located in rural areas. Primary market areas may cross 15 to 35 miles in a particular county. Relocating a facility a few miles from a current location to a site located on a State highway or in outskirts of the primary town will improve the CAHs access for all residents in the area. We believe that, in most cases, relocating a CAH more than 250 yards will not result in a substantial change in the patient population served by that CAH. This determination should be made by the appropriate State agency.

Additionally, terrain and available land influence a CAH's decision to relocate. Land on current location may be too small to build new facility or other land in general location of current site may not be available for sale or prohibitively expensive. In many areas, new sites are limited due to terrain: mountainous areas, swamps, and other issues that either prevent development of the land site or become very costly to develop.

In many instances, in small communities, rural hospitals are able to obtain land donations for a new building site. The 250-yard criterion will void this opportunity to the CAH. The Medicare program traditionally encourages philanthropy, and the proposed regulation would certainly discourage willing benefactors from making such gifts.

If CMS does insist on using a distance criterion, it should study the trends of hospital relocation in this country and devise quantitative as well as qualitative rulres to determine such criterion. Utilizing rules established for other types of providers may result in poor relocation decisions that ultimately may harm access for the beneficiaries of a certain area. Such an analysis would result in a clearer public policy for the CAHs and the communities they reside in.

If CMS cannot remove the mileage criterion altogether,we would suggest that the distance be at least 3 miles with greater distances upon approval of the regional office. Increasing the distance will be a much more workable public policy for the CAHs and the communities they reside in and one still subject to review by CMS.

SPECIFIC QUESTIONS AND COMMENTS

Deadline of Dec 8, 2003 is unfair to hospitals converting to CAH during 2004 and 2005.

A number of hospitals converted to CAH status after December 8, 2003. A large number of hospitals will be or have converted since January 1, 2004 with revision of the bed count limitation to 25 from previous 15 acute patients and 10 swing bed patients. Hospitals that have converted since Dec 8, 2003 and obtained CAH status on basis of necessary provider designation will not be able to construct new hospital facilities and maintain CAH status and cost based reimbursement unless they construct at current location and site.

The requirement that construction projects be significantly in progress by December 8, 2003 be should be removed from the proposed regulations. Even though December 8, 2003 date is the date of passage of the Medicare Modernization Act, CMS has the obligation to promulgate clear and definitive instructions to the provider community. CMS has clearly established policies with dates that differed from the enactment dates on various pieces of legislation in the past. There is nothing in the statutory language to require CMS to set a date with retroactive consequences.

Can a CAH construct a outpatient ancillary and patient care building in another location, retain some hospital functions at current location and maintain necessary provider designation?

Assuming the proposed regulations become final as proposed, we are seeking clarification on when a CAH will be considered to have "ceased" operations at the existing facility. A number of examples:

Example 1
CAH constructs an outpatient ancillary building including laboratory, diagnostics, surgical suites, therapy services and outpatient clinics 5 miles away from the current location. Such services are transferred to the new outpatient ancillary building and patients are treated at such location. Inpatient services are still provided at the old facility including major diagnostics and

surgical services and emergency room services. New building and operations would all comply with CMS current provider based regulations.

Example 2
Same as above except minimum inpatient services would be provided at existing facility. Only 2-6 beds inpatient beds would be kept in service and only utilized in when patient beds were fully occupied at the new facility. Hospital administration, laundry services, dietary, and miscellaneous other support services would be housed at the old facility.

Example 3
Same as Example 2, except the old facility would also have a separately certified Medicare Skilled Nursing Facility, 10 bed exempt psychiatric unit at the existing facility. No acute care inpatient services would be provided in the old building.

There is not an appeals process established in the proposed regulations for CAHs that do not receive approvals from State Agencies and or Regional Office to relocate facility and retain necessary provider designation.

Since this is such a significant issue for affected CAHs, it is only reasonable that the provider have an opportunity to appeal adverse decisions in accordance with the Administrative Procedures Act.

If a CAH is deemed to ceased operations upon relocating to another physical plant and hospital obtains a new provider number as an acute care hospital, will all Medicare program liabilities from the CAH be assigned to the new provider number? Will liabilities resulting from CMS or other governmental agencies enforcement proceedings resulting from filing of false claims, inaccurate cost reports and other penalties accessed be the responsibility of the new provider?

We assume not since as proposed, the regulations would effectively terminate the existing provider number and participation agreement. If CMS policy is that a "necessary provider" designation cannot follow a facility or plant 251 yards down the road, then benefits associated with the provider agreement should also terminate.

Will CAHs that relocate facility, and obtain a new provider number, qualify for capital pass through payments as a new provider under CFR Section 412.324(b).

CFR Section 42 412.324(b) allows for capital pass through cost reimbursement for new hospital facilities. If a CAH facility replacement is considered a cessation of business for purposes of continuing as a CAH, they should be considered a new provider under Capital PPS.

Will CAHs that relocate facility and obtain new provider number be treated as "new providers" under all CMS and State Medicaid program payment and certification regulations?

Exempt units and other provider based type entities might also be affected by a CAHs that ceases business and becomes a new provider.

Other Issues and questions relating to Critical Access Hospitals: Clarification on bed counting policies;

We have heard conflicting statements from CMS and State survey offices regarding counting of beds. As you are aware, CAHs may only have 25 beds effective January 1, 2005, 10 beds for psychiatric unit and 10 beds for a rehabilitation unit. Licensed Skilled Nursing Facility and nursing facility beds are not counted towards as part of the CAH 25 bed compliment.

Prior to January 1, 2005, CAHs could maintain 25 beds with requirement that only 15 patients could be acute inpatients and 10 patients in swing bed status. The beds, in accordance with Swing Bed regulations, could be used interchangeably.

Current State Operations Manual guidelines define beds for counting purposes and specifically exclude beds used for patients recovering from anesthesia, beds used exclusively for labor and delivery, stretchers and generally beds that are not utilized for inpatient care. However, some CMS representatives and State survey offices state that they would in fact count beds used only for outpatient observation services, patient stretchers, beds and stretchers housed in emergency room for purposes of observation and emergency room care. We ask that CMS clarify its policies regarding bed counts and patient census in Critical Access Hospitals, with particular emphasis on whether patients in observation status are to be included in the count. This issue is extremely important from a certification and compliance standpoint and a hospital operations and staffing standpoint. In addition, as CAHs go through building renovations or construction of new

physical plants, they will want to ensure that the new facility design and lay out will not cause a compliance issue.

We suggest that CMS consider interpreting and implementing the 25 bed count requirement in a manner that promotes patient safety, patient access to care, minimize need to transfer patients and provides the hospital with some level of flexibility. In addition, we would like to remind CMS that the State Departments of Health do have the ability to "waive" the 25 bed requirement when areas are stricken with unusual epidemics. For example, we are aware of 2 instances within the past 2 years where States have allowed CAHs to house more then 25 patients due to pneumonia outbreaks during winter months. In both cases, other hospitals in the region were fully occupied and not accepting patient transfers.

In addition, some specific questions need clarification:

1) If a Critical Access Hospital staffs a distinct observation room department, will such beds be counted for purposes of the 25 bed count rule? The unit would be separately staffed, have distinct designated patient rooms in order to ensure accurate Medicare cost reporting. Inpatients would never be placed in the beds.

2) Can beds be used interchangeably between floors and units? For example, CAH has 6 licensed intensive care unit beds, 25 medical/surgical beds and 6 beds utilized for obstetrics' for a total of 30 beds. All beds are located in separately staffed distinct floors of the hospital. On day at the midnight census count, the CAH has 6 patients in ICU, 6 in obstetrics and 13 patients occupying the medical surgical beds. On the next day, due to patient admissions and discharges, the CAH now has 2 patients in ICU, 2 in obstetric beds, and 21 in the medical /surgical beds. In this example, would the CAH be in violation of the 25 bed count rule? (John, both examples have 25 patients in licensed beds. Did you mean for one of these examples to have more than 25 patients?)

3) Depending on answer to above, for purposes of bed count rule, is the bed count rule directly tied to bed licensure? In other words, in example above, would the CAH be in violation of the 25 bed count rule simply because State bed licensure exceeded 25 beds?

4) Should CAHs rely upon other published regulations and manual sections that define "available" beds for purposes of CAH bed count regulation? Specifically Provider Reimbursement Manual Sections 2405.4(G) and other published commentary regarding

bed counting for purposes of hospitals subject to the inpatient PPS indirect medical education reimbursements.

Billing of ancillary services by nursing personnel

We understand current CMS payment and billing policy to be that when a licensed nurse performs respiratory services for an inpatient while the patient is physically located in a patient bed, that such services cannot be billed to the Medicare program. This policy exists since the CAH is already obtaining reimbursement for nursing service costs through the cost report as inpatient routine service costs. Assuming our interpretation of current policy is accurate, does this policy also apply to other procedures or diagnostics performed by nursing personal? For example, EKGs conducted in the patient room. The nurse would be licensed by appropriate State licensure boards to conduct the service.

Required level of outpatient coding required on outpatient claims submitted to Medicare by CAHs.

Regulation found at CFR 419.20 exempts CAHs from the Medicare outpatient prospective payment system. Medicare Intermediary Manual (CMS Pub. 13-3) Section 3627.8 states that CAHs are not required to report HCPCS codes unless the service is paid under a fee schedule. We are requesting clarification on this issue and assurance that CAH outpatient claims submitted without HCPCS codes will be processed and paid by the fiscal intermediary.

SUMMARY

Like many others in the provider community, QHR respects the efforts CMS has made in devising and developing the CAH program. CAHs are important providers in the country's health care system. Without them, Medicare beneficiaries in rural communities would be without many primary care services. The CAH program needs to have the flexibility so that the CAHs can service their communities and CAHs need to have clear and concise guidelines in planning their capital needs.

Sincerely,

Mr. James J. Free
President, Consulting Division

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CMS-1500-P-646

Submitter : Bonnie Haines

Date: 06/23/2005

Organization : Idaho Hospital Association

Category : Hospital

Issue Areas/Comments

Heffer
Hartstein
Collins
Murray
Smith
Kelly

CAH/Kusar
CAH/Reloc
400 Reclass

GENERAL

GENERAL

See Attachment

CMS-1500-P-646-Attach-1.DOC

CMS-1500-P-646-Attach-2.DOC

Attachment 646

IDAHO HOSPITAL ASSOCIATION
P.O. Box 1278
Boise, ID 83701-1278

June 23, 2005

Sent by e-mail to:
http://www.cms.hhs.gov/regulations/ecomments
File Code CMS-1500-P

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/madam:

On behalf of the Critical Access Hospitals in the State of Idaho, I am writing in regard to the Critical Access Hospital sections contained in the Proposed Changes to the Medicare Hospital Inpatient Prospective Payment Systems and FY2006 Rates. The proposal relative to relocation of necessary provider CAHs is extremely concerning to Idaho hospitals currently affected and to those who could potentially find themselves in this situation at a later date by not action on their part, e.g. in the event of a non-CAH hospital moving into the distance radius of a CAH.

Necessary Provider Status Relocations

The Medicare Modernization Act 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. This is imperative in Idaho where 12 of our 26 CAHs are necessary providers. We believe that CMS is exceeding its authority and independently developing a policy that is in conflict with the law.

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.

We believe that the date restrictions proposed by CMS are unrealistic and unreasonable. 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.

Many of Idaho's CAHs are housed in old buildings in desperate need of renovation. Prior to converting, these facilities could not gain access to capital due to their poor financial situation. Once stabilized – largely due to Medicare payments which cover allowed costs – they have become creditworthy and are at last able to proceed with updating their aged facilities. Their desire to replace existing facilities is not frivolous – but of necessity. They need to modernize buildings (often from the 1950's and 60's) to better function in today's health care delivery system. It is untenable to leave our smallest rural hospitals in the position of patching together very outdated facilities in lieu of risking continued access to CAH designation – the financial lifesaver for these most fragile hospitals. CAHs seek to relocate to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, updating 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. Should rural residents not have access to these advancements?

Many facilities need to, or choose, to rebuild on a new site which affords them the ability to be closer to a highway, connect to municipal water and sewer, to address seismic safety concerns, or other reasons that again, will improve patient safety and the quality of care provided. Sometimes, the population that is served has, itself, shifted within the market area. 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. Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving. In fact, these facilities will reduce costs through efficiencies. And they will incur less construction cost when building on "green field" than undertaking a more disruptive attempt to build around themselves.

It is unreasonable for CMS to assert that hospitals moving a few miles from their current location have ceased business and are new providers. This reflects a general lack of knowledge about rural areas. These CAHs are integral to their communities and often one of the biggest employers. They *are* their community. Moving down the road will not demonstrably change the population served. In fact, the CAH may be moving to better serve the population's movement within the area. Like AHA, we strongly believe that CMS should automatically consider

any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.

For others – those moving further than five miles -- we would recommend an approach similar to the 75 percent test described by CMS. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, some modification 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. These 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.

We join the American Hospital Association in recommending that CMS alter its criteria to allow three out of five to be satisfied. That is, in addition to the staff, services and population measures (amended to accommodate issues raised), 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, 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 even if the hospitals do not meet the specificity of the criteria.

Regardless of the criteria chosen, CMS should clearly delineate them in advance. CAHs need clear expectations and advanced warning of the standards to which they will be held. For example, when counting the staff, how should the hospital ascertain if the staff would continue employment at the new location? Perhaps efficiencies of a new building will reduce staffing needs. 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 the CAH plans 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. Population shifts in the "out years," such as an influx of tourists or migrant laborers, should not jeopardize a facility's CAH designation. Nor should new technological advances be denied CAHs into the future.
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 condition under the prospective payment systems. Thus, it is 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 that would need to be surmounted in an effort to build volume to survive under the PPS. These include getting licensed for additional beds or hiring additional staff to expand services when there are staff shortages in many areas For many CAHs, loss of their status would force them to close. Given the role of these facilities in their communities, such closures would have devastating effects 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. CMS should instead expand and use the criteria recommended above.

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. 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. We support the continued transition for these hospitals to give them the opportunity to reclassify and would expect similar provisions each year as labor market redefinition occur.

Sincerely,

/s/

Bonnie K. Haines
Senior Vice President

290

CMS-1500-P-647

Submitter : Mr. James T. Kirkpatrick

Organization : Massachusetts Hospital Association

Category : Health Care Professional or Association

Date: 06/23/2005

Issue Areas/Comments

GENERAL

GENERAL

Please find attached:
a) MHA general comments on Proposed IPPS Rule
b) Copy of previously submitted comments on the Proposed IPPS rule related to Countywide Reclassifcation

CMS-1500-P-647-Attach-1.DOC

CMS-1500-P-647-Attach-2.DOC

MHA

Massachusetts Hospital Association

Attachment 647

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:

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed rule for the FY 2005 Inpatient Prospective Payment System (IPPS). We are very concerned that several of your proposed changes to the IPPS will have significant negative impacts on our hospitals and the Medicare beneficiaries they care for and we are providing comments on those proposals. We are particularly concerned about the proposed expansion of the post-acute care transfer policy and the potential underestimation of the market basket.

MHA has previously submitted comments on wage index issues, specifically countywide group reclassification criteria and these are attached.

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PROPOSED EXPANSION OF THE POST-ACUTE CARE TRANSFER POLICY

MHA opposes CMS' proposal to expand the post-acute care (PAC) transfer policy. In the proposed rule, CMS discusses the possibility of expanding the policy from 30 DRGs to either 223 DRGs (later revised to 231) or all DRGs. CMS proposes to expand the list of DRGs subject to this policy by making substantial revisions to the DRG selection criteria with little justification or evidence.

Existing Criteria	Proposed Criteria
FORMER CRITERIA • At least 14,000 total post acute transfers • Decline of at least 7% over past 5 years in mean LOS of the DRG	PROPOSAL TO CHANGE TO • At least 2000 total post acute transfers • At least 20% of cases discharged to post acute care
FORMER CRITERIA • At least 10% of post acute transfers occurring before mean LOS • Mean LOS at least 3 days • Both paired DRGs in a CC/non CC set to be included if either meets above criteria	UNCHANGED • At least 10% of post acute transfers occurring before mean LOS • Mean LOS at least 3 days • Both paired DRGs in a CC/non CC set to be included if either meets above criteria

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The revised criteria have no explained relationship to specific policy objectives CMS might have for the changes. And CMS provides no backup data or arguments to justify the changes. For example:

- CMS proposes a sharp drop in the post acute transfer volume that a DRG must have for the policy to apply (from 14000 to 2000, an 85.7% drop). CMS also proposes to add a new criterion that 20% of the Medicare cases for the DRG be transferred to PAC in order for the transfer policy to apply. Both these thresholds seem to have been arbitrarily set to achieve the desired budget results. In section 1886(d)(4)(J) of the Social Security Act directs CMS to focus on those DRGs that have a high volume of discharges to post-acute care and a disproportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have *disproportionate* use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to a post-acute care in FY 2004. Clearly 88 percent of DRGs with *any* post-acute care use cannot have *disproportionate* use.

-CMS is capturing DRGs that are not at all *high-volume*. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2070 discharges to post-acute care as compared to DRG 544 (major joint replacement or reattachment of lower extremity) 349,085 discharges to post-acute care. It cannot be argued that while DRG 473 does not have a *high-volume* of discharges to post-acute care, it still has *disproportionate* use. Only 22.7 percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. **CMS' proposed criteria cast far too wide of a net and capture far more DRGs than appropriate.**

-Minor changes in the criteria will have huge impacts on reimbursement to hospitals. For example, in Massachusetts, MHA analysis shows that the negative impact of the expansion of the PAC policy would be decreased by an estimated 60% simply by increasing the transfer rate criterion to 30% and there would be an 80% decrease in the negative impact by changing the transfer rate threshold to 40%. Without backup arguments or data to support the expansion of the PAC transfer policy, it seems that CMS has conveniently tweaked the criteria to maximize budgetary savings.

- CMS proposes to remove the declining length of stay criterion which is directly relevant to the issue CMS claims to be addressing by expanding the PAC transfer policy. The stated purpose of the IPPS transfer payment policy is to avoid providing an incentive for a hospital to transfer patients to another hospital early in the patients' stay in order to minimize costs while still receiving the full DRG payment. The removal of the "declining LOS" criterion seems to have been done to justify an expansion of the policy where there is no evidence that hospitals are changing behavior (transferring patients earlier) to take advantage of the payment system. In fact, while in implementing the policy for the initial 10 DRGs, CMS included an analysis showing that across almost all lengths of stay for each of the 10 DRGs, hospitals would, on average, be paid in excess of their costs even after the implementation of the provision, we have not seen any such data for the new proposed 231 DRGs. We believe expansion of the provision is just a back door budget cut to hospitals – especially given that Health Economics Research,

Inc. in its report of July 31, 2000 showed that short-stay post-acute transfer cases are 7.4 percent more costly than short-stay non-post acute care transfer cases. **While the length of stay may be shorter, the level of services provided during the stay is more intense and costly.**

-The post-acute transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by the AHA and others show that the majority of patients who use post-acute care have longer – not shorter – hospital stays than patients who do not use post-acute care, demonstrating that these patients are truly "sicker" and in need of additional care.

-The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place. The policy disadvantages hospitals that make sound clinical judgments about the best setting of care for patients. Hospitals should not be penalized for greater than average efficiency. Particularly, facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients are disproportionately penalized.

-The PPS payment system depends on the idea of "averaging" where 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 simply reduces payments to short stay low cost cases while not simultaneously increasing payments for long stay cases. This 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. For all practical purposes, such an extensive expansion of the post-acute transfer policy acts as an across-the-board reduction in Medicare payments. It provides a perverse incentive to extend the stay of the patient beyond that which is clinically appropriate, despite the fact that more specialized attention may be provided in a PAC setting. **It appears that the decision to expand the PAC transfer policy has been done for budgetary reasons and CMS has conveniently tweaked the criteria so that almost all DRGs are now subject to a policy that defies the idea of averaging. This change is being proposed without regard to what the right policy is for beneficiaries and the healthcare system.**

-This is particularly problematic given that more than 50 percent of hospitals are already loosing money treating Medicare inpatients and overall Medicare margins have been dropping every year since 1997 to an estimated *negative* 1.9 percent. The AHA estimates that Massachusetts will have the second highest percentage drop in Medicare payments in the nation, an amount in excess of $40 million per year. Massachusetts hospitals comprise only 1.8% of the nation's hospitals but would suffer 4.7% of the impact. This comes at a time when hospitals in the state have had declining Medicare margins for years and more than a third of our hospitals have negative total margins. The drop in Medicare payments due to the expansion of the PAC transfer

policy would convert our already slim Medicare margins to negative and would force many more of our hospitals into the red.

We strongly object to an expansion of the post-acute care transfer policy, which is not in the best interests of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. This provision must be withdrawn in its final rule. Without further review and analysis of the impact on patient care and the impact on other post-acute provider's ability to provide efficient care, CMS should retain the current criteria for determining the post-acute transfer policy.

PROPOSED REDUCTION IN LABOR-RELATED SHARE

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to update the inpatient PPS market basket at least once every five years. CMS proposes to update it every four years, beginning with rebasing and revising the market basket for FY 2006. For FY 2003, CMS rebased the market basket using 1997 data; however, CMS continued to calculate the labor-related share based on the 1992 data. The 1997 data would have raised the labor-related share to 72.5 percent from 71.1 percent, but there was concern at the time that the increase would hurt rural facilities that primarily have area wage indexes (AWIs) below 1.0. *CMS cited the need to conduct additional analyses in deciding to leave the labor related share at the 1992-based 71.1 percent.*

For FY 2006, CMS is proposing to **reduce** the labor-related share from 71.1 percent to 69.7 percent, which is due to the use of more recent data and the removal of postage from the labor-related share. This proposed change, if adopted, would adversely affect hospitals with an AWI greater than 1.0. In the MMA, Congress included a provision that held hospitals with a wage index below 1.0 at a 62 percent labor-related share. The proposed reduction in labor share will have a detrimental affect on high-wage area hospitals while diverting funds back to low-wage hospitals that have already been protected through the MMA

Additionally, we are concerned about the removal of postage from the labor-related categories. CMS's assertion in 2003 that additional analyses are needed still stands today. We believe that CMS should continue to consider this category labor-related until a broader look at the calculation of the labor-related share is taken. We are also concerned about the large drop in the other labor-intensive services category (landscaping, protective services, laundry, etc.). We would urge CMS to investigate this drop and whether it is a result of a flaw in the methodology. For instance, an inappropriately low growth factor could cause an improper category weight and the underestimation of the market basket.

We are concerned about CMS making any changes to the calculation of the labor-related share devoid of a broader plan to refine the methodology. Given that CMS was unable to discover an alternative methodology that is accurate, reliable, and reasonably easy to apply; we believe CMS should leave the labor-related share at 71.1 percent.

MHA urges CMS to leave the labor-related share at 71.1 percent for FY 2006 and recommends that CMS continue investigating alternative methodologies for computing the labor-related share.

UNDERESTIMATION OF THE HOSPITAL MARKET BASKET

The hospital update is based on a market basket factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish inpatient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate inflationary update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

We are deeply concerned that for 7 of the last 8 years, ***the market basket projection has been lower than the actual increase***. While the market basket was over-estimated for a number of years prior to that time, a methodology change was made in 1998 that appears to have over corrected for the previous estimations. CMS reports that, based on the most recent data, the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. We are concerned that ***the methods used to project the market basket increase are flawed and fail to provide a reliable estimate of hospital cost increases.***

We request that CMS review the methodology that was used to determine the projected FY 2005 market basket and revise it for the FY 2006 projection. We also urge CMS to make the details of the calculation available to the public.

HOSPITAL QUALITY DATA

The proposed rule for FY 2006 states several requirements for Hospital Quality Alliance data to be considered submitted for purposes of receiving the full market basket update. These requirements include ***the validation of the hospital's 3rd quarter 2004 data***. While MHA supports the need for validation of the data that are submitted for the HQA to ensure that information is being collected and processed similarly, we note that the law only calls for the submission of the data for hospitals to qualify to receive the full payment update. We believe that Congress recognized that taking submitted data and turning it into information that could be publicly reported is a process, and that there could be imperfections in that process. In linking payment to the *submission* of data, Congress suggested that hospital payments should not be held hostage to CMS or its contractors being able to correctly carry out the processing of the hospital data. The fact that all hospitals in Massachusetts a clear majority around the country are actively participating in the data submission process should not be minimized. As a result, we should not be penalized for meeting the basic mandates of the law.

Further, there is enough evidence of flaws in the validation process-data collection, logistics and processing- to suggest that passing additional validation should not be a criterion for receiving the full Medicare market basket update.

Until the validation process is reliable, MHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update. The CMS' validation process is not currently reliable and needs improvement before it is used in determining which hospitals receive full updates.

WAGE INDEX

Wage Index Calculation Change

The inpatient PPS proposed rule for 2006 contained a change in the wage index calculation. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 in the *Federal Register*.

The change is in the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

1. Determine the ratio of overhead hours to revised hours.
2. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step 1 by wage-related costs.
3. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in step 1. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step 1, which results in an increase in the overhead cost allocated to excluded areas. This change lowers affected hospitals' average hourly wages.

MHA is concerned that CMS would make such a change to the calculation of the wage index with out any discussion. We request that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers should be given an opportunity to comment on this revision to the methodology *before* it is implemented. We believe that this methodological revision will have a significant impact on the wage indexes for some hospitals. **Accordingly, we believe that CMS should return to the established methodology and go through the full notice and comment process before making such a change. We further recommend that hospitals be given an opportunity to withdraw or reinstate their requests for geographic reclassification within 30 days of the publication of the Final Rule.**

Out-Migration Adjustment

Hospitals that qualify for an out-migration adjustment and do not waive the application of the adjustment are not simultaneously entitled to reclassification pursuant to Sections 1886 (d)(8) or (d)(10). Because of significant changes to the wage index that took place in FY 2005, CMS allowed hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the FY 2005 Final Rule. By doing so, CMS acknowledged that changes made between the proposed and final rules could affect whether a hospital was better off accepting the out-migration adjustment or whether it would be more advantageous for a hospital to waive the out-migration adjustment and pursue geographic reclassification.

Although the changes to the wage index are not as extensive for FY 2006, MHA believes there is still a likelihood that revisions made between the proposed and final rules may impact a hospital's choice of whether to accept the out-migration adjustment or whether to apply for geographic reclassification. Thus, MHA requests that CMS implement a policy similar to last year's that allows hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the date that the Final Rule is published.

CMS should release and make available the hospital commuting data collected by the Bureau of Labor Statistics (BLS) utilized by CMS in the out-commuting adjustment. While the data are supposed to be on the BLS website, we have been unable to locate it. This information will assist us in verifying the adjustment calculations and aid us in our research of labor market areas.

We **strongly support** CMS' interpretation of the law that hospitals will receive the same outmigration adjustment in each of the three years of eligibility for the adjustment *(42 CFR 412.64(i)(3)(iii): Any wage index adjustment made under this paragraph (i) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment).* Especially in the case of FY2006, hospitals have based their decision to withdraw their reclassification by the June 20, 2005 deadline on the specific published amount of their outmigration adjustment and MHA recommends that CMS maintain its policy to keep the out-migration adjustment unchanged to minimize uncertainties and instability in Medicare reimbursement to hospitals.

DSH ADJUSTMENT DATA

Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. MHA believes that this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine whether the data based on the federal fiscal year or their own fiscal year is advantageous. **MHA supports CMS' plans to release a MedPAR limited data set for both SSI and Medicare but we strongly object to CMS' decision not to make available Medicaid information.** Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA, states that the Secretary of Health and Human Services must arrange to provide information hospitals need to calculate the Medicare DSH payment formula. This same section in the version of the MMA passed by the House of Representatives states specifically that the Secretary is required to provide the information to hospitals so they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital field has brought this issue regarding the problems of obtaining Medicaid information from the state programs to the attention of CMS for a number of years. CMS then as now, continues to ignore this problem.

CMS states in the rule that it believes hospitals are best situated to provide and verify Medicaid eligibility information and that the mechanisms are currently in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting, and justifying the Medicaid days is problematic, complex, time-consuming and labor

intensive. Moreover, the penetration of Medicaid managed care can add an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals.

We recommend that CMS impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information and that CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state, and that the state make this information available to the providers and contractor audit staff.

PROPOSED LTC-DRG RECLASSIFICATION AND RELATIVE WEIGHTS

A review of the December 2004 MEDPAR data by a Long Term Care Hospital 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. 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. By failing to include data from interrupted stays or from beneficiaries who exhaust benefits, the MEDPAR data is only able to document a small percentage of true LTCH cases. This will result in significant under-funding to LTCH providers.

Therefore, the proposal to recalculate LTCH-DRG using truncated MEDPAR data would effectively reduce LTCH FY 2006 payments by 4.7% (thereby eliminating any market basket updates for FY 2006). LTCH providers have relied on the FY 2006 LTCH-PPS final rule provisions to base their payment levels. Such a substantial change in policy without any consideration of the FY 2006 payment adjustments, will destabilize several LTCH providers and their ability to effectively provide care.

To that end, MHA urges CMS to either implement any proposed DRG changes in a budget neutral manner or provide for a "**dampening policy**" similar to that applied by CMS to APCs under the outpatient prospective payment system. By using more recent data and carefully selecting claims to use in relative weight calculations, a similar dampening policy easily could be and should be considered for application to LTCH-DRG weights.

OTHER ISSUES

Outlier Payments

The rule proposes to establish a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including IME, disproportionate share hospital DSH, and new technology payments, plus $26,675. While this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, we are concerned that the threshold is too high. CMS states in the proposed rule that actual outlier payments for 2005 are estimated to be 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments and that the payments in 2004 were 1.6 percentage points lower than the funds withheld. MHA questions the

inflation methodology used by CMS in coming up with the proposed threshold and strongly urges CMS to adopt the methodology proposed by AHA in its comments.

Occupational Mix Adjustment-Future Data Collection

The occupational mix adjustment to the wage index was intended to control for the effect of hospitals' employment choices rather than geographic differences in the costs of labor. CMS has indicated that the results of the adjustment were counter to the agency's expectations and that nearly one-third of rural areas and over one-half of urban areas would see a decrease in their wage index as a result of this adjustment. Given the expense, administrative effort and time that hospitals have to put into filling out yet another detailed survey and the fact the there are ongoing concerns regarding the data and the impact, **we urge CMS to work with Congress to eliminate this requirement and the adjustment.**

Meanwhile, CMS should release a proposed survey for comment as soon as possible. The sooner the survey is out in the field, the more likely the data will be accurate and reliable. We urge CMS to allow for an appropriate amount of time to develop the survey, provide clear instructions, adapt the systems, collect the data, prepare the survey responses, audit the data, correct the data, and calculate the adjustment. Given that CMS must have the adjustment ready for the FY 2008 adjustment (or the April 2007 proposed rule), **we recommend that CMS release the proposed survey this summer to meet this timeframe and allow hospitals adequate time to prepare for the data collection and reporting.**

Graduate Medical Education- Initial Residency Period

Last year, CMS instituted a new policy for weighting the direct GME resident count for residents that pursue specialties requiring an initial year of broad-based training, such as anesthesiology. The new policy allows the initial residency period to be based on the period of board eligibility for the specialty, rather than the clinical-base year. CMS now further proposes to base the initial residency period on the period of board eligibility for the specialty when a resident matches directly to an "advanced program" without regard to fact that the resident did not match for an initial clinical base-year training program. This would allow hospitals to be paid an entire full-time equivalent (FTE), rather than half of an FTE for such residents until they are board eligible. **MHA supports this change.**

Determination of Relocation Status of Critical Access Hospitals (CAH)

The proposed rule change to impose restrictions on relocating Critical Access Hospitals provides no advance notice or flexibility for those hospitals to maintain their CAH status. As the sole provider of necessary acute care services in the communities, a CAH should be provided the ability to make additional improvements to its facility in order to provide more efficient care and better patient outcomes. The proposed restrictions will prevent many of these providers to make such improvements.

As a result, MHA urges CMS to remove the "under development" criteria as that has no bearing on a CAHs ability to make such improvements now or in the future. Further, the criteria should provide some flexibility in the measures so that providers would only need to meet 3 out of the 5 measures. However, there should be some additional criteria related to a needs assessment

(similar to what is required under the state plans) that shows that the need for the changes and costs related to building in the new area will lead to improved patient care.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (781) 272-8000, ext. 173.

Sincerely,

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care

Submitter : Ms. Mary Therriault **Date:** 06/23/2005

Organization : Healthcare Association of New York State

Category : Health Care Provider/Association

Data

Issue Areas/Comments

GENERAL

GENERAL

Comments regarding Hospital Quality Data. See Attachment.

CMS-1500-P-645-Attach-1.DOC

Hefter
Hartstein
Budden
Krinsky

Attachment 645

Healthcare Association of New York State

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:

Issue Identifier: **Hospital Quality Data**

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. 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.

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

292 GME/AFFIL
IME

TRUONG
LEFKOWITZ
RUIZ
HEFTER
HARTSTEIN

CMS-1500-P-536

Submitter : **Dr. Ian Jackson** **Date:** **06/22/2005**

Organization : **Craniofacial Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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,

Ian T Jackson, MD
Craniofacial Institute
Providence Hospital
St. John Health

Submitter : Dr. Michael Turner **Date:** 06/22/2005

Organization : Indianapolis Neurosurgical Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The new rechargable spinal cord stimulators represent a quantum leap in technology. They allow better treatment of the debilitating chronic pain as well as offer significant cost reduction to insurers over time.

They are more effective because previous totally implantable systems had batteries that were very expensive and required surgery to replace. Therefore we made programming adjustments to optimize battery survival, that limited the effectiveness of the systems. The pulse width , rate of stimulation, and amplitude of stimulation as well as the number of electrodes available for programming are variables that affect battery life. The more juice used, the faster the battery is depleted.
The current rechargable systems remove the necessity to limit battery drain, because they are rechargable. Therefore higher rates, pulse width and amplitues as well as more complex electrode arrays are possible. The current systems are not similar to the radiofrequency external systems. Those systems require an external power source to be attached continuosly to get stimulation. The patients have difficulties keeping the antennae the drives the system attached to the body, often due to motion, and tape allergies. Long term compliance and relief with those systems is limited

The rechargable systems have a predicted battery length of 9 years. The current implantable systems have battery survival that will vary from less than a year to a typical max of 3 years. Each of those battery replacements requires $12-15000 dollars for hardware and surgery and anesthesia costs on top of that for every replacement.

The rechargeabloe systems offer such great patient and cost benefits that I would expect them to become the standard of care in the near future.

Please contact me for further information. I currently implant 50 new stimulator systems each year.

Michael Turner MD
mturner@ingmdgroup.com

CAH/Reloc 294 COLLINS MOREY SMITH HEFTER HARTSTEIN

CMS-1500-P-539

Submitter : Dr. Thomas McIntosh **Date:** 06/22/2005

Organization : Melissa Memorial Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Phone: (970) 854-2500 FAMILY PRACTICE OF HOLYOKE Fax: (970) 854-3440
THOMAS MCINTOSH, M.D.
520 South Interocean
Holyoke, CO 80734

June 21, 2005

Centers for Medicare & Medicaid Services
www.cms.hhs.gov/regulations/ecomments
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am a family physician and have been on the staffs of civilian hospitals for more than 30 years. I have practiced in fairly large city hospitals and very small rural/small town hospitals. Over the years I have seen some hospitals make it and some not make it.

Because small rural/small town hospitals do not have many, if any, large revenue-producing items such as major surgeries and large populations to fill their beds, they need to gather all the income possible to remain afloat. The critical access hospital designation has enabled many of these hospitals to survive.

Unfortunately, many of these hospitals, including my town?s hospital, Melissa Memorial Hospital, have become obsolete or run down with information technology, laboratory, x-ray, outpatient specialty, inpatient, emergency department, surgical, obstetrical, medical records, food service, purchasing and supply, admissions, business office, administration, continuing education, roofing, plumbing, electrical, phone system, asbestos, heating, air conditioning, etc. space, maintenance, or repair needs.

Also, our town is somewhat unique in that our patient population is dependent directly or indirectly upon the local agri-economy. Our patients, therefore, need to be close to their agricultural jobs at all times. Thus, they need primary medical care, and, at least outpatient, specialty care close to their homes and job sites. Because of the above and with the influx of many Hispanic and non-Hispanic people moving to the area for local jobs, we need to upgrade and expand our health care services for these people, including our aging population.

The hospital problems are complicated by the fact that we have little room in which ?to grow? i.e. our hospital and the adjacent family practice clinic are surrounded by streets and houses. In order to meet our current and future health care needs for the area and, at the same time, not disrupt our current health care services, a new hospital will need to be constructed at a location devoid of streets and buildings. (We

Continued?

have such a location). Therefore, our community and health care staff would appreciate your allowing us to go through with these plans without jeopardizing our current and future critical access hospital status.

Now, I could ramble on at great length regarding C.M.S. policies and stumbling blocks, but I am not going to do so. All I know is that I am a family physician, there are sick people here who need the best and closest health care available, and I want to see that that mission is accomplished. Please help us!

Yours for continuation of excellence in rural health care,

Thomas G. McIntosh, M.D.

/cmc
cc: Senator Ken Salazar Fax # (303) 455-8851
Senator Wayne Allard Fax # (970) 461-3658
Representative Musgrave ? District 4 Fax # (970) 521-9685

DRG/GEN 295

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : Dr. Barry Rayburn **Date:** 06/22/2005

Organization : University of Alabama at Birmingham

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Regarding the proposed CPT code for placement of the Acorn CorCap cardiac support device, I feel that the assigned code(s) of 110/111 do not adequately reflect the complexity and expenses required for placement of this device. The Acorn CorCap device has been shown to be efficacious in reducing the clinical manifestations of heart failure, one of the most costly and mortal cardiac conditions, and one which the United States House of Representatives recognized as an epidemic. It requires surgical placement via an open sternotomy procedure under general, endotracheal anesthesia in a patient who is, by definition, seriously ill. The propsed code(s) do not adequately reflect this level of complexity. An alternative existing code that would better reflect the necessary hospital resources utilized would be 108.

Thank you.

296 DRG/GEN

BROOKS
FAGAN
GRUBER
KELLY
HUB
HEFTER
HARTSTEIN

CMS-1500-P-541

Submitter : **Dr. Barbara Czerska** **Date:** **06/22/2005**

Organization : **Henry Ford Hospital**

Category : **Physician**

Issue Areas/Comments

Issues

DRG Reclassifications

June 22, 2005

VIA: ELECTRONIC MAIL

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

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

Dear Administrator McClellan,

Please consider reassignment of the new procedure code (37.41) for Implantation of a prosthetic cardiac support device to DRG 108 from DRGs 110/111. DRG 108 will better reflect the clinical characteristics and resource utilization of this procedure than will the proposed DRGs.

The clinical benefits of the CorCap CSD device are significant. Not only do patients experience improvements in clinical function and quality of life, but the Medicare program can also benefit from the reduction in major cardiac procedures experienced by CorCap CSD patients. If however, the DRG assignment is not changed producing a payment level that reflects the cost of the procedure, neither patients nor CMS will see the benefits of this breakthrough heart failure treatment.

Sincerely,

Barbara Czerska, MD
Medical Director
Cardiac Transplant Program
Henry Ford Hospital

297 DRG/GEN BROOKS GRUBER KELLY HUIE HEFTER HARTSTEIN

CMS-1500-P-543

Submitter : Dr. Margarita Camacho **Date:** 06/22/2005

Organization : North Shore University Hospital and Albert Einstei

Category : Physician

Issue Areas/Comments

Issues

DRG Reclassifications

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

Dear Administrator McClellan,

I served as a principal investigator during the CorCap CSD US Randomized Trial implanting a novel new device for the treatment of heart failure. The procedure to implant this device was recently granted a new ICD-9-CM procedure code to facilitate reporting of the service and implementation of payment policy. While the establishment of a new code is important, establishing adequate payment is even more important. Unfortunately, the proposed payment for the newly established code to describe the CorCap CSD implant (37.41), fails to provide hospitals a payment level that would cover the costs of the device and the procedure to implant creating a situation where hospitals have a disincentive to implant these devices.

The proposed rule provided no explanation as to why 37.41 was assigned to DRGs 110 and 111. This is puzzling since the procedure bears no similarities to other procedures grouping to this payment category. Unlike most procedures in the proposed DRG, the CorCap CSD implant requires a full median sternotomy, full resection of the pericardium to access the heart, and involves an operation directly on the heart itself. When comparing these clinical and anatomical characteristics to other procedures, it is clear that the CorCap procedure is much more similar to procedures in DRG 108 and can be closely compared to an open TMR procedure which also groups to 108. In fact, an open TMR procedure is actually less intensive because it is performed via a thoracotomy rather than a sternotomy and skin-to-skin time is also slightly less: therefore, it is more appropriate to assign 37.41 to DRG 108.

Please reconsider your assignment of 37.41 to DRGs 110/111. Placing it in DRG 108 with other more similar procedures will ensure that patients are afforded the opportunity to benefit from this innovative new therapy for the treatment of heart failure.

Sincerely,

Margarita Camacho, M.D.
Cardiothoracic Surgeon
North Shore University Hospital
Adjunct Associate Professor of Cardiothoracic Surgery
Albert Einstein College of Medicine

298 DRG/GEN

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

CMS-1500-P-544

Submitter : **Dr. Gaetano Paone** **Date:** **06/22/2005**

Organization : **Crittenton Heart Center**

Category : **Physician**

Issue Areas/Comments

Issues

DRG Reclassifications

Dear Administrator McClellan,

As a cardiac surgeon that has been following the CorCap US Randomized Clinical Trial, I am concerned that the payment assignment made for the new procedure code for the implantation of the CorCap device will be inadequate to cover the costs of the procedure. It is clear to me that the CorCap procedure would be more appropriately placed in DRG 108 with procedures such as TMR and other procedures that are performed on the internal and external structures of the heart. These procedures are more comparable both in terms of clinical characteristics and resource utilization.

Thus, I respectfully request that the procedure code 37.41 be reassigned to DRG 108.

Sincerely,

Gaetano Paone, MD
Assistant Professor of Cardiothoracic Surgery
Crittenton Heart Center
University of Michigan Heart Surgery Program

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : **Dr. Geetha Bhat** **Date: 06/22/2005**

Organization : **U of L School of Medicine**

Category : **Physician**

Issue Areas/Comments

Issues

DRG Reclassifications

June 22, 2005

VIA: ELECTRONIC MAIL

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

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

Dear Administrator McClellan,

The proposed rule establishing payment for inpatient hospitals in FY2006 announced the creation of a new procedure code describing the implantation of the CorCap Cardiac Support Device. 37.41-Implantation of prosthetic cardiac support device was assigned to DRGs 110 and 111-Major cardiovascular procedures with and without complications and comorbidities. Assignment to this payment category will fail to adequately reimburse hospitals for the costs they incur during the procedure and the subsequent care provided to patients.

This procedure is more appropriately compared to procedures falling under DRG 108 ? Major Cardiothoracic procedures. This DRG also contains the codes describing open transmyocardial revascularization a procedure that closely parallels the CorCap implant. Like the CorCap procedure, open TMR is a procedure involves a full circumferential pericardiotomy and is performed directly on the surface of the heart. If you specifically look at some indicators of relative resource utilization, you will find that skin-to-skin time is actually slightly greater than with open TMR although lengths of stay are equivalent.

I have seen first hand how my patients responded following CorCap implantation. Without the device many of them would have faced further decline potentially requiring expensive LVADs or heart transplants. I urge you to reconsider the DRG assignment and instead place 37.41 in DRG 108 to assure that patients are not denied access to this potentially life-saving device due to inadequate reimbursement policy.

Sincerely,
Geetha Bhat, PhD MD FACC
Heart Failure/Cardiac Transplant Center
U of L School of Medicine and Jewish Hospital
And
Professor of Medicine
Division of Cardiology
University of Louisville

300

NURS/AN/PHARM

TRUONG
LEFKOWITZ
RUIZ
HEFTER
HARTSTEIN

CMS-1500-P-547

Submitter : **Dr. Randy Kuiper** **Date:** **06/22/2005**

Organization : **Dr. Randy Kuiper**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear CMS:

I am a pharmacist who works at Benefis Healthcare in Great Falls, Montana. As clinical pharmacy cordinator, I oversee all the clinical activities of our pharmacists within the hospital. We have pharmacists who are specialists that have received specialty training in 2nd year specialty pharmacy residencies. For example, we currently have a pharmacist who serves the unique needs of our pediatric ward and neonatal intensive care unit. To obtain these skills he completed a specialty residency in pediatrics. We would not have a pharmacist able to provide the high level of care we currently provide to these patients were it not for specialized pharmacy residency programs.

It is absolutely vital that the funding of the specialty residencies be maintained as they are vital to the provision of specialized care in our nation's hospitals. We currently have alot of difficulty finding applicants for positions with these unique skills. Cutting this funding would make it even more difficult and adversely affect our ability to provide high quality specialized care to our patients.

Sincerely,
Randy Kuiper, PharmD BCPS FASHP RPh
Clinical Coordinator
Benefis Healthcare
1101 26th Street South
Great Falls, MT 59404
406-453-8928

Submitter : Dr. Jason Crompton **Date:** 06/22/2005

Organization : University of Utah Hospitals and Clinics

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

I wish to express serious concern over the failure of the proposed Hospital Inpatient Prospective Payment System (HIPPS) rule to restore funding for specialized pharmacy residency programs for the 2006 fiscal year.

As a former pharmacy practice and specialized resident and a current residency preceptor, I know the value of such programs to providing well-educated pharmacy practitioners to the healthcare community. On a daily basis, I am involved as an integral part of the multidisciplinary medical team that includes fellow physicians, surgeons, and nurses. The value of a pharmacist in this practice model is critical to improve patient outcomes, optimize therapy, and prevent medical errors. I speak from the experience of working in a field where drug regimens are complex due to number of medications and the multiple drug characteristics one must consider in appropriate usage.

As a preceptor, I am concerned on the impact of this proposed change to the HIPPS on our residency program. Our program is dependent on this support for financial sustainability. The need for specialty trained pharmacists in solid organ transplant is growing as noted recently by the United Network for Organ Sharing (UNOS) who revised their bylaws to recommend all transplant programs include a pharmacist. Additionally, the structure of our pharmacy team is dependent on our specialized resident for the critical tasks of inpatient and outpatient care including the detailed patient counseling received at discharge after transplant and 24/7 on-call availability for new transplants and readmissions.

Furthermore, our transplant program does not consider any candidates for pharmacist positions without the experience of a specialized residency. In the event that the HIPPS rule passes under current wording, the number of eligible candidates may be drastically reduced. This is particularly concerning given the recent start of both liver and pancreas transplant programs at our institution that will demand another pharmacist position. Given the complex nature and depth of our practice areas, along with other major areas such as cardiology, gastroenterology, oncology, it is absolutely necessary to have pharmacy providers with formal, focused training in the respective field to understand the fine intricacies of the disease states and medications.

In consideration of continued funding for second-year specialized residencies, one must look at the long-term impact of specialty-trained pharmacists on medical costs and clinical outcomes. Without such analysis, removal of funding is short-sighted and will most certainly lead to future increased medical costs as a result of not having appropriately tailored medical therapy\.

Sincerely,

Jason A. Crompton, Pharm.D.
Clinical Pharmacist
Solid Organ Transplant Program
University of Utah Hospitals and Clinics

302 NT

TREITEL
WALZ
HEFTER
HARTSTEIN

CMS-1500-P-581

Submitter : **Dr. Allen Burton** **Date:** **06/22/2005**

Organization : **UT MD Anderson Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir(s):
On behalf of MD Anderson and my patients, I appreciate the opportunity to submit commentary on the proposed rule CMS-1500-P. I am specifically writing to request that CMS grant the new technology add-on payment request for rechargable implantable neurostimulators.

This technology is a significant advance over previous RF and non-RF systems in that it allows the patient to be untethered from any external power source while utilizing their stimulator to maximal effect, without the constant need to limit battery usage. RF systems are unwieldy, especially in a hot humid climate like Texas where with a sweaty patient, the old RF unit will become non-functional.

In the long run, this technology will save a great deal of CMS dollars by avoiding the need for frequent re-operation/battery changes.

I appreciate the agencies recognition of access to newer, better technologies for Medicare patients.

Sincerely,

Allen W. Burton, MD
UT MD Anderson Cancer Center
awburton@mdanderson.org

CMS-1500-P-532

pH

Submitter : Scott Clark **Date:** 06/22/2005

Organization : National Surgical Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attached Document

CMS-1500-P-532-Attach-1.PDF

CMS-1500-P-532-Attach-2.PDF

CMS-1500-P-532-Attach-3.PDF

30 South Wacker Drive
Suite 2302
Chicago, Illinois 60606

312 627 8400 Phone
312 474 1950 Fax

June 21, 2005 Attachment 532

National Surgical Hospitals

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

Re: File Code CMS-1500-P: Medicare Program- Clarification of the Definition of "Hospital" in Connection With Specialty Hospitals

Dear Dr. McClellan:

National Surgical Hospitals ("NSH") welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed clarification of the definition of "hospital" in connection with specialty hospitals, as published in the May 4, 2005 *Federal Register*. NSH, the nation's leading developer and manager of specialty surgical hospitals, is pleased to provide information relevant to CMS'examination of the definition of "hospital" as applied to healthcare facilities in the country. NSH is a partner in 15 surgical facilities specializing in orthopedics, neurosurgery, and more complex general surgery cases.

Section 1861(e) of the Act provides a definition for a "hospital" for purposes of participating in the Medicare program. In order to be a Medicare-participating hospital, an institution must, among other things, be primarily engaged in furnishing services to inpatients. This requirement is incorporated in CMS regulations as a condition of participation for hospitals at 42 CFR 482.1. CMS has advised that any "institution that applies for a Medicare provider agreement as a hospital but is unable to meet this requirement will have its application denied in accordance with our authority at 42 CFR 489.12." We note that CMS has extended this caution to all "institutions that have a Medicare hospital provider agreement but are no longer primarily engaging in furnishing services to inpatients". These existing institutions are subject to having their provider agreements terminated pursuant to 42 CFR 489.53.

CMS has expressed concern that some institutions that describe themselves as surgical or orthopedic specialty hospitals may be primarily engaged in furnishing services to outpatients, and thus might not meet the definition of a hospital as contained in section 1861(e). Therefore, CMS has initiated a review of its procedures for hospital certification to, "determine whether additional or different standards should apply to specialty hospitals in light of the focused nature of their services". (See *Medicare Fact Sheet*, June 9, 2005)

While NSH recognizes the concerns expressed by CMS we feel the agency is misguided in attempting to redefine hospital for purposes of Medicare certification. CMS seems to have undertaken this initiative in a rushed and haphazard fashion without a compelling reason to disturb the established certification process. As discussed below, the proposed "clarification" is unneeded at this time as CMS has better alternatives to pursue in correcting the payment system rather than corrupting long-standing definitions.

First, NSH believes CMS should clarify what it is actually proposing under its May 4, 2005 proposed rule as published in the *Federal Register*, p. 23447. The proposed rule refers to possible changes intended as "clarification of the definition of a hospital as it relates to 'specialty hospitals'". However, the text of the proposed rule suggests no changes in the law. Instead, it discusses the possible selective and amplified application of one of the existing elements of the definition of hospital, as applied to specialty hospitals. This is not a change in law but rather a change in interpretation and enforcement. CMS added more confusion in publishing a *Medicare Fact Sheet* on June 9, 2005 informing the public that, "CMS will review its current standards for approval for participation and payment, to determine whether additional or different standards should apply to specialty hospitals in light of the focused nature of their services." We are left to wonder what CMS intends with its proposed rule. Is CMS seeking to redefine hospital or recalibrate its enforcement? Does the agency intend to add new and different criteria to the definition of hospital or re-interpret existing law? This lack of clarity in the CMS proposed rule hinders our ability to provide useful comments.

Second, NSH is concerned that CMS has decided to undertake this clarification of the definition of a hospital only as to specialty hospitals. This narrow focus would be highly discriminatory and lacking both legal and logical justification. While specialty hospitals are of interest to CMS, partly because of section 507 of Pub. L. 108-173, the statutory definition of hospital and the Medicare hospital certification requirements do not provide for a separate set of rules for different types of hospitals. In particular, we believe that CMS is misguided in considering a plan to selectively enforce one particular element of the hospital definition against specialty hospitals. Singling out specialty hospitals for more stringent measurement against the "primarily engaged in furnishing services to inpatients" standard of the Act presents substantial equal protection concerns. A valid statute may be rendered invalid as violative of equal protection if its provisions are selectively enforced.

CMS has very seldom relied upon the primarily engaged standard in declining to certify a hospital applicant or in revoking the certification of an existing hospital. The "primarily engaged" standard is not statutorily defined nor is there a body of case law or administrative interpretations adequately defining what it means for a hospital to be primarily engaged in furnishing services to inpatients. Should CMS choose to heighten its scrutiny of compliance with the "primarily engaged" standard it must do so even-handedly and in a non-discriminatory manner. All hospitals, large and small, general and specialized, urban and rural, must comply. The law makes no allowance for CMS to consciously and deliberately enforce certain requirements against some hospitals, while premeditatedly abstaining from enforcement of the same requirements against others.

We anticipate that CMS will act in compliance with the law and consistent with their representations in the May 4, 2005 proposed rule. CMS stated that "institutions that have a Medicare hospital provider agreement but are no longer primarily engaging in furnishing services to inpatients are subject to having their provider agreements terminated pursuant to 42 CFR 489.53." CMS should note that an unbiased application of this standard might well result in the termination of Medicare provider agreements for **over 620 hospitals**. This is based upon analysis of 2003 Medicare admissions data for all hospitals. Lacking a clear definition of the meaning of primarily engaging in furnishing services to inpatients, we have assumed that primarily engaged means performing more inpatient cases than outpatient cases.

The preceding analysis highlights several other problems with the proposed rule. The first of these is the definition of "primarily engaged in furnishing services to inpatients". Does this mean a bear majority of cases performed at the hospital must be inpatient cases? How are these cases counted, i.e. what type of cases are included in the inpatient count? Should the measurement of primarily engaged be based upon revenues rather then case numbers? It is interesting to note that CMS itself in a recent specialty hospital related publication has used a 45 percent standard in trying to define primarily engaged.[1] These and other questions leave hospitals to guess as to their status under the law.

Previous attempts by CMS to define "primarily engaged" have been less than illuminating. In an October 25, 2002 Program Memorandum addressing the definition of hospice, CMS explained, "Although the law does not explicitly define its expectations for 'primarily engaged', CMS has interpreted it to mean exactly what it says, that a hospice provider must be primarily engaged in providing hospice care and services." It is hoped that if CMS chooses to terminate Medicare hospital provider agreements based on a determination that a facility is no longer primarily engaging in furnishing services to inpatients, the agency will have a more precise and intelligible standard of measure than the tautology stated above.

Finally, NSH sees significant practical difficulty for CMS in carrying out its intention to deny the application of any institution that applies for a Medicare provider agreement as a hospital but is unable to meet the primarily engaged requirement. How will CMS decide whether a new facility, which is not yet open for business, is primarily engaged in inpatient care? How will such a facility be identified as a specialty hospital if the definition of specialty hospital requires the examination of cases performed? As a practical matter, a new hospital is not able to predict, with a high degree of certainty, what type of cases and the case mix that will come to the facility. This will leave both CMS and hospital administrators to question whether and how a modified definition of hospital applies to a specific facility.

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[1] See CMS letter dated June 9, 2005 to State Survey Agency Directors – "Hospitals – Suspension of Processing New Provider Enrollment Applications for Specialty Hospitals". The letter states: "For purposes of this suspension, specialty hospitals are identified as those hospitals that have attested to the FI that: 1) they are primarily engaged in cardiac, orthopedic, or surgical care; or 2) project they will have a least 45 percent of inpatient cases in cardiac, orthopedic, or surgical care."

NSH recommends that CMS be very circumspect in attempting to redefine hospital for purposes of Medicare certification. As yet, there has been no compelling reason presented which should cause CMS to create additional or different standards of certification for any type of hospital. If, as CMS conjectures, there are incentives for some surgical cases to be brought to specialty hospitals rather than other sites, this issue should not be addressed through definitional changes. Rather, CMS and healthcare in general, will be better served by changing the DRG system and ASC reimbursement schedule to eliminate the site of service differential. This levels the reimbursement playing field without creating artificial and unnecessary distinctions between specialty and other hospitals. NSH commends CMS for its insights into the reimbursement problems, as set forth in the May 2005 specialty hospital study presented to Congress.

NSH asks that CMS resist suggestions that a discriminatory enforcement policy be adopted to punitively terminate Medicare provider agreements for hospitals which perform a substantial number of outpatient cases. The trend in healthcare is decidedly towards outpatient care and it would be a poor healthcare policy decision to remove from the Medicare provider rolls those facilities which provide both inpatient and outpatient services, but have special capacity to provide outpatient care. If any change is to be made in the definition of hospital it should be to temper the primarily engaged standard to better reflect current healthcare policies and practices.

Sincerely

Scott B. Clark

Scott B. Clark
Vice President and General Counsel

SBC:sm

Submitter : **Pettis Susan** **Date: 06/22/2005**

Organization : **Clifton Springs Hospital & Clinic**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-529-Attach-1.DOC

Attachment 529

Clifton Springs Hospital & Clinic

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, Clifton Springs Hospital & Clinic believes that the final rule governing the FY'06 Inpatient PPS should establish a clear documentation and communications process for this purpose. Additionally, Clifton Springs Hospital & Clinic 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, Clifton Springs Hospital & Clinic 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. Clifton Springs Hospital & Clinic proposes that any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- Clifton Springs Hospital & Clinic 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, Clifton Springs Hospital & Clinic 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. Clifton Springs Hospital & Clinic 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 Clifton Springs Hospital & Clinic hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). Clifton Springs Hospital & Clinic 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.

Thank you for the opportunity to submit our opinions on this matter.

June 22, 2005

Submitter : **Mr. Kenneth Tobias** **Date:** **06/22/2005**

Organization : **Ardent Health Services**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Wage Data Provider Based Clinics

Comment to Proposed Changes to the Hospital Inpatient Prospective Systems and Fiscal Year 2006 Rates

See Attachment

CMS-1500-P-527-Attach-1.DOC

Attachment 527

Wage Data – Provider Based Clinics

Comment to Proposed Changes to the Hospital Inpatient Prospective Systems and Fiscal Year 2006 Rates

Provider Based Clinics (defined below) should be designated as IPPS "Excluded Areas" for purposes of IPPS wage index and the associated wage data should be removed accordingly.

It is important to accurately define "Provider Based Clinics", as described in the FY2006 proposed rule, so as to separate by difference those services which are provided in "departments of a provider".

"Departments of a provider", according to §413.65(a)(1)(J), "perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments). Further, "departments of a provider", according to §413.65(a)(2) **may not** by itself be qualified to participate in Medicare as a provider under §489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity."

"Provider-Based entity", according to §413.65(a)(2), "means a provider of health care services... that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section... A provider-based entity **may**, by itself, be qualified to participate in Medicare as a provider under §489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity."

According to the OIG 2004 Red Book (October 22, 2004), "Hospitals often purchase a variety of other medical entities, such as physician practices... Under Medicare, hospitals may account for medical entities they own either as freestanding or as part of the hospital. If a hospital accounts for an entity as part of the hospital, it is referred to as a "provider-based" arrangement. This arrangement requires approval from CMS."

Provider Based Clinics, for purposes of this comment should be described as "hospital-owned provider-based physician practices" and accordingly defined similar to the definition as described in the OIG reference above.

Therefore, since a "hospital-owned provider-based physician practice" may, by itself, be qualified to participate in Medicare as a provider under §489.2, "provider based clinics", better described as "hospital-owned provider-based physician practices" by definition are not "departments of a provider."

These "hospital-owned provider-based physician practices" are reported on the main provider's Medicare cost report as an outpatient service cost center, on Worksheet A, Line 60. Similarly, RHCs and FQHCs, as mentioned in the FY2006 proposed rule, are "reported on the main provider's Medicare cost report as an outpatient cost center. However, for purposes of IPPS wage index, to date, only hospital-owned provider-based RHCs and FQHCs have been removed, reasoned by CMS that the services provided were not paid for under the IPPS. Importantly, neither are the services provided by "hospital-owned provider-based physician practices" paid for under the IPPS.

Regardless of whether a Provider Based Clinics, better described as a "hospital-owned provider-based physician practice" is or is not a "department of the provider", it is important to note the OIGs perspective on Provider-Based designations.

The OIG, in its OIG 2004 Red Book (October 22, 2004), has proposed that CMS should eliminate "provider-based" designations for hospital-owned physician practices and other entities reasoning that "hospitals purchased entities such as physician practices and billed for these entities as "provider-based" without CMS approval. CMS regional offices and fiscal intermediaries did not consistently follow CMS processes for review and approval of provider-based status and were frequently unaware of hospital practices in purchasing and billing for other entities." Accordingly, in its Work Plan for FY2005, the OIG states it will continue to "determine the extent to which health care entities that have been designated as "provider based" are in compliance with requirements for receiving this designation.

Therefore, another question for discussion is, if those reported provider-based hospital-owned physician practices are truly not provider-based and there is no resolve to determine which of those entities are actually freestanding entities, would it be more accurate and practical to the determination of wage index to exclude all hospital-owned provider-based physician practices?

Lastly, with regard to the statement made in the FY2006 proposed rule that CMS has "historically included the salaries and wages of hospital employees working in the outpatient departments in the calculation of the hospital wage index since these employees often work in both the IPPS and in the outpatient areas of the hospital" is inaccurate with respect to "hospital-owned provider-based physician practices".

"Hospital-owned provider-based physician practices" referred to as Provider Based Clinics in the FY2006 proposed rule do not provide employee services to the inpatient type activities or IPPS areas of a hospital. Where an entity meets the criteria as promulgated in §413.65, the cost of non-professional services have been deemed by CMS to be most appropriately categorized as Outpatient and therefore reimbursed using the OP PPS methodology. Consistent with CMS' own philosophy regarding separate and distinguishable reimbursement for such services, the wage related cost of these services should likewise be separate and distinguishable from the inpatient services used to determine the inpatient wage index.

In summary, "Hospital-owned provider-based physician practices" referred to as Provider Based Clinics in the FY2006 proposed rule should be designated as IPPS "Excluded Areas" for purposes of IPPS wage index, because these hospital entities are not "departments of the provider", they are strictly outpatient services providers unrelated to the inpatient services of the main hospital, and they are not reimbursed under IPPS. (All similar reasons for the exclusion from wage index of RHCs and FQHCs)

Submitter : Ms. Ellen Kugler **Date:** 06/23/2005

Organization : National Association of Urban Hospitals

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1500-P-616-Attach-1.DOC

Attachment 6/2

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

June 23, 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: Post-acute-care transfers

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals to express our opposition to the proposal by the Centers for Medicare & Medicaid Services (CMS) in the FY 2006 Medicare inpatient PPS regulation to extend the Medicare post-acute-care transfer policy from the current 21 Medicare DRGs to 238 Medicare DRGs.

We oppose this proposed change for several reasons.

First, we believe that this policy would unfairly and disproportionately harm urban safety-net hospitals such as those represented by the National Association of Urban Hospitals. Because of the broader mix of services these hospitals provide and their tendency to care for the more severely ill patients covered by this policy, and because they have more post-acute-care options than other hospitals because of the more densely populated regions in which they are located, these hospitals are much more likely to be affected, and much more likely to be hurt, by the extension of the post-acute-care transfer policy to 238 DRGs. CMS has an appropriate goal of reducing average length of stay in hospitals, but the extension of this policy would penalize hospitals for helping the agency meet this worthwhile goal.

Second, we believe that the proposed method of paying for cases involving post-acute transfers undermines the incentives built into the Medicare inpatient prospective payment system – and shortchanges many hospitals in the process. The DRG system is based on averages, and under this proposal, hospitals that transfer patients to post-acute-care settings in a period of time more than one day shorter than the average length of stay receive less than the full DRG payment, which is based on an average case. This has the effect of penalizing hospitals that have managed to treat patients quickly – in effect, penalizing them for their efficiency. Medicare has worked hard to foster this behavior over the years, and now it proposes to punish hospitals for it. While hospitals that care for patients more than a day less than the average length of stay are penalized for such timely transfers, those that must care for patients longer than the average length of stay do not receive additional reimbursement (unless they become outliers). When the averages that constitute DRGs are calculated, they take into account both cases that fall below the average length of stay and those that fall above the average. We do not understand why all cases are not paid the DRG amount as is intended by the DRG system.

Third, the proposed regulation does not address the problem posed by inhomogeneous DRGs, which include more than one distinct type of case and different average lengths of stay within the same DRG. NAUH believes that using a severity-based DRG system would help alleviate this problem, but applying the proposed policy to the current DRGs will exacerbate both the systematic underpayments and

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

systematic overpayments of providers in some cases. We do not believe CMS should either underpay or overpay for any care.

Fourth, we believe that the proposed regulation would expand the post-acute-care regulation to too many DRGs. Originally, the regulation applied to 10 DRGs, and then, it was expanded to the current 21. The original 10 were selected based upon "a high volume of discharges to postacute care and a disproportionate use of postacute services," as were the additional 11 to which the policy was extended. We do not understand how an additional 217 DRGs – roughly 44 percent of all DRGs – can possibly be considered to have "a disproportionate use of postacute services." While the enabling legislation authorized the Department of Health and Human Services to extend the regulation to additional DRGs, we believe that CMS has already extended the policy to DRGs with "a disproportionate use of postacute services" and should extend it no further. As it is, the proposed policy is not budget-neutral and will result in a reduction in federal Medicare expenditures. The National Association of Urban Hospitals believes that CMS should not reduce Medicare hospital expenditures by potentially hundreds of millions of dollars, hurting many hospitals, without specific direction from Congress to do so.

For these reasons, we urge CMS to remove the provision extending the post-acute-care transfer policy to 238 DRGs from the final version of the FY 2006 Medicare inpatient PPS regulation.

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.

Sincerely,

Ellen Kugler, Esq.
Executive Director

Submitter : Mr. Russ Ranallo

Organization : Owensboro Medical Health System

Category : Hospital

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-542-Attach-1.DOC

Attachment 542

June 16, 2005

The Honorable Mark B. McClellan M.D., Ph.D
Administrator
The 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 the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.

Dear Administrator McClellan:

The Owensboro Medical Health System (OMHS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule which establishes new policies and payment rates for hospital inpatient services for fiscal year (FY) 2006. We are pleased by CMS' openness in soliciting comments on the numerous changes it proposes to this remarkably complex and difficult payment system.

Attached are our detailed comments regarding CMS's proposed changes to the inpatient payment system, including those related to the wage index, transfer DRG, occupational mix adjustment, and other areas.

We appreciate the opportunity to provide comments on the Proposed Rule on Changes to the Medicare Inpatient Prospective Payment System and Payment Rates for Fiscal Year 2006. We hope that CMS will consider our recommendations and make the appropriate adjustments. Please feel free to contact me at (270) 688-2855 if you have any questions or if you require additional information.

Sincerely,

Russ Ranallo
Vice President, Financial Services

Owensboro Medical Health System
Comments on FY 2006 Medicare Hospital Outpatient PPS
October 1, 2006

Occupational Mix and Blended Wage Index

Again, OMHS is concerned with the lack of apparent impact of occupational mix on the wage index for FY 2006.

On July 23, 2002 Glenn Hackbarth, Chariman of the Medicare Payment Advisory Commission provided testimony to the Subcommittee on Health Committee on Ways and Means regarding adjusting Medicare payments for local market input prices.

According to the testimony the objective of the occupational mix adjustment "is to account for differences beyond the control of the provider – local market prices – and not for the differences created by management decisions – the mix of labor. Thus, using aggregate wages and hours may distort the wage index by elevating the average wage per hour in markets where providers employ a costly mix of labor and depressing the average wage in markets where hospital employ a relatively inexpensive labor mix. These inaccuracies in the wage index may have substantial effects on payment accuracy."

CMS has only included a 10% occupational mix impact in the proposed FY 2006 Blended Wage Index. We disagree with this position. By not factoring in the occupational mix adjustment at a higher percentage, the problems and inequity that reside in the wage index continue to exist. Those providers that have employed a cheaper occupation mix should no longer continue to be punished through lower payments while those hospitals that employ a more expensive mix are rewarded for their inefficiency.

We agree with the judgment in the Bellevue Hospital Center v. Leavitt case that the relevant sentence of the statute is mandatory and that Congress did not give the Secretary the authority to implement the occupational mix adjustment beginning October 1,2004 other than in full.

We are requesting that CMS review the position and change the Blended wage index to include 100% of the average hourly wage adjusted for occupational mix. We believe that hospitals were provided with enough time and several opportunities to ensure that the data collection was accurate. CMS seems to be more concerned with not changing the status quo and impacting providers rather than fixing an inequity that many hospitals have suffered under for years. We ask for the higher percentage to help those providers negatively impacted by the inaccuracy.

Hospital Redesignations and Reclassifications

We do not believe the current rules regarding wage reclassifications are equitable when applied to single-hospital CBSAs. While it is true that the hospital in a single-hospital CBSA receives it own unique index, CMS fails to realize that the rules allow other

hospitals within the same region to access wage indices that are ***higher*** than what their own unique wage index would be.

For example, Owensboro Medical Health System (OMHS) is in a single-hospital CBSA (#36980) with a proposed wage index of .8806. The Medical Center of Bowling Green and Greenview Hospital reside in a CBSA (#14540) less than 50 miles away with a wage index of .8222. However, both hospitals are reclassified to the Nashville MSA with a wage index of .9757. These hospital secure millions more in Medicare payments per year even though its wage rate is lower than OMHS.

The vast majority of hospitals that reclassify their wage index are securing an index that exceeds an index that would be capped at their own wage rate level. That is, these hospitals are receiving payments in excess (or greater than 100%) of the wages they are currently paying.

Hospitals that reside in Single Hospital CBSAs cannot access an index adjustment that would afford them these additional payments and consequently are put at a disadvantage in acquiring staffing, technology, and physical plant with competitors in their region.

We recommend that CMS allow single-hospital MSAs to pursue reclassifications to other areas area where the index may be higher.

Another alternative would be to never allow a hospital to receive a higher wage index through reclassification or rural floor than its own hospital hourly rate compared to the national rate. This would eliminate some of the inequity that exists among providers.

Post-acute Care Transfers

OMHS opposes any expansion of the post-acute care transfer policy to additional DRGs.

In 2003, after "an extensive analysis to identify the best method by which to expand the transfer policy," the agency adopted four specific criteria that a DRG must meet, for both of the two most recent years for which data are available, in order to be added to the post-acute care transfer policy:

1. The DRG must have at least 14,000 cases of post-acute care transfers;
2. The DRG must have at least 10 percent of its post-acute care transfers occurring before the mean length of stay for the DRG;
3. The DRG must have a length of stay of at least three days; and
4. The DRG must have at least a 7 percent decrease in length of stay over the past five years (1999 – 2004).

This resulted in expanding the provision from 10 DRGs in FY 2003 to 29 DRGs in FY 2004. Now, only two years later, the agency is proposing to adopt replacement set of alternative criteria that would be applied to the DRGs. The new criteria state that the DRG

only needs to have 2,000 cases of post-acute care transfers, and the percentage of transfer cases that are short-stay transfer cases is at least 20 percent of the discharged cases. Of this 20 percent at least 10 percent of the cases are discharged before the mean geometric length of stay. That means a DRG could qualify to be a transfer DRG with only 200 cases that are discharged before the mean geometric length of stay vs. a minimum of 1,400 cases under the current criteria to qualify as a transfer DRG.

OMHS objects to the implementation of alternative criteria for which there is no sound policy rationale. We fail to see how 2,000 post acute discharges can be considered "relatively high volume" in contrast to the current methodology that uses 14,000 total post acute care transfer cases as the benchmark.

Further, we believe this expansion of the transfer policy weakens the incentives inherent in the inpatient prospective payment system. A new transfer policy covering 223 DRGs would effectively undermine and incentive based system fueled by per-case cost control, to one focused on per-diem costs.

We do not believe that the expansion would be in the best interests of the patients or providers. We ask that the provision be withdrawn in its final rule.

We have also reviewed specific DRGs within the proposed lists of transfer DRGs and have the following comments:

DRG 107 Coronary Bypass with Cardiac Cath

We have strong concerns that DRG 107 is not included as a proposed Special Pay DRG under the transfer DRG proposed methodology.

We do not understand the logic behind DRG 109 (Bypass without Cardiac Cath) being included in the Special Pay DRG listing and DRG 107 (a higher intensity service) not being included in the listing.

We reviewed the cases we have incurred and have determined that these cases experience more than half of the cost per case in the day of surgery (typically day one). We request that CMS either remove this DRG from the transfer DRG list or change the status of the DRG and include it in the list of special pay DRGs.

DRG 108 Other Cardiothoracic Procedures

We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 8,878 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 126 Acute & Subacute Endocarditis
We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 5,823 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 440 Wound Debridement for Injuries
We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 5,613 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 473 Acute Leukemia w/o Major OR Procedure
We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 8,778 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 485 Limb Reattachment, Multiple Significant Trauma
We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 3,420 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 487 Other Multiple Significant Trauma
We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 4,644 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 285 Amputation of Lower Limb

We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 7,623 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 287 Skin Grafts & Wound Debridement

We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 6,114 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

DRG 20 Nervous System Infection

We do not understand how this DRG could be included as a proposed Transfer DRG.

Table 7A of the proposed rule states that the DRG had 6,532 discharges.

In order to meet the criteria to be on the list, the DRG needs to have at least 10,000 discharges (2,000 minimum transfer and 20% of the total = 10,000 minimum necessary). The DRG does not have a pair based on co-morbidity. We request that this DRG be removed form the transfer DRG list.

If CMS chooses to impose the expanded transfer policy, we would ask that each DRG be reviewed again to ensure that it meets the criteria to be included as a transfer DRG.

Rural Referral Centers

Several hospitals that qualified for Rural Referral Center (RRC) Status that once were in rural areas are now designated in urban areas due to population growth over time. These hospitals have been allowed to keep their RRC status and access special wage index rules

while their counterparts in other nearby urban areas (that have never been rural) are denied this opportunity.

We believe there are some hospitals that, due to geography and market size, are located in an urban area yet serve a high number of rural patients. As CMS has noted, RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular hospital is physically located in a rural or an urban area. We are asking CMS review the RRC criteria and revise it so that urban hospitals can qualify for RRC status if it can meet all the criteria except residing in a rural area. This would allow urban hospitals to be put on the same level as their Urban RRC counterparts and provide equal access to the benefits afforded by the status.

CC List

While we understand the reasoning behind the proposal of code 424.0 (Mitral valve disorder) being removed from the CC list, we ask CMS to review this code again. Our analysis of our internal records shows that cases with this code have higher treatment costs on certain conditions than those same conditions without the code. We ask that CMS keep on the CC list.

308

CMS-1500-P-553

Submitter : Dr. Arthur Malkani

Organization : R. G. Shea, M.D., P.S.C.

Category : Physician

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1500-P-553-Attach-1.DOC

June 22, 2005 Attachment 553

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

Dear Dr. McClellan:

I am an orthopaedic surgeon who works at the University of Louisville taking care of patients with Medicare, Medicaid, and private insurance. I have been in practice now for 12 years doing total joint replacement.

The traditional polyethylene liners in total hip arthroplasties used to wear at a rate of greater than .1 mm per year and would lead to significant osteolysis, bone loss, and revision surgery, especially in younger patients. I have several patients who have had hip replacements done in their 20's, and by the time they are 30-years-old, they have absolutely no bone for fixation, leading to the use of substantial allograft (cadaver) bone with high complication rates and decreased functional outcomes.

In an effort to alleviate these problems of hip arthroplasties in more active patients, the ceramic technology has shown great promise with almost seven-year data at the present time. I am confident that the use of ceramic hips will decrease the overall cost in health care by decreasing the incidents of revision hip arthroplasty performed in these active patients who will eventually wear out their hips.

The other alternatives we have in younger patients are the metal-on-metal hips. However, these are somewhat concerning because of the metal ion levels in these patients, and we do not know the long-term consequence of these high levels of cobalt in these patients. These metal-on-metal hips are contraindicated in younger patients during pregnancy and in patients with impaired renal function. If a 40-year-old patient who undergoes a total hip arthroplasty with a metal-on-metal hip and decides to become pregnant, we would have a real problem.

I would encourage you to consider recognizing the ceramic-on-ceramic technology for a higher DRG payment to hospitals. As physicians, we are at crossroads since we want to use the best technology for our patients which will give them a durable implant that will last for a long time. However, we are challenged by the hospital administrator saying that the DRG does not provide for this additional expense in their budget.

I would be happy to answer any questions you may have.

Yours truly,

Arthur L. Malkani, M.D.
Associate Professor
Chief Adult Reconstruction
University of Louisville

ALM/ce

Submitter :

Organization :

Category : **Nurse**

Date: 06/22/2005

Q Data
Hefter
Hartstein
Balden
Kinsot

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-554-Attach-1.DOC

Attachment 554

Baptist Memorial Hospital for Women
Memphis, Tennessee

Hospital Quality Data

Thank you for allowing us to submit our concerns.

Data Submission

Data definitions should be stated clearly, and hospitals need to have access to information that does not require a lengthy search on the Q-net exchange. Changes need to be communicated to hospitals at least 90 days prior to their taking effect in order for hospitals to be able to comply. It would be helpful to have a process in place that insured that hospitals had received notification of changes.

Data Validation

The parameters of the validation process should be stated clearly. Currently, by the time feedback data is received on a quarter of data, the next quarter of data has already been submitted and changes cannot be made to impact the next quarter. Any changes must be communicated within a timeframe for hospitals to change their processes. Also, data validation could be directed more at care, and not just at abstraction. For example, a RN documents that an antibiotic was given at 7:30 a.m., and then anesthesia documents it at 7:35 a.m. We have to include both in our abstractions. The important thing is that the patient received it in the correct timeframe prior to incision.

310-0

CMS-1500-P-638 (49)

Submitter : Dr. asdget eayqe **Date:** 06/23/2005

Organization : aha

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

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CMS-1500-P-638-Attach-1.DOC

Attachment 638

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CMS-1500-P-588

311

Submitter : Mr. Michael Pelc

Date: 06/23/2005

Organization : Detroit Medical Center Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1500-P-588-Attach-1.PDF

TRANSFERS
IME
GEO RELOC
LABOR S/N
MB/H
PYMT RTS/OUTLIER
NT
DRG/GEN
DSH
GME/IRP/APPEL
PBE/CLAR
PPE/NICU

WALZ
HART
HEFTER
HARTSTEIN
TRUONG
LEFKOWITZ
RUIZ
KENLY
KNIGHT
KRAEMER
SEIFERT
TREITEL
BROOKS
FAGEN
GRUBER
KELLY
HUE
SMITH
MOREY

Attachment 588

Detroit Medical Center
Wayne State University

June 22, 2005

Centers for Medicare and Medicaid Services
Attn: CMS 1500-P
Room C5-14-03
Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1500-P
Hospital Inpatient PPS Proposed Rule for FY 2005

Dear Sir or Madam:

The Detroit Medical Center (DMC), consisting of the following hospitals – Children's Hospital of Michigan, Detroit Receiving Hospital, Harper-Hutzel Hospital, Huron Valley Hospital, Rehabilitation Institute of Michigan and Sinai-Grace Hospital welcomes this opportunity to comment on the proposed rule (the "NPRM") promulgated by the Centers for Medicare and Medicaid Services ("CMS") entitled Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates (70 Fed. Reg. 23306 (May 4, 2004)).

A. Post Acute Care Transfers

The DMC strongly disagrees with CMS' proposed changes to the post-acute care transfer payment policy. Under criteria presently in effect, cases assigned to one of 30 designated DRGs are paid as transfers when the patient is discharged to a post-acute care setting. 70 Fed. Reg. at 23413. In the NPRM, CMS has proposed to expand this policy to include all DRGs that have the following characteristics: (a) the DRG has at least 2,000 post-acute care transfer cases; (b) at least 20 percent of all cases in the DRG were discharged to post-acute care settings; and (c) 10 percent of the post-acute care discharges occurred prior to the geometric mean length of stay for

the DRG. Id. at 23416. As a result of this proposal, 223 DRGs[1] would be subject to the post-acute care transfer payment policy, representing a seven-fold increase over existing policy. Id.

The DMC asserts that CMS' proposal is inconsistent with both the intent of the governing statute, as well as with the strong policy frequently articulated by CMS for both providers and CMS to know prospectively the amounts payable for covered services. The statute specifically mandates that CMS' selection criteria for DRGs which shall be paid as transfers when the patient is discharged to post-acute care must take into account whether cases assigned to the DRG reflected a "disproportionate use of post discharge services." SSA, § 1886(d)(5)(J)(iv) (referring to (J)(iii)(I)). By definition, "disproportionate" must be measured relative to a norm. It is a statistical impossibility for half of the universe of DRGs to have "disproportionate use of post-discharge services."[2] For treatment of a discharge as a transfer, CMS has established the low threshold that 20 percent of the cases in the DRG are discharged to post-acute care. 70 Fed. Reg. at 23416. CMS' proposed rule and the rulemaking record includes no data on how frequently Medicare patients discharged from a hospital need some post-acute care services.

In proposing to include almost half of all DRGs in the post-acute care transfer payment policy (and apparently more than half of all discharges), CMS can hardly claim that it has only selected DRGs which exhibit a "disproportionate use" of discharges to post-acute care. Rather, even DRGs that exhibit fairly ordinary use of post-acute care services after discharge are encompassed by CMS criteria. Indeed, CMS only requires that two percent of discharges for a given DRG be discharges to a post-acute care setting occurring prior to the geometric mean length of stay for that DRG (i.e., 10 percent of 20 percent). This low bar to inclusion does not reflect Congress' intent in creating this policy. Again, the rulemaking record is insufficient because there is no empirical basis articulated by CMS for selecting the 2 percent criterion.

Indeed, the only evidence considered by CMS actually supports that revisions to the post-acute care transfer payment policy are not warranted at this time. CMS' policy has been to include a DRG within the scope of the policy if, among other factors, there had been a recent decline in the DRG's geographic mean length of stay. Id. at 23415. Presumably, this criterion reflects that the purpose of the policy is to create a disincentive to prematurely discharging patients. CMS' data, however, indicate that, even among many of the DRGs experiencing an increase in post-acute care utilization, there has been an increase in lengths of stay. Id. The data, as presented by CMS, therefore show that a trend towards higher patient acuity has resulted in a greater need for both acute care and post-acute care services. Yet, by CMS' own description, what drove its criteria was determining which criteria would encompass the vast majority of active DRGs with a length of stay over three days. Id. at 23415-16. In other words, CMS has not objectively analyzed its data to determine whether an expansion of the number of DRGs subject to its policy is warranted. Instead, CMS determined first that it would expand its policy and then "reverse engineered" its revised post-acute care criteria from its data.

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[1] CMS has characterized these 223 DRGs as having "relatively high volume" but does not disclose what percentage of discharges are accounted for by these 223 DRGs.

[2] CMS' proposed "option one" would treat *all* discharges as transfers. That CMS would propose this illustrates that it has read out of the statute the requirement that discharges treated as transfers reflect a "disproportionate use of post-discharge services."

CMS' proposed policy is also antithetical to the prospective nature of the inpatient reimbursement system. Since its inception, the DRG payment system has focused on setting hospital rates prospectively, such that similar diagnoses would be paid similarly irrespective of the actual resources used in treating a particular patient. See, e.g., SSA, § 1886(d)(2). However, by including such a large percentage of DRGs within the ambit of the transfer payment policy, CMS is essentially converting inpatient PPS into a per-diem payment system with a length of stay cap set at the geometric mean length of stay for that DRG. Not only does this remove incentives for hospitals to be efficient in the delivery of care, but also this policy is patently inequitable in that there is no offsetting payment for discharges that exceed the geometric length of stay and do not involve post-acute care, until the outlier threshold is finally reached. Because this policy is not in accord with Congressional intent and is otherwise inequitable, the DMC requests that CMS not finalize its proposal.

B. Indirect Medical Education Adjustment

The indirect medical education (IME) adjustment factor is calculated using a hospital's ratio of residents to beds and a formula multiplier, which is represented as "c" in the equation: c x [((1 + ratio of residents to beds) raised to the power of 0.405) - 1]. The formula is traditionally described in terms of a certain percentage increase in payment for every 10 percent increase in the resident-to-bed ratio. Before enactment of the Medicare Modernization Act of 2003, the formula multiplier was set at 1.35 for discharges occurring during FY 2003 and thereafter, which equates to a 5.5 percent payment adjustment. The MMA modified the formula as follows:

• For discharges occurring during FY 2005, the formula multiplier is 1.42 (equivalent to a 5.8 percent adjustment).

• For discharges occurring during FY 2006, the formula multiplier is 1.37 (equivalent to a 5.55 percent adjustment).

The DMC is opposed to the reduction in the FY 2006 IME formula, which will result in a projected $2 million decrease in payments, and urges CMS to maintain the formula at its current percentage. Inadequate payments to teaching hospitals will jeopardize the ability of hospitals to adequately train residents of internal medicine, who are the physicians of the future. In addition, during their training, hospital interns and residents are a vital resource for many hospitals since they serve as inexpensive and skilled members of the health care workforce.

C. Geographic Reclassification

The DMC requests that CMS make several revisions to its geographic reclassification policies. First, the DMC believes that CMS should, through FY 2007, allow hospitals to continue to have the option to qualify for qualification for reclassification if either the Combined Statistical Area ("CSA") or the Consolidated Metropolitan Statistical Area ("CMSA") eligibility criterion is met. Further, the DMC believes that CMS should revise its urban county reclassification provisions to allow hospitals reclassified under Section 508 of the MMA to request a postponement of the reclassification effective date until the expiration of the Section

508 reclassification. Finally, while Section 508 reclassifications remain in effect, the DMC maintains that urban hospitals should not be required to include hospitals reclassified under Section 508 in any request for an urban group hospital reclassification.

1. Labor market Are Criterion in Urban Group Hospital Reclassification

The DMC believes that CMS should delay implementation of its proposed revision to the qualifying criteria used to determine whether the hospitals within an urban county can reclassify to another urban area. CMS has acknowledged that the FY 2005 changes to labor market areas have been of a significant magnitude. 70 Fed. Reg. at 23437. Accordingly, CMS has allowed for a three year transition period to phase in the payment reductions resulting from the redefined labor market areas. 69 Fed. Reg. 48916, 49032 (Aug. 11, 2004). Notwithstanding CMS' recognition of the sea change represented by the new labor market areas, CMS is now proposing not to allow an urban county group reclassification located in the same CMSA as the urban area to which the group seeks reclassification, unless the targeted urban area is also in the same CSA. 70 Fed. Reg. at 23437. In keeping with the graduated approach towards implementing the new labor market areas, the DMC requests that CMS delay implementation of this policy until at least FY 2008, which would coincide with the expiration of the payment reduction transition period.

2. Delayed Effective Date For Urban Group Hospital Reclassifications

The DMC also requests that CMS effect a limited modification to its urban group hospital reclassification rules to account for the timing of the expiration of the reclassifications effected pursuant to Section 508 of the MMA. In accordance with the MMA, hospitals qualifying for reclassifications under Section 508 are allowed to maintain their reclassified status until March 31, 2007. MMA, § 508(a)(3). However, urban group hospital reclassifications take effect as of October 1 of a given year. 42 C.F.R. § 412.274(b). Thus, in FY 2007, hospitals will be faced with the difficult choice of either: (a) sacrificing six months of the Section 508 reclassification so that they can reclassify as part of an urban group in that year (i.e., the period from October 1, 2006 through March 31, 2007); or (b) pursuing no reclassification for a six month span, even though the hospitals otherwise qualify to reclassify as an urban group (i.e., the period from April 1, 2007 through September 30, 2007). In enacting Section 508 of the MMA, Congress intended to create reclassification options for hospitals with limited choices. There is no evidence that Congress intended to force hospitals to forego other reclassification options that would otherwise be available upon the expiration of their Section 508 reclassification. Accordingly, CMS should allow hospitals with Section 508 status to obtain reclassification with a delayed effective date.

The DMC recommends that CMS consider a rule change to regulation 412.234 that allows for group wage index reclassification applications for counties where there are SEC 508 hospitals. The group could apply and if it meets all of the criteria it would be approved, and the Sec 508 hospitals would keep their status until March 31, 2007. For these Sec 508 hospitals, the regular 412.234 wage reclassification would take effect April 1, 2007 until the end of the three year reclassification period. This would be the most effective way of making both sets of hospitals hold-harmless given the current conflict in the rules.

3. Partial Urban Group Hospital Reclassifications

Similarly, CMS should not require an entire urban group to simultaneously seek reclassification when some of the constituent hospitals are presently reclassified under Section 508 of the MMA. Currently, CMS regulations require that "all urban hospitals in an urban county must apply for redesignation as a group." 42 C.F.R. § 412.234(a)(1) (emphasis added). When CMS initially promulgated this regulation over a decade ago, it could not have contemplated that Congress would enact Section 508 of the MMA, which has allowed some, but not all, of the similarly situated hospitals within some counties to obtain reclassification. In effect, CMS' regulation twice penalizes the hospitals in these counties not qualifying for reclassification under Section 508: once when they failed to qualify for a Section 508 reclassification, and again when they are unable to obtain unanimous consent to seek reclassification as an urban group. Such a result is inequitable and warrants a limited exception during the period in which Section 508 reclassifications remain in effect.

D. Labor-Related Share

(Federal Register page 23391)

Background: The wage index adjustment is only applied to a portion of the PPS standard rate. This labor-related share is based on an estimate of the national average proportion of hospital operating costs that vary with the local labor market determined using data from the hospital marketbasket calculation. The FY 2005 labor-related share is 71.066 percent. Based on a MMA requirement, effective beginning in FY 2005, CMS reduced the labor share to 62 percent for hospitals located in areas with an area wage index equal to or less than 1.0.

CMS Proposal: ... In FY 2006, CMS is proposing to continue to calculate the labor-related share by adding the relative weights of the operating cost categories that are related to, influenced by, or vary with the local labor markets. These categories include wages and salaries, fringe benefits, professional fees, contract labor and labor-intensive services.

Since CMS no longer believe that postage costs meet the definition of labor-related, those costs are being excluded from the labor-related share. Based upon this methodology, CMS calculated a labor-related share of 69.731 for FY 2006. The proposed elimination of postal services decreases the labor share by 0.272 percent; the most significant factor in the change is a 3.049 percent decrease in the weight for "other labor-intensive services" from 7.277 to 4.228. This category includes costs for landscaping services, services to buildings, detective and protective services, repair services, laundry services, advertising, auto parking and repairs, physical fitness facilities, and other government enterprises.

The DMC opposes the proposed decrease in the labor-related share of the PPS rate. In the inpatient PPS rule for FY 2003, CMS examined the methodology used to determine the labor-related share. CMS calculation of the labor-related share for FY 2003 resulted in an increase from 71.06 percent to 72.495 percent. However, CMS did not implement the increase pending further research to determine whether a different methodology should be adopted for determining

the labor-related share. In the FY 2006 proposed rule, CMS discusses continuing research on alternative methodologies for calculating the labor-related share. However, they state that the analysis has not yet produced sound enough evidence to propose a change and that they will continue to study the issue. It is clearly inequitable to decline to implement a labor-share increase pending an analysis of the methodology and then propose a labor-share decrease while that analysis is still not completed.

The DMC recommends that CMS maintain the labor-related share of the PPS rate at the current 71.066 percent for hospitals with a wage index of 1.0 or greater and 62 percent for hospitals with an area wage index equal to or less than 1.0, until further research is completed.

E. Frequency of Updates to the Marketbasket

(Federal Register page 23401)

Background: The MMA requires that CMS provide an explanation of the reasons for the current marketbasket revision intervals, and provide options for more frequent hospital marketbasket updates. CMS states that the decision to rebase and revise the index is largely data driven. The calculation depends upon Medicare cost report data that is available on an annual basis and on Bureau of the Census data that are typically available only every five years. As a result, historically, CMS has rebased the marketbasket at approximately five-year intervals.

CMS Proposal: First, CMS reviewed the frequency and availability of the data needed to produce the market basket. Secondly they analyzed the impact on the market basket of determining the market basket weights under various frequencies and used results from these areas of research to assist in determining a new rebasing frequency. Based upon this analysis, CMS is proposing to rebase the hospital market basket every 4 years, meaning that the next rebasing would occur for the FY 2010 update. The last update to the marketbasket was implemented in FY 2003. Under CMS proposal for a four-year interval, the next update would be in FFY 2007. However, as described above, CMS proposes to update the marketbasket for FY 2006. It is the DMC's position that there is no compelling reason to update the marketbasket for the FY 2006 update since there is no new Census data available and CMS cites no immediate problem that must be addressed. Instead, we believe that CMS should adopt the four-year interval and implement the next update in FY 2007. Moreover, this corresponds more closely with the schedule for Census data releases.

According to CMS, the next time that a full update of the required Census data will be available is FY 2011. Therefore, it makes little sense to do marketbasket updates in FY 2006 and FY 2010 as proposed.

F. Cost Outlier Payment Thresholds

(Federal Register page 23469)

Background: CMS provides payments for outlier cases involving extraordinarily high costs when compared to average cases in the same DRG. To qualify as a cost outlier, a hospital's cost for the case must exceed the payment rate for the DRG plus a specified amount known as the fixed loss threshold. The outlier payment is equal to 80 percent of the difference between the hospital's cost for the stay and the threshold amount. The threshold is adjusted annually based upon CMS' projections of total outlier payments to make outlier reimbursement equate to 5.1 percent of inpatient payments.

CMS Proposal: CMS is proposing to establish a fixed-loss cost outlier threshold for FY 2006 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $26,675, which represents a 3.4 percent increase from the current $25,800 threshold. Although the increase is of somewhat comparable to the proposed change in the IPPS standard rate from FY 2005 to FY 2006, we are concerned that CMS is not distributing the total funds set aside for outlier payments. CMS estimates that actual FY 2004 outlier payments were 3.5 percent of total payments and that projected FY 2005 outlier payments are approximately 4.4 percent of total payments. Given the shortfall in the prior two years compared to the 5.1 percent target for outlier payments, we are concerned that the proposed threshold increase will result in another year of underpayments for outliers, which are vital for compensating hospitals for the increased costs of providing care to extraordinarily ill patients. In addition, without a corresponding increase in the standardized amount, this outlier decrease would not maintain budget neutrality. Rather the savings would accrue to CMS. As such, the DMC recommends that CMS maintain the outlier threshold at the current $25,800, until additional analysis is completed to confirm that the agency is dispersing the entire pool of funds set aside.

G. New Technology Applications

(Federal Register page 23353)

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

- 75 percent of the standardized amount (increased to reflect the difference between costs and charges); or

- 75 percent of one standard deviation for the DRG involved.

For FY 2006, CMS is essentially proposing to reject all eight applications (six new and two reevaluations) and only maintain payment for only one currently approved technology.

The DMC is concerned that CMS continues to resist approving new technologies for add-on payments. In addition, the DMC is disappointed that CMS did not propose to increase the marginal payment rate to 80 percent rather than 50 percent, which the agency has the authority to do without reducing payments to other services. The DMC urges that CMS re-evaluate the eight applications that it has previously rejected and, upon approval increase the marginal payment rate to 80 percent. This is essential for ensuring that Medicare beneficiaries continue to have access to new medical devices and technologies.

H. Proposed Modification of DRGs 535 and 536 for FY 2006

Proposed Modification

CMS has proposed to remove hospital procedure code 37.26 (cardiac electrophysiological and recording studies [EPS]) from the list of cardiac catheterization procedures that lead defibrillator cases to DRGs 535 or 536. A review of FY 2004 MedPAR data shows that when EPS is the only procedure reported from the list of cardiac catheterization procedures, the average charges and average length of stay are lower than when cardiac catheterization, but not EPS, are reported. Under the proposal, if a defibrillator is implanted with EPS and no other type of cardiac catheterization, the case would be assigned to DRG 515.

Issue

The hospital procedure code for EPS (37.26) contains three separate procedures of varying intensity: electrophysiology study, intraoperative device interrogation and non-invasive programmed stimulation (NIPS). Because three very different procedures are identified with one code (37.26), CMS cannot isolate the specific resources associated with each unique procedure. Thus, all three procedures will be reclassified to DRG 515, including diagnostic EPS which require the insertion of one or more catheters and have similar resource intensity to cardiac catheterization. Until the coding issue is addressed, the average charge data for cases in DRG 535 and 536 involving only 37.26 is invalid and should not be used as the basis for this proposed modification. 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. Further, in a meeting attended by industry, CMS coding experts acknowledged that the structure of hospital procedure code 37.26 results in flawed data.

Impact

According to the data, approximately 43% of cases assigned to DRG 535 and roughly 59% assigned to DRG 536 are cases with EPS and no other cardiac catheterization procedures. Included in this number are roughly 70% of CRT-D cases reported in the 2003 MedPAR data. These cases will be reassigned to DRG 515. The shift in cases is dramatic:

DRG	Requires	Pays	Volume Change
535	(AMI, heart failure, shock and cardiac catheterization)	$41,475.68	-43%
536	(Cardiac catheterization)	$35,485.15	-59%
515	(None)	$28,340.88	+63%

Recommendation
A change of this magnitude requires further study and analysis. CMS should withdraw its proposal to remove code 37.26 from the list of cardiac catheterization procedures that affects the DRG assignment of defibrillator cases. Code 37.26 should be retained in DRGs 535 and 536 until CMS clarifies the definition and usage of 37.26 and accumulates data to determine whether a modification of the defibrillation DRGs is justified. This is a coding issue that requires a coding solution – not a payment modification.

I. DSH Adjustment Data

While the DMC appreciates that CMS has now proposed to implement the legislative mandate requiring the release of data used by CMS to calculate hospitals' entitlement to disproportionate share hospital ("DSH") payments, the Hospital believes that the proposed implementation requires some modification. CMS' proposal would release to hospitals data from its MedPAR Limited Data Set (LDS). 70 Fed. Reg. at 23435. The Hospital believes that, standing alone, the MedPAR LDS data is insufficient. CMS' data matching of Supplemental Security Income ("SSI") data against its MedPAR data has often been inaccurate. See, e.g., 60 Fed. Reg. 29202, 29224 (June 2, 1995) (acknowledging that CMS cannot explain why its recalculation of SSI days upon a hospital's request invariably results in a lower count). Accordingly, the DMC requests that CMS release instead the source data for the SSI days that it receives from the Social Security Administration. Just as CMS has acknowledged that it is allowed to distribute MedPAR LDS data under the routine use exception, CMS' distribution of the source information could be similarly protected. 70 Fed. Reg. at 23435. Congress' mandate requires that CMS furnish data that would allow a hospital to "compute the number of patient days" used in the DSH calculation. Medicare Prescription Drug, Improvement and Modernization Act (the "MMA"), § 951. Without the source SSI data, a hospital could not truly "compute" its SSI days. The MedPAR LDS data simply shows the results of CMS' computations and therefore does not fulfill the statutory requirements.

Further, the DMC requests that CMS revise its policies to facilitate greater access to Medicaid data. Although many States may be voluntarily releasing to hospitals the requisite Medicaid eligibility data, State policies are subject to change. Only through an amendment to State plan requirements can CMS ensure that it has affirmatively "arranged to furnish" Medicaid eligibility data, as required by the MMA. MMA, § 951.

J. Graduate Medical Education

The DMC considers CMS' changes to its graduate medical education ("GME") policies to be salutary. The DMC, however, believes that several of these proposals could be further refined. In particular, the DMC believes that CMS' policies with respect to clinical base year training should provide that the initial residency period should be set in the second year of training for all residents in a specialty program, irrespective of whether they matched to that program while still in medical school. Further, the DMC believes that urban hospitals that establish new medical residency training programs should be allowed to enter into affiliation agreements without limitation.

1. Clinical Base year Training

As CMS has recognized, many specialty programs require a year of general clinical training, referred to as a "clinical base year" of training. CMS has previously adopted regulations that would allow hospitals to calculate the initial residency period using the second year of training for residents training in specialty programs requiring a clinical base year, provided that the hospital can demonstrate that the resident simultaneously matched to both the first and second year program. 42 C.F.R. § 413.79(a)(10). CMS is now proposing to expand this regulation to allow hospitals to use the second year of training to calculate the initial residency period even where the resident did not match to a first year program. 70 Fed. Reg. at 23439. Although this proposed revision represents a welcome expansion of CMS' clinical base year policy, it still does not properly reflect Congress' intent in enacting the statutory provisions governing initial residency periods.

Since Congress has envisioned a much broader clinical base year policy, CMS should revise its policy to better align it with the pertinent legislative history. As stated by Congress in connection with the initial residency period provisions:

> The conferees also clarify that under section 1886 (h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

Conference Committee Agreement Accompanying Public Law 108–173, 108 Cong., 2d Sess., 276 (2003). In revising its clinical base year policy, CMS should closely adhere to the legislative history relating to the initial residency period provisions. The legislative history does not distinguish between residents based upon their intentions in pursuing a year of clinical base year training. Rather, the initial residency period for any residency program requiring a prior year of clinical base year training in all cases is determined in the second year of training. The Hospital submits that this interpretation of the statute is entirely consistent with the language of the statute, and CMS should thus defer to this interpretation and structure its policy accordingly.

At a minimum, we believe that CMS should also allow hospitals to use the second year of training in all instances in which the resident had undertaken a year of training in a transitional year program or a preliminary position in an internal medicine program. In the case of either a transitional year program or a preliminary year program, the programs do not lead to certification. Instead, residents must complete their training in some other program. Since these residents could never receive certification from the program in which they received their clinical base year of training, the "particular specialty for which the resident is training" is the specialty program begun in the second year. 42 C.F.R. § 413.79(a)(6). Thus, a policy that takes account of transitional year programs and preliminary year programs would squarely accord with the applicable statute and regulation.

2. Affiliation Agreements

The DMC also requests that CMS consider broadening its proposed changes to the affiliation agreement requirements. CMS has proposed to allow urban hospitals that establish new medical residency training programs to enter into affiliation agreements, provided that the hospital with the new program experiences an increase in its FTE cap pursuant to the affiliation agreement. 70 Fed. Reg. at 23440. CMS has expressed a concern with allowing affiliation agreements in which new urban teaching hospitals experience a decrease in their FTE caps because CMS maintains that such a relaxation of policy would encourage gaming. Id. Specifically, CMS believes that hospitals with established medical residency training programs would establish new programs at hospitals that do not yet have any programs and then seek to shift the positions created by this new program to the established teaching hospital. Id. The Hospital believes, however, that CMS' concern is unwarranted, and therefore, its policy is too restrictive.

In claiming that affiliation agreement restrictions are necessary for new urban teaching hospitals to prevent gaming, CMS has not properly considered the various safeguards already in place. For instance, any hospital that chooses to establish a new medical residency training program must undergo accreditation by an appropriate accrediting body. 42 C.F.R. § 413.79(l). Such action can be an intensive process, involving significant attention by a number of parties across hospital medical and administrative departments. Furthermore, a hospital must maintain its new program for a period of three years before it qualifies to receive a permanent FTE cap. 42 C.F.R. § 413.79(e)(1)(i). In other words, establishing a program requires concerted action by staff throughout a facility, which actions must be sustained for a substantial period of time. It is unlikely that many institutions would undertake such action merely to help another hospital to obtain a purported improper gain in its GME payments.

CMS can also find further protection against potentially inappropriate use of affiliation agreements through changes it has made over time to the affiliation agreement requirements. For example, CMS now requires that there be a bona fide shared rotational arrangement between two hospitals as a pre-condition to entry into an affiliation agreement. 42 C.F.R. § 413.79(f)(2); 42 C.F.R. § 413.75(b). Thus, an established teaching facility could not simply shift to itself an entire program from a new teaching facility because it would no longer be possible to meet the shared rotation requirement. Moreover, an established teaching hospital could never

permanently acquire a new program initiated by a new teaching hospital because the new teaching hospital would always have the right to terminate the agreement, which would result in the return of both parties to their initial FTE caps. 42 C.F.R. § 413.79(f)(5). Since an established teaching facility could never be certain of the long-standing intentions of the prospective new teaching facility, it would be discouraged from aiding the new teaching facility in establishing a program simply to circumvent FTE cap rules. Due to these changes in CMS' affiliation agreement policy, restrictions on affiliation agreements for new teaching hospitals are no longer necessary.

As presently proposed, CMS' affiliation agreement policy could have an adverse impact on medical education. CMS has acknowledged that over the course of a year, often there are unanticipated changes in planned rotations. Accordingly, CMS allows parties to file amendments to their affiliation agreements prior to the end of an academic year. 67 Fed. Reg. 49982, 50071 (Aug. 1. 2002). Similarly, a new urban teaching hospital may intend to be a net recipient of residents, but during the year unforeseen circumstances may cause it to shift a portion of residents to another party in its affiliated group. Though these circumstances may be beyond the hospitals' control, CMS would penalize the receiving hospital by not allowing it to increase its FTE cap through a shift of a portion of the new teaching hospital's FTE cap. This lack of flexibility will inevitably discourage parties from entering into affiliation agreements with new teaching hospitals because of the fear of adverse financial implications arising from unforeseen circumstances. Accordingly, since this policy creates a disincentive for beneficial medical education arrangements without any significant offsetting value as a safeguard, the Hospital requests that CMS reconsider requiring new teaching hospitals to enter affiliation agreements only when they result in an increase in their FTE cap.

K. Provider Based Entities

We support CMS' proposed revision to the obligation in Regulation 413.65(g)(7) for a hospital outpatient department that is not on the main provider's campus to give a notice of coinsurance when no physician service is being furnished in conjunction with a hospital's service. We believe, however, that the proposed exception should be both expanded and clarified as explained below.

The current regulation does not require that a notice of coinsurance be given for services furnished on a main provider's campus. The reason that no notice of coinsurance is required for services furnished on a main provider's campus is because the patient knows that he or she is in a hospital, and that in hospital settings, there are separate charges for the technical services furnished by the hospital and the professional services furnished by physicians. Patients also understand that there will be separate coinsurance amounts for those bills. The rationale underlying an exception for the notice of coinsurance requirement for a main provider's campus is equally applicable for any hospital campus, whether that hospital is freestanding or is included on another hospital's provider number.

When CMS promulgated the provider-based regulation in 2000, it made clear that the provider-based rule would govern whether two or more hospital campuses could be included on a single provider number. In addition, CMS insisted that only a single campus be the "main provider." Thus, full-service hospitals that are obviously hospitals to anyone entering them can be subject to the notice of coinsurance requirement for any Medicare patient receiving outpatient services, based solely on the fact that they are deemed to be provider-based with another hospital that is the "main provider." There is no rational basis to require notices of coinsurance in outpatient departments of these "provider-based" entire hospitals since they are obviously hospitals and beneficiaries will be aware of the likelihood of receiving two bills with two coinsurance amounts to the same extent as on the main provider's campus or any other hospital's campus.

Accordingly, we strongly recommend that CMS amend the regulation so that the notice of coinsurance requirement does not apply to services furnished within the main buildings of a facility with Medicare certified and available hospital inpatient beds. The logic that supports not requiring a notice of coinsurance for outpatient departments on a main provider's campus is equally applicable in this situation.

In addition, we suggest that CMS clarify what is an "outpatient department" within the meaning of (g)(7). Many departments are not devoted to outpatient services at all but rather serve both inpatients and outpatients concurrently. The most dramatic illustration of this is outpatient observation services that are typically furnished in inpatient routine beds. Similarly, many diagnostic services such as imaging are furnished in ancillary departments that serve both inpatients and outpatients. "Outpatient department" is not defined within the provider-based regulation nor elsewhere within the regulations known as the "principles of reimbursement." To clarify what is an "outpatient department" within the meaning of (g)(7), we recommend that CMS define "outpatient department" as used in (g)(7) as meaning a department whose principal function is to serve outpatients.

Thank you for your review of this submission. Please call me at (313) 578-2820 with any questions regarding these comments you may have.

Sincerely,

Michael A. Pelc

Vice President, Finance

The Detroit Medical Center

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COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

Submitter : **Dr. Craig Johnson** **Date: 06/22/2005**

Organization : **Amery Regional Medical Center**

Category : **Physician**

Issue Areas/Comments

CAH/RELOC

GENERAL

GENERAL

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

To Whom It May Concern:

I am writing you in regard to recent published rules by the Center for Medicare and Medicaid Services (CMS) pertaining to the construction of replacement facilities by Critical Access Hospitals. As you may be aware, the rules which were published by CMS, are quite restrictive regarding the definition of new facilities which are replacement, relocation, or regarded as establishing a new business. As a result of the newly published rules, very few critical access hospitals within the United States would be able to build replacement facilities, either now or in the future. This would have a significantly negative impact on the long-term access to quality patient care by Medicare patients in the communities in rural Wisconsin. If the proposed regulations are enacted, Critical Access Hospitals that have obtained ?necessary provider? designation from the state will not be able to replace their planned facility, unless it is reconstructed on the property that it currently occupies and still maintain their Critical Access Hospital status.

In our case, in Amery, Wisconsin, in order to remodel the hospital and expand to provide current state of the art care, we would have to virtually shut down our facility there-by significantly restricting access to care. We are currently land-locked on approximately 1 ? acres of land within a residential area. It is unreasonable to think that relocating our facility within the city limits would render our medical center unable to serve its underserved rural market, or hamper access to patient care. In fact, it may well improve access to patient care by an improved location and upgrading our facility will not only improve access to care as well as quality of care.

The point of Critical Access Hospital designation recognizes that providing healthcare services to rural populations is difficult. The Federal Government has chosen to support the existence of these hospitals with cost-based reimbursement. The CMS proposal to effectively prevent Critical Access Hospitals from replacing their existing facility eventually will result in these hospitals closing due to fire and safety code issues, or the inability to provide quality services. Eventual closure of Critical Access Hospitals or inability to provide quality care and utilize modern technology is contrary to the original congressional intent when the Critical Access Hospital program was initiated as part of the Balanced Budget Act of 1997.

Therefore, I urge you to address the rule changes that CMS has proposed to make them more reasonable for Critical Access Hospitals to build a new facility in their community and still maintain their Critical Access Hospital status. I am sure you have received many proposed scenarios for this, such as requiring a facility to locate within 2-3 miles of their current site or within the city limits and not have to reapply for Critical Access Hospital status through CMS. I believe that the necessary provider status granted to many of the rural hospitals in Wisconsin is allowing us to effectively serve our rural population.

CMS plans to make a final ruling by August 1st and your prompt attention to this matter is appreciated. Thank you very much for your consideration.

Respectfully submitted,

Craig T. Johnson, M.D.
Chief Medical Officer - Amery Regional Medical Center
CTJ:gw

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BROOKS
FAGAN
GRUBER
KELLY
HUE
WALZ
HARTSTEIN
HEFTER
HARTSTEIN

DRG/GEN
TRANSFERS
ICD-9-CM

Submitter : Ms. M.B. Schuh

Organization : St. Anthony's Medical Center

Category : Individual

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

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

CMS-1500-P-575

314

COLLINS
MOREY
SMITH
NEFTER
HARTSTEIN

Submitter : Ms. Anne Oglevie

CAH/RELOC

Date: 06/22/2005

Organization : Weiser Memorial Hospitla

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Iam writing today to express my 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 their current location unless the project was under development before December 8, 2003. While I 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. Weiser Memorial Hospital is not a necessary provider but we are not 35 miles from the nearest hospital. When we were designated CAH Ontario OR was not considered because it is in another state. I believe if we were to build and move now we could lose our CAH status.

This hospital and CAHs are the sole providers of inpatient acute-care services and offer outpatient 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 date requirements and establish reasonable criteria to ensure that the hospitals are moving within their services areas. At least allow us to move three miles.

315

KNIGHT
SEIFERT
BODDEN
KRUSHAT
WALZ
HART
HEFTER
HARTSTEIN
Kenly
Collins
Morey
Smith

Submitter : Ms. Nancy C. Galvagni **Date:** 06/23/2005

Organization : Kentucky Hospital Association

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1500-P-592-Attach-1.DOC

MB/H
Q DATA
TRANSFERS
CAH/RELOC
Geo Reclas
Hosp Redes.

Attachment 592

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 all hospitals in the Commonwealth of Kentucky, the Kentucky Hospital Association appreciates the opportunity to comment on the fiscal year (FY) 2006 inpatient prospective payment proposed rule.

Our comments, which are fully outlined below, address discrepancies between the actual and estimated market basket used to increase hospital base payment rates, the validation process for quality data and the failure of CMS to extract all diagnosis and procedure codes on the bill, expansion of the post-acute transfer policy which would reduce payments to Kentucky hospitals by an estimated $16 million annually, restrictive criteria for the relocation of critical access hospitals, and the need to revise the criteria for countywide geographic reclassification for rural hospitals.

Market basket Update

Current law sets the FY 2006 inpatient PPS update for hospitals at the rate of increase in the market basket, now estimated at 3.2 percent. Legislative and proposed regulatory changes as well as technical adjustments to ensure budget neutrality would result in a proposed average per case payment increase of only 2.5 percent. However, the current estimates of the actual market basket increase for FY 2005 is 4.1 percent, indicating that the CMS estimate of 3.2 percent for FY 2006 is greatly understated.

Since 1997, Kentucky hospitals have experienced nearly a 10 percent gap between Medicare payment rate updates and actual cost increases as measured by the CMS Market basket. This gap is even larger when the projected market basket used by CMS is compared to the final market basket as calculated by the CMS Office of the Actuary. For the last five years, the final market basket has exceeded CMS's projected market basket by an additional 3.5% - the equivalent of a full year's update. CMS's continued underestimation of market basket inflation will only widen the gap between inflationary cost increases and payment, making it harder for hospitals to meet the costs of providing services to Medicare patients.

Recommendation: KHA requests that CMS review the methodology that was used to determine the projected FY 2005 market basket and revise it for the FY 2006 projections. CMS should make the details of the calculation available to the public.

Validation of Hospital Quality Data and Recognition of All Diagnoses and Procedure Codes

All Kentucky PPS hospitals are submitting quality data and all have passed the validation process. However, Kentucky hospitals have expressed extreme frustration and displeasure with the validation process. CMS has contracted with an organization that will re-abstract the required data from a sample of records. However, because hospitals keep charts differently, the abstraction centers often overlook or miss data that is actually contained in the record. The abstraction center has been extremely difficult for hospitals to work with to get these oversight errors corrected. Although Kentucky hospitals passed validation, many remain concerned that their error rate is not accurate, since these rates will be publicly displayed.

In addition, hospitals are concerned that CMS is not evaluating all diagnoses and procedures that could possibly affect a patient's severity of illness and the resources utilized. The current DRG grouper only considers nine diagnoses and up to six procedures. However, under the HIPAA compliant electronic transaction 837i standard, hospitals are submitting up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospitals since they are not needed by the current grouper to assign a DRG. The failure of the grouper to recognize additional complications and co-morbidities is penalizing hospitals that treat sicker patients in terms of payment as well as the use of claims data for performance reporting and risk adjustment.

Recommendation: KHA urges that CMS improve the validation process to be both workable and reliable, and until this occurs, validation should not be linked

to a hospital's receipt of the full market basket update. We also urge CMS to modify the DRG grouper and instruct fiscal intermediaries to expand the number of diagnoses from 9 to 25 and the number of procedures from 6 to 25, in order to include all reportable diagnoses and procedures in the DRG calculation and any risk adjustment methodology applied to performance data.

Post-Acute Transfers

Medicare patients in certain DRGs who are discharged to a post acute care setting – such as rehabilitation hospitals and units, long term care hospitals, or skilled nursing facilities – or are discharged within three days to home health services are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount, up to the full inpatient PPS rate. In the proposed rule, CMS discusses the possibly of expanding the policy from 30 DRGs to either 223 or 231 DRGs, or all DRGs. This misguided policy will have a devastating impact on hospitals by reducing overall payments by an estimated $900 million, and will reduce payments to Kentucky hospitals by $16 million in FY 2006 alone.

One-half of Kentucky hospitals are already losing money on patient care services, and Medicare margins continue to decline. Overall Medicare margins for Kentucky hospitals remained steady at about 2.5 percent until 2001, when they became negative, declining to a -1.7 percent in 2002 and a staggering -4.1 percent in 2003. From 1997 to 2003, the percent of Kentucky hospitals with negative total Medicare margins has grown from 13 percent to 45 percent, and the proportion with margins below one percent has increased from 19 percent in 1997 to 61 percent, or nearly two out of every three hospitals in 2003. The majority of Kentucky's hospitals are the sole providers of health care in their community, and two-thirds serve a rural population. Clearly, a $16 million additional payment reduction will have a devastating impact on Kentucky hospitals and the patients they serve.

In addition, we believe that expansion of the transfer policy runs counter to the basic principles and objectives of a prospective payment system, where payment is based on a system of averages. Cases with higher than average lengths of stay and costs tend to be paid less, but these losses are offset by cases with shorter than average stays which are paid more than cost. If the transfer policy is expanded to all or nearly all DRGs, it will be impossible for hospitals to break even because they would lose money both on high cost and long length of stay cases as well as short stay patients.

The final rule implementing the current transfer policy provided an analysis showing that across almost all lengths of stay for each of the DRGs, hospitals would be paid in excess of cost even after implementation of the provision. No