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Submitter : Ms. Gina Barrett

Organization : Greene County Memorial Hospital

Category : Hospital

Date: 06/23/2005

CAH/LUGAR
Hosp Redes.

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-594-Attach-1.DOC

CMS-1500-P-594-Attach-2.DOC

Greene County Memorial Hospital

Attachment 594

June 23, 2005

Greene County Memorial Hospital is a 34-bed, not for-profit community hospital located in Waynesburg, Pennsylvania, and serving residents of Greene County and surrounding counties in both Pennsylvania and West Virginia. The Hospital employs approximately 320 people in the community, and has approximately 40 physicians on active staff.

Background: Lugar Reclassification

CMS classifies all counties throughout the country as either "urban" or "rural" by using the metropolitan area classification system devised and maintained by the U.S. Office of Management and Budget (OMB). The OMB classification system is somewhat crude, and not always an accurate indicator of hospital labor markets.

In 1987, Congress sought to correct a shortcoming in the OMB metropolitan area classification framework, and benefit certain rural hospitals, through legislation that required the Centers for Medicare and Medicaid Services (CMS) to treat rural counties meeting certain commuting pattern criteria as being part of an adjacent Metropolitan Statistical Area (MSA).[1] Reclassifications made under this provision became known as "Lugar Reclassifications" because of the Senator who championed the 1987 law.

Rural counties qualifying for Lugar Reclassification are considered to be joined with the neighboring MSA, and so all hospitals located in the reclassified rural county are also considered to be "urban" for all Medicare payment purposes. At present, 98 counties and approximately 75 hospitals are reclassified as a result of this provision.

The Lugar Reclassification opportunity was intended to benefit qualifying hospitals, and, as a practical matter, virtually all redesignated hospitals do in fact benefit. As "urban" hospitals, these providers typically are eligible for a higher wage index, more favorable disproportionate share adjustments and other favorable Medicare reimbursement treatments extended to urban hospitals. However, in rare instances, a Lugar Reclassification actually can harm a rural hospital. Greene County Memorial Hospital is one such hospital.

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[1] Sec. 4005, Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203 (Dec. 22, 1987); codified as 42 U.S.C. § 1395ww(d)(8)(B).

The Problem with Lugar Reclassification

Currently, Greene County Memorial Hospital qualifies for Medicare Dependent Hospital (MDH) status. The MDH designation is conferred upon hospitals that are located in a rural area as defined in Section 412.63b, has 100 or fewer beds, is not classified as a Sole Community Hospital and at least 60% of the hospital's inpatient days or discharges were attributable to individuals receiving Medicare Part A benefits during at least two of the last three most recent audited cost report periods for which the Secretary has a settled cost report.

In years past, Greene County Memorial Hospital met all the tests to be reclassified to the Pittsburgh MSA for the wage index under the geographic reclass rules. In those years, we received both the MDH add-on payments in addition to the Pittsburgh MSA wage index. For the current fiscal year, October 1, 2004, we did not qualify for the MSA reclassification. We were thrilled to hear about our county being able to reclassify using the Lugar Rule due to the out-migration of workers to the adjacent counties, which are in the Pittsburgh MSA. However, our joy was short lived when we were told by the fiscal intermediary that if we wanted to use the Lugar classification, we would have to forfeit our MDH status. This would have been very financially detrimental to our facility so we remained rural and kept our MDH status.

While Greene County Memorial Hospital's urban-to-rural reclassification resolved one problem, it created others. First, Greene County Memorial Hospital was forced to forfeit Lugar Reclassification and all of the attendant benefits, including the higher Pittsburgh wage index that would have applied had Greene County Memorial Hospital been able to retain its Lugar Reclassification. Moreover, Greene County Memorial Hospital is now barred from trying to otherwise improve its wage index, because Medicare regulations prevent hospitals that reclassify from an urban area to a rural area from seeking a subsequent wage index reclassification.[2] Since we are not able to reapply, we do not know if we would have met the test for the upcoming fiscal year.

Proposed Solution

Greene County Memorial Hospital should not have to choose between the Lugar Reclassification and the MDH status. The two programs are independent of one another, and designed for entirely different purposes. Congress did not intend for the two programs to be mutually exclusive. Moreover, there is no policy justification supporting forcing a hospital that qualifies for the Lugar Reclassification to forfeit its MDH status. Greene County Memorial Hospital should be permitted to retain and benefit from the Lugar Reclassification for which it qualifies, and concurrently retain its MDH status, for which it also qualifies.

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[2] *See*, 42 C.F.R. § 412.103.

At the very least, Greene County Memorial Hospital should be permitted to waive its Lugar Reclassification without having to resort to an urban-to-rural reclassification (which was not at all intended to be used as a mechanism for avoiding Lugar Reclassification), and without being subsequently barred from seeking a wage index reclassification. If Greene County Memorial Hospital were able to waive or reject its Lugar Reclassification, it could subsequently seek to improve its wage index by applying for wage index reclassification.

In light of the foregoing, Greene County Memorial Hospital requests that Congress correct this problem by either:

- Providing that a hospital reclassified pursuant to a Lugar Reclassification will not lose MDH status; or

- Permitting hospitals to opt out of Lugar Reclassification.

Sincerely,

Gina G. Barrett
Chief Financial Officer

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Submitter : Mr. Robert Plaskey

Organization : Oakwood Healthcare, Inc.

Category : Hospital

Date: 06/23/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-599-Attach-1.DOC

TRANSFERS
DSH
GME/IRP/AFFIL
PBE/CLAR
GEO/RECLASS
Q DATA
LABOR S/N
MB/H
PMT RED/OUTLIER
NT
PBE/NICU

Attachment 599

June 22, 2005

By Overnight Courier

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
Postacute Care Transfers, DSH Adjustment Data, Graduate Medical Education, Provider-Based Entities, Geographic Reclassifications, Hospital Quality Data, Labor-Related Share, Frequency of Updates to the Marketbasket, Cost Outlier Payment Thresholds, New Technology Applications

Dear Sir or Madam:

Oakwood Healthcare, Inc. 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)). Oakwood Healthcare, Inc., located in Dearborn, Michigan, operates four not-for profit acute care hospitals with 1,307 licensed beds.

I. Postacute Care Transfers

Oakwood Healthcare, Inc. 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.*

Oakwood Healthcare, Inc. 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

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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."

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.

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, Oakwood Healthcare, Inc. requests that CMS not finalize its proposal.

II. DSH Adjustment Data

While Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. 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. Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. 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.

III. Graduate Medical Education

Oakwood Healthcare, Inc. considers CMS' changes to its graduate medical education ("GME") policies to be salutary. Oakwood Healthcare, Inc., however, believes that several of these proposals could be further refined. In particular, Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. believes that urban hospitals that establish new medical residency training programs should be allowed to enter into affiliation agreements without limitation.

A. 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. Oakwood Healthcare, Inc. 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.

B. Affiliation Agreements

Oakwood Healthcare, Inc. 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 Oakwood Healthcare, Inc. 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.* Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. requests that CMS reconsider requiring new teaching hospitals to enter affiliation agreements only when they result in an increase in their FTE cap.

IV. **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.

V. **Geographic Reclassifications**

Oakwood Healthcare, Inc. requests that CMS make several revisions to its geographic reclassification policies. First, Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. maintains that urban hospitals should not be required to include hospitals reclassified under Section 508 in any request for an urban group hospital reclassification.

A. Labor Market Area Criterion in Urban Group Hospital Reclassifications

Oakwood Healthcare, Inc. 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, Oakwood Healthcare, Inc. 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.

B. Delayed Effective Date for Urban Group Hospital Reclassifications

Oakwood Healthcare, Inc. 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.

C. 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.

VI. **Hospital Quality Data** (*Federal Register page 23424*)

Background: Based on the MMA, hospitals that submit data to CMS on ten specific measures of care will receive a full marketbasket update in fiscal years 2005 through 2007, equating to a 3.2 percent increase in FY 2006 for hospitals that submit data and a 2.8 percent

update for those that do not, since the MMA provided an increase of marketbasket minus .4 percent for hospitals that fail to submit the necessary data or withdraw from the program. The MMA restricts the application of this provision to hospitals paid under the Inpatient PPS, resulting in being non-applicable for hospitals and hospital units excluded from the Inpatient PPS. It also does not apply to payments to hospitals under other payments systems such as the Outpatient PPS.

CMS Proposal: During the first year, FY 2005, there were no chart-audit validation criteria in place. However, for FY 2006, CMS is proposing to place the following additional requirements on hospitals for the data in order to receive the full payment.

- In order to receive the full market basket update in FY 2006, the hospital must have passed the CMS validation requirement of a minimum of 80 percent reliability, based upon the chart-audit validation process, for the third quarter data of calendar year 2004.
- The hospital must have two consecutive quarters of publishable data. The information collected by CMS through this rule will be displayed for public viewing on the Internet. Prior to this display, hospitals are permitted to preview their information as recorded by CMS. Based upon past experience, a number of hospitals requested this information not be displayed due to errors in the submitted data that were not of the sort that could be detected by the normal edit and consistency checks. CMS acquiesced to these requests in the public interest and due to the agency's desire to present correct data; however, CMS continues to believe that the hospital bears the responsibility of submitting correct data that can serve as valid and reliable information.

The rule requires that the accuracy of hospital submitted data be validated through chart re-abstraction. A sample of five charts will be re-abstracted by the Clinical Data Abstraction Center (CDAC) and compared to the hospital's submission. CMS will require an 80 percent agreement rate between the original submission and the re-abstraction. If a hospital disagrees with the abstraction results from the CDAC, the hospital can appeal the results to their Quality Improvement Organizations (QIO).

While we recognize that audits and data validation are necessary to ensure that the data reported on the internet is reliable, Oakwood Healthcare, Inc. strongly opposes any attempt by CMS to link this validation process with the hospital update factor, which seems to contradict the MMA's intent. In addition, CMS proposes to base the update on data from the third quarter of 2004 although the audits of earlier periods in 2004 were often unreliable due to data problems and inconsistent definitions. In many instances, these issues were not completely resolved by the third quarter of 2004. Oakwood Healthcare, Inc. does not believe that hospitals should suffer a payment reduction due to technical problems with the data submission and validation process.

VII. **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.

Oakwood Healthcare, Inc. 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. The 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. Projections indicate that this change would decrease payment to Michigan hospitals by $3.3 million in FY 2006.

Oakwood Healthcare, Inc. 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.

VIII. **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 the 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 Oakwood Healthcare, Inc.'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.

IX. **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 somewhat comparable to the proposed change in the IPPS standard rate from FY 2005 to FY 2006, Oakwood Healthcare, Inc. is 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, Oakwood Healthcare, Inc. 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.

X. **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. Oakwood Healthcare, Inc. is concerned that CMS continues to resist approving new technologies for add-on payments. In addition, Oakwood Healthcare, Inc. 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. Oakwood Healthcare, Inc. urges that CMS re-evaluate the eight applications that it 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.

Thank you for your review of this submission. Please call me at 313-586-5642 with any questions you may have regarding these comments.

Sincerely,

Robert Plaskey
Director, Reimbursement

F:\Medicare\FY2005\Comment on FY05 6-22-05.doc

318

BROOKS
FAGEN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : Dr. Rodney Leacock

Date: 06/23/2005

Organization : East Carolina Neurology, Inc. / PCMH

Category : Physician

Issue Areas/Comments

GENERAL

DRG/GEN

GENERAL

See attachment

CMS-1500-P-601-Attach-1.PDF

Attachment 601

EAST CAROLINA NEUROLOGY

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Anthony C. Brewer, M.D.
Robert C. Frere, M.D.
Rodney O. Leacock, M.D.

John W. Gibbs, III, M.D., Ph.D.
J. Bryan Cooper, M.D.
Christine T. Burch, M.D.
Robert F. Saul, M.D.
Richard Daves, M.A.
Karen Tucci-Herron, F.N.P.
Roger Nelson, F.N.P.
Linda Pyun, F.N.P.

June 22, 2005

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

Dear **CMS**,

I am a Neurologist with subspecialty training in Neuro-Critical Care and Stroke. Currently I am participating in a collaborative effort to build a Stroke Center at Pitt County Memorial Hospital in Eastern North Carolina. I have been involved in the care of patients with stroke for about ten years. Since the approval of intravenous thrombolysis with recombinant Tissue Plasminogen Activator (rT-PA) in 1996, I have participated in 50 to 75 cases of rT-PA use. As you know it remains an under utilized intervention. In support of my colleagues who utilize reperfusion therapies for acute stroke I concur it is time to implement changes in Medicare inpatient reimbursement for advanced stroke treatment in FY2006.

Pitt County Memorial Hospital (PCMH) is a 735 bed tertiary center located in Greenville North Carolina. PCMH is located in the buckle of the Stroke Belt (Eastern North Carolina). The effects of stroke are devastating and very costly in terms of death and disability. Immediate response to an individual who presents with acute stroke signs and symptoms in the community we serve remains problematic. The most significant problem is that of early recognition and EMS/911 activation. Our records indicate that from 2001 to 2004 we have treated 18 patients with rT-PA. There has been an annual incremental utilization of rT-PA: 2001 – 2 patients, 2002-4 patients, 2003 – 5 patients, and 2004 – 8 patients. We are expecting to double its use over the next year albeit adhering to the strict guidelines for its use.

We continue to strive to improve stroke care with continued staff education with conferences, literature, internet website access, and in-house programs. Community programs have been implemented to raise public awareness of stroke recognition and to activate EMS/911 for emergent evaluation. We are also in the process of preparing for JACHO certification as a Stroke Center.

Each year PCMH treats over 800 Stroke survivors, both during the acute phase of their illness and the Rehabilitation phase of Recovery. Most of the patients treated with rT-PA have good outcomes ranging from complete recovery to good recovery. Savings for these persons cannot be measured in monetary figures. Their life has been given back to them after a devastating event.

Administration of reperfusion therapy requires a well-orchestrated program, from prehospital to hospital diagnosis and treatment. Activation and availability of the Stroke Team, which includes the Emergency Physician, Neurologist, Nursing Staff, EMS, Radiology and Pathology services, and other personnel 24/7 is costly, as is the therapy. Close monitoring during and after infusion in a Critical Care setting is also necessary. The important factor is the recovery of the patient. Higher reimbursement would help improve care, increase efficiency in drug administration and help raise community awareness. The goal of the Stroke Center is to deliver the best care in the timeliest manner to all that qualify for treatment following best practice recommendations.

Please support this initiative of increasing reimbursement for reperfusion therapy to all that meet the criteria for administration. This would result in increased savings to the health care systems, because of the resultant decrease in long term disability costs—lost productivity or long term placement. Creation of a new DRG for reperfusion would insure adequate reimbursement. Additionally because Stroke Care has become more collaborative and comprehensive between many medical services described above it is imperative to compensate Stroke Centers for meeting the task of improving the delivery of reperfusion therapies to those who will benefit.

Thank you for all of the attention you have given to this issue on behalf of Medicare beneficiaries and this special attention you have given to stroke patients. For more information, I can be reached at 252-752-4848 (office) or facsimile 252-752-6985 or email contact: rleacock@ecneurology.com

Sincerely,

Rodney Leacock

Rodney O. Leacock, M.D.
PCMH/ECN

cc: Marie Welch, Clinical Nurse Specialist
Stroke Center Coordinator

Martha Dixon, Vice President
General and Rehabilitation Services

Jay Briley, Administrator for Special Projects

319

WALZ
HART
TREITEL
HERTER
HARTSTEIN

Submitter : Ms. Karen Ryan **Date:** 06/23/2005

Organization : Geisinger Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached for Geisinger Health System, Danville PA comments on CMS 1500-P

CMS-1500-P-602-Attach-1.DOC

TRANSFERS
PYMT RTS/OUTLIER

DRAFT

Attachment 602

Geisinger Health System

Heal. Teach. Discover. Serve.

June 16, 2005

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

REF: CMS 1500-P
Comments on Proposed Medicare Inpatient Changes for Fiscal Year 2006 (Federal Register Vol. 75, No. 85, May 4, 2005)

Dear Dr. McClellan:

The purpose of this letter is to provide comments on the Centers for Medicare and Medicaid Services ("CMS") "Proposed changes to the hospital inpatient prospective payment system for FY 2006". These proposed regulations were published in the Federal Register on May 4, 2005.

Geisinger Health System ("GHS") is an integrated healthcare delivery system with corporate offices located in Danville, PA. The Geisinger Health System includes Geisinger Medical Center (provider #39-0006), a 364 bed tertiary care center located in Danville, PA and Geisinger Wyoming Valley Medical Center (provider #39-0270), a 137 bed acute care facility located in Wilkes-Barre, PA. In total, Medicare activity accounts for approximately 24% of the combined net patient revenue of both facilities.

We have reviewed the proposed rule, and are providing comments on several issues, as follows:

I. Post Acute Transfers

CMS is proposing to expand the post acute care transfer policy from the current 30 DRG's to 223 DRG's in FY 2006. The expansion of the transfer policy undermines the basic premise of a prospective payment system, and penalizes hospitals for providing the highest level of care in the most appropriate setting.

GHS strongly opposes this proposed major revision to the post-acute care transfer policy. The adoption of "Option #2" by CMS will result in significant payment reductions to providers.

When the current Prospective Payment System ("PPS") was transitioned from a cost reimbursed system in 1984, the standardized rate was based on a national cost per discharge. Since then, inflation factors to this rate have been inadequate when compared to the inflation rate of healthcare costs. CMS continues to pass legislation to make significant reductions to provider payments – this proposed policy change is such an example. Hospital margins will continue to deteriorate if CMS

implements this drastic change to the post-acute transfer policy, potentially impacting the services currently being provided to Medicare beneficiaries.

The change in the criteria that was used by CMS to develop the proposed 223 post-acute transfer DRG's is arbitrary and capricious. Virtually all DRG's, with the exception of DRG's with a geometric mean length of stay of three days or less, and short stay DRG cases will be subject to the post-acute transfer methodology.

This change in the process used to select DRG's for inclusion in the post acute transfer policy has no valid basis, other than the common characteristics of all 223 proposed DRG's, :

1) Annual post acute discharges of 2,000 (current threshold is 14,000 discharges)
2) At least 20% of all DRG cases discharged to post acute care (new criteria)
3) Cases discharged to post acute care- at least 10% occur before the geometric mean length of stay (current criteria)

This criteria is not sufficient basis or evidence to support such a significant change in Medicare payments.

The transfer payment system has also become increasingly more difficult to administer. If 223 DRG's are included in the current policy, 133 of these DRG's would qualify to receive a "special payment" consideration (fifty percent of the full DRG plus the single per diem for the first day of the stay and fifty percent of the per diem for the remaining days), while the other DRG's will be reimbursed based on the normal post-acute transfer methodology. This complexity puts an additional burden on hospitals and Fiscal Intermediaries to reconfigure information systems to accommodate these changes.

Hospitals are being financially penalized for making clinical decisions regarding the most appropriate setting for the patients care. Patients are requiring more complex care, and the cost of this care, including new technology is escalating at a rapid rate. If Option #2 is adopted, this will result in a significant decrease in Medicare payments to providers, and put an additional strain on the ability of hospitals and healthcare systems to sustain themselves. It is estimated that hospitals will see their overall payments decrease 1.1%. The financial impact to GHS is estimated at $1.5M, or 1.2% of total Medicare payments.

We strongly recommend that CMS does not incorporate the revised criteria for post-acute transfer payments in the Final Rule.

II. Outliers

CMS is proposing to increase the outlier threshold from the current $25,800 to $26,675, a modest increase of 3.4%. Any increase to the threshold will make it more difficult for hospitals to qualify for outlier payments, and put them at greater financial risk when treating high cost cases.

CMS has projected actual outlier payments for FY 2004 to be 3.5% of total inpatient payments, a 1.6% reduction in the estimated 5.1% of total PPS payments that is used to fund outlier payments. CMS is also projecting outlier payments for FY 2005 will fall short of the estimated 5.1% outlier funding rate by .6%

Based on section 1886(d)(5)(A)(iv) of the Social Security Act, the outlier funding pool is to be no less than 5% or more than 6% of the total PPS operating payments. Historically, the pool percentage has been less than the 5% minimum. Cumulatively for 2004 and 2005, providers were underpaid by 2.2%, using the 5.1% as the expected payment.

Due to the underpayment of projected outlier payments for both years, and the significant changes in the outlier payment policy that were implemented in August, 2003, CMS should decrease the outlier threshold for FY 2006.

CMS needs to reevaluate the process for determining changes to the outlier threshold based on more current charge data (which they have attempted to do in this Proposed rule), the impacts of the significant outlier payment changes, and the shortfalls to the projected 5.1% funding appropriations for outlier payments. It is imperative that hospitals receive the entire allocation of outlier payments that they are entitled to in order to receive additional payments for high cost cases, and reduce the financial risk of treating the most critically ill Medicare beneficiaries.

If shortfalls to this estimated outlier funding occur, there should be policies developed to include the shortfalls in subsequent years outlier funding pool, with the thresholds adjusted accordingly to compensate for the previous years outlier underpayments.

GHS recommends that CMS roll forward these underpayments from prior years to future years to ensure that the total projected outlier funding pool is used for outlier payments.

GHS agrees that retroactive payments to individual providers may not be the most efficient solution. A possible alternative would be to return these underpayments to the providers via a mid -year threshold correction based on the final data available from the previous two fiscal years.

Thank you for the opportunity to comment on these very important issues.

Sincerely,

Karen Ryan
Director, Hospital Reimbursement
Geisinger Health System
Danville, PA

KR/vj

H/pub/Medicare 2006 Inpatient Comments

320

KENLY
HEFTER
HARTSTEIN

CMS-1500-P-603

Submitter : Ms. Anne Little **Date:** 06/23/2005

Organization : Provena United Samaritans MC

Category : Hospital

Issue Areas/Comments

GEO RECLASS

GENERAL

GENERAL

See attachment.

CMS-1500-P-603-Attach-1.DOC

Attachment 603

June 23, 2005

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

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

Dear Sir or Madam:

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

Sincerely,

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

321

VALZ
HART
TREITEL
ROMANO
HEFTER
HARTSTEIN

Submitter : Mr. Kenneth Becker
Organization : Catholic Health East
Category : Hospital

Date: 06/23/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-604-Attach-1.PDF

TRANSFERS
PYMT RTS/OUTLIERS
SPH

CATHOLIC HEALTH EAST

Attachment 604

CORPORATE OFFICE

14 Campus Boulevard, Suite 300
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www.che.org
(610) 355-2000 (610) 355-2050 fax

June 23, 2005

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

Re: CMS-1500-P – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule (70 *Federal Register* 23306)

Dear Administrator McClellan:

On behalf of Catholic Health East, I would like to thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Proposed Changes to the Hospital Inpatient Prospective Payments Systems and Fiscal Year 2006 Rates; Proposed Rule, published on May 4, 2005 in the *Federal Register*.

Catholic Health East (CHE) is a multi-institutional, Catholic health system with facilities in 11 eastern states from Maine to Florida. Catholic Health East is comprised of 31 acute care hospitals, 46 free-standing and hospital-based long term care facilities, 12 assisted living facilities, five continuing care retirement communities, three behavioral health facilities, three rehabilitation facilities, 18 home health/hospice agencies, and numerous ambulatory and community-based health services.

I would like to offer comments on the following provisions of the proposed rule:

- Post-Acute Care Transfers
- Outliers
- Specialty Hospitals

Post-Acute Care Transfers

In the background to this section of the IPPS NPRM, CMS explains, "the 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." To that end, CMS is proposing its third set of criteria for inclusion in the transfer policy in three years.

Section 1186(d)(5)(J) of Title XVIII of the Social Security Act grants the Secretary the authority to include in the transfer policy diagnosis-related groups (DRGs) based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services. In order to establish criteria for which DRGs will be included in the transfer policy, CMS should offer a definition of "high volume discharges" and "disproportionate use of post discharge services." Instead, in this proposed rule, CMS has employed the following logic. Of those DRGs that have geometric mean lengths of stay that are greater than or equal to 3.0 days, 64 have fewer than 100 short-stay transfer cases. Without indicating its reasoning, CMS states those 64 DRGs do not have a high volume of discharges to post-acute care facilities or involve a disproportionate use of post-acute care services. CMS then takes the remaining 223 DRGs, finds the common denominator among them in terms of the number of post-acute care transfers, the percent of all cases within the DRG that were discharged to post-acute care settings and the percent of all discharges to post-acute care prior to the geometric mean length of stay for the DRG and deems that as the new proposed criteria for the transfer policy.

CMS has clearly "put the cart before the horse" in creating the criteria for the transfer policy. More importantly in crafting this policy, CMS has disregarded the intent of Congress as laid out in the statute. If these proposed criteria were created to carry out the legislative intent, then CMS should provide better reasoning than "we examined the characteristics of the remaining 223 DRGs [and]... found that these DRGs had three common characteristics." To do otherwise is to draft an arbitrary set of standards for inclusion in the post-acute care transfer payment policy.

In addition, clinically speaking, the post-acute care transfer policy is not in the best interest of patients or caregivers. It undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting.

CHE commented on this issue in 2004 and again respectfully urges CMS to withdraw the proposed selection criteria for including a DRG within the post-acute care transfer policy. If the transfer policy must be expanded, CHE requests that CMS craft a set of criteria that is in line with the intent of Congress as laid out in the statute and takes into account the clinical ramifications of the transfer policy.

Outliers

CMS is proposing to set the fixed-loss cost outlier threshold for FY 2006 at $26,675, which is only about an $800 increase from the threshold set for FY 2005. In the proposed rule, CMS estimates that the outlier payments for FY 2005 will be approximately 4.4 percent of actual DRG payments, which is a smaller percentage than the statute anticipates. Section 1886(d)(5)(A)(iv) of the Act requires that outlier payments be between five and six percent of total DRG payments. We are concerned that, given only 4.4 percent of total DRG payments, the proposed FY 2006 fixed-loss threshold will again result in total outlier payments that are less than five percent of total DRG payments.

CHE urges CMS to amend the fixed-loss cost outlier threshold to ensure that outlier payments will at least meet the minimum statutory threshold of five percent of total DRG payments. Hospitals need to be appropriately reimbursed for high cost cases.

Specialty Hospitals

CHE supports CMS' scrutiny of certain physician-owned limited service hospitals by ensuring that hospitals that are reimbursed through Medicare program are primarily engaged in the provision of inpatient services. Physician self-referral to specialty hospitals can have serious repercussions on community hospitals. Until the loophole in the Stark law that permits specialty hospitals to qualify under the "whole hospital" exemption is closed and incentives in the payment system to cherry-pick the healthiest and most profitable patients are eliminated, holding Medicare participating hospitals accountable for meeting the definition of a hospital by primarily providing inpatient services works to ensure there is a level playing field between specialty hospitals and community hospitals.

Thank you for your review and consideration of these comments.

Sincerely,

Ken Becker
Vice President
Advocacy and Government Relations

322

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : Dr. Steven Bolling
Organization : University of Michigan
Category : Physician

Date: 06/23/2005

DRG/GEN

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1500-P-612-Attach-1.DOC

University of Michigan
Hospitals and
Health Centers

Section of Cardiac Surgery

Attachment 612

Steven F. Bolling, MD
Professor of Surgery
Gayle Halperin Kahn Professor
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Office (734) 936 -4981

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Mitral Clinic: 800-792 -6782
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Ann Arbor, MI 48109 - 0348
www.surgery.med.umich.edu/cardiac

Pediatric Clinic Appointments
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Fax: (734) 763 -7353
Mott Children's Hospital
F7830, Box 0223
Ann Arbor, MI 48109 – 0223

June 23, 2005

RE: Implantation of Prosthetic Cardiac Support Device from DRGs 110/111 to DRG 108

To whom it may concern:

Please reconsider the assignment of procedure code 37.41-Implantation of Prosthetic Cardiac Support Device from DRGs 110/111 to DRG 108. The current assignment is inconsistent with the logic of DRG assignment which groups procedures that are similar clinically and have similar resource utilization profiles.

Procedures in DRG 110/111 are primarily endovascular procedures and those that do not require a full sternotomy. Few, if any, procedures in this DRG even involve operations directly on the heart itself. The CorCap requires a full median sternotomy, full circumferential pericardiotomy and involves suturing the device to the myocardium. Clearly this procedure is more clinically complex and requires significantly more resources than those in DRG 110/111. Procedures in DRG 108 are much more comparable to the CorCap implant procedure. They are all open chest procedures involving operations either on the surface of the heart or within the heart itself. It is interesting to note that an open TMR procedure is very similar to the CorCap implant in that it is an open chest procedure that is performed directly on the surface of the heart. While it does not involve the permanent implantation of a device, it does utilize device technology that adds costs to the procedure.

As an investigator for the Acorn CorCap CSD US Randomized clinical trial, I am concerned that my patients will have limited access to this potentially life-saving technology if the Agency fails to correct this error in DRG assignment. Please reconsider and place the CorCap procedure code (37.41) into DRG 108 to be more consistent both clinically and with respect to resource utilization.

Sincerely,

Steven F. Bolling

Steven F. Bolling, MD
Professor of Surgery
Adult Cardiac Surgery
Gayle Halperin Kahn Professor of Integrative Medicine

323

COLLINS
MOREY
SMITH
HEFTER
HARTSTEIN

Submitter : Ms. Amy Barkholz

Organization : Michigan Health & Hospital Association

Category : Health Care Professional or Association

Date: 06/23/2005

CAH/Reloc

Issue Areas/Comments

GENERAL

GENERAL

See Attachment on "Critical Access Hospitals" file code: CMS-1500-P

CMS-1500-P-614-Attach-1.DOC

Attachment 6/4

MHA
MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Linking patients, communities, and providers together for better health.

TO: Centers for Medicare and Medicaid

FROM: Amy Barkholz, Senior Director, Advocacy, Michigan Health & Hospital Association

DATE: June 23, 2005

SUBJECT: **Critical Access Hospitals**
File Code: CMS-1500-P
Position: Opposed

The Michigan Health & Hospital Association **opposes** the proposed rule (file code: CMS-1500-P) to limit Critical Access Hospitals categorized as "necessary providers" from relocating their facilities more than 250 yards from their current location unless they can prove that their construction plans were underway prior to December 8, 2003.

24 hospitals in Michigan are either currently or in the process of becoming Critical Access Hospitals through the sunsetted 'Necessary Provider' designation. The proposed additional rule to regulate the future relocation of 'Necessary Provider' hospitals represents a drastic over-reaction to a perceived problem, is unnecessarily restrictive and arbitrary, and will result in greater costs and inefficiencies for the hospitals that it effectively "land-locks."

Three Michigan hospitals are immediately precluded from continuing their construction plans and the remaining 21 hospitals are likely to be negatively impacted in the future. There are many reasons why it is appropriate and cost efficient for an aging health facility to relocate more than 250 yards from its current location.

Here are the most important reasons why this proposed rule should be withdrawn or amended to eliminate the requirement that construction plans be underway prior to December 8, 2003:

- Many rural hospitals were built 50 to 60 years ago and the physical plant is nearing the end of its usefulness. Additionally, since these hospitals were built, other construction has occurred around them. Thus, they have become land-locked. There is no room on the hospital campus to build a new facility and renovation costs are larger than new construction costs.

- In some cases, these facilities can no longer meet HIPAA requirements, fire-safety codes, engineering guidelines, and other state and federal regulations because of the constraints of their aging facilities.

- The CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location may cost Medicare more money, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly higher cost of rebuilding versus renovating.

- Michigan's strong Certificate of Need laws already adequately regulate hospital construction, renovation, and relocation. It is unnecessary and duplicative for CMS to regulate this area.

- Without Congressional direction, this proposed regulation transfers control to the federal government over the basic structure of local rural health care that represents a loss of local control and sets a precedent that is a threat to all hospitals and communities.

- It was not the intent of Congress in the Medicare Modernization Act that Critical Access Hospitals designated as Necessary Providers be perpetually prohibited from replacing or relocating their facility.

- The CMS proposed ban is based on the misguided belief, in a break with CMS's past policy, that the relocation of a Critical Access Hospital can be treated differently. There is no basis for the premise that the relocation within a community of a Critical Access Hospital with Necessary Provider status constitutes a cessation of business and loss of its provider number. It is a longstanding policy that the provider number describes the legal entity and services provided not the physical structure or location.

- This proposed ban on all construction developed after December 8, 2003 is an over-reaction against potential problems that can be appropriately managed by CMS's proposed rule requiring assurance that, after the construction "the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff."

Thank you for the opportunity to comment on this proposed rule. The Michigan Health & Hospital Association and the 142 hospitals we represent strongly oppose this provision as written.

324

WALZ
HART
HEFTER
HARTSTEIN
BROOKS
FAGAN
GRUBER
KELLY
HUE

Submitter : Dr. Jean Douglas

Date: 06/23/2005

Organization : Moses Cone Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

TRANSFERS
DRG/GEN

CMS-1500-P-617-Attach-1.PDF

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

June 23, 2005 Attachment 6 17

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

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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

325

COLLINS
MOREY
SMITH
KRAEMER
HEFTER
HARTSTEIN

Submitter : Mr. Craig Becker

Date: 06/23/2005

Organization : Tennessee Hospital Association

Category : Health Care Professional or Association

CAH/RELOC IMPACT

Issue Areas/Comments

GENERAL

GENERAL

Request deletion of the the arbitrary deadline on Critical Access Hospital replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule.

CMS-1500-P-618-Attach-1.DOC

Attachment 618

TENNESSEE HOSPITAL ASSOCIATION

June 24, 2005

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

To Whom it May Concern:

In the recently released inpatient prospective payment system (IPPS) proposed rule (2006), the Centers for Medicare and Medicaid Services (CMS) only provides continued critical access hospital (CAH) status for state-designated necessary providers, which includes all Tennessee CAHs, that are building replacement facilities at another location and can demonstrate their construction plans began before Dec. 8, 2003.

The Tennessee Hospital Association (THA) believes this arbitrary date restriction has no statutory basis, and will hurt many rural communities' health care. It puts many relocation projects in Tennessee in jeopardy that were started or planned in the year and a half since the passage of the Medicare Prescription Drug Improvement and Modernization Act (MMA).

As outlined in the proposed rule, CMS seeks to clarify the issue of CAH relocations and offers the stark reality that only a few CAHs will be grandfathered prior to the cut-off date of Jan. 1, 2006, with no other exceptions. To maintain their CAH status, all necessary providers must submit an application to CMS for relocation prior to Jan. 1, 2006, and be able to: 1) demonstrate they will continue to meet the necessary provider criteria that was used to originally receive a state waiver at the new location, serve at least 75 percent of the same service area, offer 75 percent of the same services, utilize 75 percent of the same staff, maintain compliance with all conditions of participation (42 CFR 485); and 2) demonstrate that construction plans were under development prior to the enactment of the MMA. CAHs moving within 250 yards of their current buildings, or to contiguous land that was owned prior to Dec. 3, 2003, will be exempted from the relocation rules.

THA's concern is the CMS inpatient prospective payment system (IPPS) proposed rule prohibits any CAH operating with a necessary provider designation from relocating its facility and maintaining its CAH status unless the move is completed by Jan. 1, 2006, or grandfathered. Necessary provider CAHs that had construction plans already under development as of Dec. 3, 2003, also must

demonstrate this fact in their applications for relocation and submit them to CMS prior to Jan. 1, 2006.

It was clearly not the intent of congress in the MMA that a CAH designated as a necessary provider be perpetually prohibited from replacing or relocating its facility, which often are 40 to 50 years old. Many rural hospitals are located on a small campus in the middle of residential neighborhoods with relocation being the most appropriate, and sometimes only, alternative.

Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more money over time, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly higher cost of rebuilding. A ban on major construction projects developed after Dec. 8, 2003, is an overreaction against a potential problem that can be appropriately managed by the portion of CMS' proposed rule that would require assurance that, after construction, the CAH would be servicing the same community and operating essentially the same services with the same staff.

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

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

With the exception of a select group of CAHs that may receive grandfather status under the relocation sunset provision, this proposal makes it virtually impossible for any CAH operating with a necessary provider designation, including approximately 14 hospitals in Tennessee, to ever afford an offsite replacement facility project, as it would immediately become ineligible for cost-based reimbursement.

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

The Tennessee Hospital Association is requesting CMS take all steps necessary to eliminate the arbitrary deadline on critical access hospital replacement or relocation in the inpatient prospective payment system final rule.

Sincerely,

Craig A. Becker
President

326 WALZ HART COLLINS MOREY SMITH HEFTER HARTSTEIN

Submitter : Mr. Kevin Lofton **Date:** 06/23/2005

Organization : Catholic Health Initiatives

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-619-Attach-1.DOC

TRANSFERS CAH/RELOC

CATHOLIC HEALTH INITIATIVES

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Attachment 619

June 21, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1500-P
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Dr. McClellan:

Catholic Health Initiatives (CHI) appreciates the opportunity to comment on the Fiscal Year 2006 Hospital Inpatient Prospective Payment System (PPS) proposed rule. CHI operates 61 community hospitals in 17 states, including 15 Critical Access Hospitals (CAHs).

While CHI supports many of the provisions in the proposed rule, we are very concerned about proposals to dramatically expand the post-acute transfer policy and to prevent CAHs with necessary provider status from relocating.

EXPANSION OF POST-ACUTE CARE TRANSFER POLICY

CHI strongly opposes the proposed relaxation of the criteria for including a DRG within the post-acute care transfer policy. The Centers for Medicare and Medicaid Services (CMS) raises the possibility of expanding the transfer policy from 30 Diagnosis Related Groups (DRGs) to either 231 DRGs or all DRGs.

Under the transfer policy, a hospital is paid a per diem rate, rather than the full DRG amount, if a patient is discharged to a post-acute setting (or home health within three days) and the hospital length of stay is at least one day less than the national average.

Expansion of the transfer policy to most or all DRGs undermines the basic principles, promises and objectives of the Medicare Prospective Payment System (PPS). PPS is based on a system of averages with gains of shorter than average stays offsetting losses of longer than

average stays. The PPS system creates incentives for efficiency and reduction of unnecessary inpatient days.

The incentives of PPS would be reversed by a massive expansion of the transfer policy. The proposed expansion would undermine clinical decision-making, penalize hospitals for providing efficient care and create incentives to retain inpatients longer.

These arbitrary changes to the criteria for applying the transfer policy appear designed to obtain budget savings (in excess of $880 million in FY 2006), not to ensure that patients receive the right care in the right setting at the right time. CMS has not provided a scientific, clinically sound basis for setting these criteria, nor has it justified how these criteria satisfy congressional intent that the transfer policy be focused on those DRGs with a high volume of discharges to post-acute care and a disproportionate use of post-discharge services.

The proposed expansion of the post-acute care transfer policy is not in the best interest of patients or providers. It is contrary to the intent of Medicare PPS, lacks scientific justification, and appears driven by budgetary goals rather than the desire to provide appropriate care to Medicare beneficiaries. This provision should be withdrawn in the final rule.

CRITICAL ACCESS HOSPITAL "NECESSARY PROVIDER" RELOCATIONS

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) terminates, effective January 1, 2006, a state's authority to allow a hospital closer than 35 miles to another hospital (or 15 miles in mountainous areas) to obtain CAH status by designating it as a "necessary provider." However, Congress clearly intended that CAHs designated as necessary providers by states before January 1, 2006 would be allowed to continue their CAH status.

In the proposed rule, CMS has invented restrictions that would cause a necessary provider to lose its CAH status if it builds a needed replacement facilities on a different site, even though it continues to serve the same community. This proposed rule violates congressional intent to continue the CAH status of necessary providers after the expiration of the state waiver authority.

A necessary provider would lose its CAH status if it rebuilt anywhere except on its existing site (or contiguous property purchased by December 8, 2003) unless the new hospital was "under development" as of December 8, 2003 and an application for relocation had been submitted to the state agency prior to January 1, 2006. These date restrictions are unrealistic, unreasonable and not required by the MMA.

Many CAHs are housed in deteriorating, older buildings that need to be replaced in the coming years to improve patient safety and quality of care. The payment improvements for CAHs included in MMA finally provided some financial stability that allows these vulnerable hospitals to begin thinking about replacing their aging plants. Very few CAHs had these plans underway by December 8, 2003 or would be in a position to submit a relocation application to the state by January 1, 2006.

Rebuilding on existing or adjacent sites is not always an option. In addition to the disruption to patient care caused by construction at the existing hospital, a CAH may be landlocked where it is and have no choice but to move to meet the health care needs of its community. CAHs may need to move to new sites to be closer to highways, connect to municipal water and sewer, modernize telecommunications to support health information technology, and improve patient care delivery.

CHI currently operates 15 CAHs, several of which obtained their critical access status through state designation as "necessary providers". Continuation of these hospitals is vital to the rural communities and individuals they serve. Our Lady of the Way Hospital in Martin, Kentucky, is a prime example of the problems created by the proposed rule's deadlines.

Our Lady of the Way Hospital serves an impoverished, mountainous area of eastern Kentucky. Floyd County is one of the poorest counties in Kentucky with 25.3% of the population living in poverty, according to the most recent Census report. Median household income in Floyd County is $21,168, compared to $41,994 for the rest of the United States. This small, critical access facility operates six rural health clinics and provides more than $6 million a year in charity care -- 38% of the hospital's net patient services revenue -- to meet the health care needs of area residents. The cost-based reimbursement available through CAH status helps to sustain this needed facility.

Our Lady of the Way Hospital is in a landlocked, aging building that sits adjacent to the downtown area of Martin -- near the river. The river frequently floods the town, so the U.S. Army Corps of Engineers will be moving much of the downtown to a site higher up the mountain as part of a flood control project. The hospital and town leadership are hoping to obtain a site for the new hospital at the new town center but no decisions have been finalized. The hospital fell just outside of the floodplain even though its parking lot floods.

This is a hospital that is vital to the economic health of the town of Martin and to meeting the health care needs of individuals, particularly the elderly, with limited or no means of transportation to more distant facilities. However, Our Lady of the Way Hospital could not meet the requirements of the proposed rule to have had its construction plans "under development" by December 8, 2003 or to submit a relocation plan to the state by January 1, 2006.

CMS should not, as proposed, consider hospitals that have moved a few miles from their current location as having ceased business and reopened as new providers. If a CAH designated as a necessary provider continues to serve the same communities, it should not be penalized for moving a few miles down the road to better meet the health care needs of its patients. If CMS is concerned that grandfathered CAHs could move to new markets without seeking new CAH approval, the proposed criteria for serving the same population with the same staff and providing the same services should be sufficient. However, any criteria should accommodate changes in demographics, the practice of medicine and community needs over time.

Grandfathered necessary provider CAHs should be allowed to relocate as needed to increase efficiency, improve care and meet the health care needs of their communities. CMS should remove all construction plan deadlines from any criteria used to determine continued CAH status for grandfathered necessary providers who relocate.

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

Sincerely,

Kevin E. Lofton
President and Chief Executive Officer

327

WALZ
HART
HEFTER
HARTSTEIN

Submitter : Ms. Ellen Zane

Organization : Tufts-New England Medical Center

Category : Hospital

Date: 06/23/2005

Issue Areas/Comments

GENERAL

TRANSFERS

GENERAL

See attachment

CMS-1500-P-620-Attach-1.PDF

Attachment 620

Tufts-New England Medical Center

The principal teaching hospital for Tufts University School of Medicine

June 24, 2005

Executive Office
Tel: 617-636-9589
Fax: 617-636-7623

Ellen M. Zane
President and
Chief Executive Officer

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room 443-G
200 Independence Ave, SW
Washington, DC 20201

Attention: **CMS-1500-P**

Dear Administrator McClellan:

Tufts-New England Medical Center, an academic teaching hospital in Boston, Massachusetts welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates."* 69 Fed. Reg. 28196 (May 18, 2004). We would like to comment on certain proposals that have specific importance to teaching hospitals. In particular, we urge the Agency not to expand the post-acute care transfer policy.

POST-ACUTE CARE TRANSFER PAYMENT POLICY

Medicare patients who are sent from one acute care hospital to another are viewed as "transfers." The transferring hospital is paid a per diem rate based on the DRG payment and the number of days spent at the transferring hospital; the receiving hospital receives the full DRG payment.

In FFY 1999, in accordance with the BBA, CMS expanded its transfer policy such that hospitals that discharge patients associated with one of 10 specified DRGs to a post-acute care (PAC) facility – such as rehabilitation hospitals and units, psychiatric hospitals and units, cancer, long-term care and children's hospitals, skilled nursing facilities, or are discharged home and receive home health services within three days after the date of discharge – would receive payments under the "post-acute care (PAC) transfer" policy. In subsequent years, CMS further expanded the post-acute care transfer policy, and as a result, a total of 30 DRGs were subject to the PAC transfer policy in FFY 2005.

CMS is proposing to expand--again--the post-acute care transfer policy, from 30 to 223 DRGs. DRGs that meet the following criteria would be subject to the PAC policy:

- The DRG has at least 2,000 discharges to post-acute care;
- It has at least 20 percent of cases in the DRG were discharged to post-acute care;

Tufts-New England Medical Center
Established 1796

750 Washington Street
Tufts-NEMC #451
Boston, Massachusetts 02111

- Out of the cases discharged to post-acute care, at least 10 percent occur before the geometric mean length of stay for the DRG;
- The DRG has a geometric mean length of stay of at least 3 days; and
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

According to CMS, this proposed expansion would result in $880 million less in Medicare program payments to hospitals, the equivalent of a 1.1 percent decrease in payments, although our analyses show a reduction of $894 million when the effects of IME, disproportionate share, capital and outlier payments are considered.

Simply put, CMS should not implement an expansion of the post-acute care transfer policy. Such a policy penalizes hospitals that ensure that Medicare patients receive care in the most appropriate setting. Moreover, it undercuts the fundamental principle of the PPS, which is that some cases will cost more than the DRG payment, while others will cost less, but on average, the overall payments should be adequate. It also is important to recognize that to the extent there still are cost reductions associated with discharging patients to post-acute care facilities (a debatable presumption given the current low average lengths of stay), such reductions will be reflected in lower DRG case weights during the DRG recalibration process.

We also agree with comments by the American Hospital Association that this proposal does not comport with the statutory directive that CMS focus on those DRGs that have a *high volume* of discharges to post-acute care and a *disproportionate use* of post-discharge services (emphasis added). (SSA section 1886(d)(40(J)(ii)). Moreover, contrary to CMS's assertion that the PAC transfer policy levels the playing field for rural hospitals that do not have access to post acute care that is comparable to urban hospitals, AHA analyses show that rural patients have essentially the same access. Consequently, the proposed rule would harm all hospitals. We urge the Agency to rescind this proposal.

Thank you for this opportunity to present the views of Tufts-New England Medical Center. If you have any questions, please feel free to contact me at 617-636-9589.

Sincerely,

Ellen Zane
President and Chief Executive Officer
Tufts-New England Medical Center

cc: Senator Edward M. Kennedy
Senator John F. Kerry
Representative Michael E. Capuano
Robert Dickler, AAMC
Karen Fisher, AAMC

328

MILLER
WALZ
HART
SMITH
TREITEL
HEFTER
HANSTEN

Submitter : Ms. Susan Johnson
Organization : Iowa Health Des Moines
Category : Hospital

Date: 06/23/2005

WI/GEN
WI/Bd
WI/OM
TRANSFERS
DSH
PYMT RTS/OUTLIER
NT

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-621-Attach-1.DOC

Attachment 6.21

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

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

Dear Dr. McClellan,

I would like to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the FY 2005 inpatient prospective payment system (PPS) published the May 4, 2005 Federal Register. I am commenting on behalf of Iowa Health Des Moines (IHDM).

FY 2006 Wage Index

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

An ongoing concern with the wage index calculation is that the hospital wage index is applied to many provider types for which wage data is excluded in the wage index calculation. I would recommend that CMS work on developing a method for computing separate wage indexes for Skilled Nursing, Acute Rehab, and Inpatient Psychiatric units by modifying the way wage index data is reported on the hospital cost reports.

Occupational Mix Adjustment

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required CMS to collect occupational mix data to be used in adjusting wage indices beginning October 1, 2004. While our hospitals have not been significantly affected by the occupational mix adjustment, we would recommend against using this apparently flawed data for any type of adjustment to the wage index.

We echo the Iowa Hospital Association's (IHA) specific concerns surrounding the process CMS instituted in collecting the occupational mix data, including vague and untimely instructions that lend themselves to further subjectivity within the wage index development; the lack of recognition of certain hospital occupational categories, e.g., radiology; and, the short time frame by which hospitals had to respond to the survey. Each of these issues intensifies concerns regarding the integrity of the data CMS collected and is using in the adjustment.

We agree with the following IHA recommendations:

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

Post-acute Care Transfers

IHDM strongly opposes any expansion of the post-acute care transfer policy to additional DRGs because it unfairly penalizes hospitals for the efficient treatment of patients.

The proposal to expand the post-acute care transfer provision – either to all DRGs or an additional 231 (increased from 223 after revisions to the proposed rule after it was released) —must be reversed. The inpatient PPS was developed with the intent of reducing the length of stay for patients by creating incentives for providing efficient care, while continuing to provide high quality medical services. To penalize hospitals for making good clinical decisions and discharging patients prior to the average length of stay when medically appropriate, is in direct conflict with the design of the payment system. In addition, the annual recalibration of the system should already take into account the cases that are transferred prior to the average length of stay and thus, hospitals caring for patients falling into these categories whose stays are longer are already experiencing the financial burden of exceeding the average stay.

Further expansion of the policy also contradicts the mathematical premise of the inpatient PPS. In a system of averages, there will be cases when the patient's length of stay is below the average, as well as above. By reducing payment for cases below the average, CMS inhibits hospitals' ability to break even in the payment system. More importantly, any concerns policymakers may have had about early discharge of patients to gain additional payment by providing post-acute care have already been allayed. Significant cutbacks in Medicare payment and the shift to PPS for home health, skilled care and other post-acute care services have removed any previous incentive that may have been in place for early discharge. Further, each of these post-acute care payment systems have admission criteria that ensures patients are not discharged prematurely to a lower level of care. Finally, the policy reduces incentives to integrate care with other community

providers, such as home health agencies, because it penalizes hospitals for doing so at a time when consideration should be given to incorporating a continuum of care in the best interests of patients' needs and in order to achieve the best quality outcomes.

For the third year in a row, CMS is proposing extensive changes to the criteria a DRG must meet to be added to the post-acute care transfer policy. These continual changes in the DRGs subject to the policy create a situation that makes it nearly impossible for hospitals to plan financially from year to year as CMS attempts to arbitrarily change the criteria to ensure certain DRGs are included in the transfer policy.

Finally, CMS' proposed policy change on the post-acute transfers in this rule is inconsistent with the statements made by the agency in FY 2006 proposed rule for the skilled nursing facility (SNF) PPS. Specifically, in the May 19, 2005 proposed rule (page 29081), CMS states "Medicare should provide payments sufficient to ensure that beneficiaries receive high quality care in the most appropriate setting, so that admissions and any transfers between settings occur only when consistent with good care, rather than to generate additional revenue". A detailed evaluation of the outcomes associated with transferred patients is necessary before any further expansion of the policy occurs to identify not only length of stay changes but other items such as inpatient readmissions and level of care received in the post-acute setting as measured by the classification systems present in the SNF and home health payment systems.

DSH Data

IHDM supports the direction contained in section 951 of the MMA that requires CMS to furnish the data necessary for hospitals to compute the number of patient days used in calculating disproportionate share percentages. However, IHDM is concerned that CMS has been misinformed as to the availability of established procedures to obtain information needed by hospitals in order to calculate their Medicaid fraction.

In my experience, this process has been cumbersome at best. IHDM recommends that CMS provide explicit direction to the state Medicaid agencies to provide the eligibility information requested by hospitals in order to support their DSH calculation for Medicare. This direction will standardize the process for releasing Medicaid eligibility information for all states. Further, this instruction must also apply to the health plans that contract with the state Medicaid agencies so that hospitals can also have reasonable access to eligibility data on the population of Medicaid recipients enrolled in managed care.

Outlier Provision

IHDM does not support any increase in the outlier threshold. Based upon actual outlier payment data, CMS outlier payments were lower than the targeted 5% of total DRG payments in both 2004 and 2005. As a trauma center, our facility treats some very high cost patients. Under the current outlier methodology, this additional cost is not recognized, often resulting in significant losses for the hospital. The combination of continued increases in the outlier thresholds and minimal reimbursement for new technology, makes it very difficult for hospitals treating complex patients to cover even

direct costs. It would be helpful if CMS could provide some type of reimbursement related to the complexity level of patients treated to ensure the continued viability of trauma hospitals. This payment could be tied to trauma center designation, case mix index, and/or the volume of patients with no health insurance.

New Technology

IHDM commends CMS for establishing a policy to reimburse hospitals for new technology items. However, we see some room for improvement in the current policy that would make it more equitable for all hospitals using designated new technology items. The current policy rewards hospitals with higher mark-ups on devices by applying an overall cost to charge ratio to determine the portion of hospital cost to reimburse as new technology. Our mark-up on high cost devices is much lower than our mark-up of other services. Thus, when an overall cost to charge ratio is applied to determine the cost of a device, the estimated cost is significantly understated. CMS has access to actual device cost information, so it would be reasonable for CMS to allow a percentage of the actual cost as an add-on for each case qualifying as new technology. C codes could be used to trigger this add-on payment.

Thank you for the opportunity to comment and please contact me at (515) 241-6290 if you have any questions or need additional information.

Sincerely,

Susan Johnson
Reimbursement Manager

Cc: Iowa Hospital Association

329

BODDEN
KRUSHAT
HEFTER
HARTSTEIN

Submitter : Mr. Gary Lowe

Date: 06/23/2005

Organization : Baptist Hospital

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

Q DATA

GENERAL

See Attachment

CMS-1500-P-624-Attach-1.DOC

Attachment 624

CMS-1500-P
V., Section B, Item 2- Reporting of Hospital Quality Data
for Annual Payment Update (412.64(d)(2))

The following narrative and recommendations are submitted in response to the proposed rules published in the Federal Register May 4, 2005.

Most healthcare organizations in the country are working hard and making a sincere effort to get all their quality data into the warehouse and do so accurately and timely. Many have probably had some type of issue in 2004 that has complicated submission, validation, or disrupted the data. These issues may have been alignment issues between CMS and JCAHO, PMS vendor problems, CART tool, or others. Whatever the issues, 2004 was a year of learning, adapting, challenge, and continuous change. Implementation and continued compliance at a non-EMR acute care facility provides a different perspective of the process than on the rule developmental side. I agree with and support the premise of submitting quality data and validating that data to ensure it's reliability and accuracy, but given the state of the processes in 2004, let us not make the 2006 APU exercise unduly complex, cumbersome, or punitive for the hospitals who are trying to get it right.

I'll comment in three areas:

1. The continuous submission of the 10 indicators by quarter through December 2004 is reasonable. This gives CMS a 12 month look back period and, if complete, demonstrates an organizations commitment to collecting and submitting the data. The criteria needs to be redefined to do the look back for only the presence of the 4 consecutive quarters/12 months of 2004 data in the warehouse. Is it there or isn't it, black or white. If the organization has the consecutive data in the warehouse, then give the organization credit for meeting the submission requirements. The data has met the front end edits and consistency checks if it is warehoused and has been accepted.

2. Validation requirements. As you know, CMS and JCAHO did not consider themselves fully aligned until Q1 2005. Although improvements in alignment were made throughout 2004, there were still known hard edit issues and violations occurring in the third and fourth quarter of 2004. This is a very real concern for those organizations utilizing PMS vendors whose software is designed to first meet the JCAHO submission criteria. An organizations validation success or failure could be tied to an alignment issue. The use of the confidence intervals should be a positive development. I think the two step process will also be helpful, especially for the organizations that submit all the HQA indicators and have CDAC exposure across 4 measures sets. To make this work well, CMS needs to advise CDAC on the application of edits and tests where known alignment issues existed for Q3 and Q4 and instruct them to exercise flexibility in their interpretation. In addition, CMS needs to be flexible with the methodology, confidence intervals, and application of the new validation criteria so it accomplishes the intended purpose.

3. Publishable data. The proposed rules already require a 4 quarter consecutive submission to the warehouse and successful validation of the data for Q3 or potentially Q3 and Q4 combined for some organizations. This part of the rule appears contradictory in that it initially states that two consecutive publishable quarters would be required but later in the paragraph it states the organization has to have published in both March and August 2005, three quarters. Ideally this component of the rules needs to be removed based on lack of any value added to the submission and validation of quality data intent or processes. In the event it does not get removed from the proposed rules, it needs to be modified. The rule need to state that hospitals desiring to participate in the 2006 APU must have two quarters of publishable data in the warehouse for the period ended with the forth quarter of 2004. Second, the upcoming August 2005 publication of data needs to be defined as a "from scratch" run. This would mean all Q1 to Q3 2004 data available in the warehouse is used, and published as if it had never been published before. All previous publications (November 2004 and March 2005) and related information would be ignored and any designation or requirement for a quarters data to have been previously published would not be a criteria for inclusion or exclusion of a particular quarter in the August 2005 run. This would level the playing field for organizations that had data or publication problems in 2004 but since have gotten the issues successfully resolved and are ready to publish.

With all the changes in the guidelines, alignment, and myriad of submission issues experience by acute care facilities in 2004, CMS needs to be fair and flexible with the hospitals for the 2006 APU.

Thank you for the opportunity to comment.

Respectfully Submitted,

Gary A. Lowe
Manager, Clinical Decision Support
Baptist Hospital
P.O Box 17500
Pensacola, Fl 32522
(850) 469-5881
Malcolm Baldrige National Quality Award 2003
Fortune 100 Best Places To Work- 4 years

330

WALZ
HART
ROMANO
KENLY
HEFTER
HARTSTEIN
MOREY
Collins
Smith

Submitter : Mr. Thomas Bell

Date: 06/23/2005

Organization : Kansas Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-626-Attach-1.DOC

CMS-1500-P-626-Attach-2.DOC

TRANSFERS
CAH/RELOC
SPH
GEO RECLASS
CAH LUGAR

KANSAS HOSPITAL ASSOCIATION

Attachment 626

June 22, 2005

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

RE: CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates; Published May 4, 2005

On behalf of the membership of the Kansas Hospital Association, we appreciate the opportunity to comment on the above referenced proposed changes to the Inpatient Prospective Payment System (PPS) for federal fiscal year 2006.

POST-ACUTE CARE TRANSFER POLICY

In the proposed rule, CMS states "*the 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 transfer policy adjusts the payments to approximate the reduced costs of transfer cases.*" While, if supported with empirical evidence, this would in some ways justify a change in policy, the rule failed to substantiate this claim. We are, therefore, only left to surmise that the proposed change was nothing more than an attempt to reduce otherwise merited reimbursement.

The estimated impact of this proposed change on Kansas' PPS hospitals is a negative $4.926 million for FFY 2006. In FFY 2002, Kansas' PPS hospitals combined for a negative 4.3 percent Medicare margin, a negative 2.3 percent for inpatient services. Given a proposed net market basket update factor of only 2.5 percent after all technical and budget neutrality factors are applied, and that current estimates of the actual market basket increase is 4.1 percent, this "stealth" payment reduction only serves to exacerbate an already negative margin situation.

KHA urges CMS to abandon this proposed change in payment policy until such time as reliable data can substantiate a need.

CRITICAL ACCESS HOSPITALS

Relocation of a CAH Using a Necessary Provider Designation:

There are 82 community hospitals that are designated and operating as CAHs in Kansas. Several of these CAHs were grandfathered into the CAH program from the earlier EACH/RPCH program. The remaining CAHs were designated based upon the necessary provider of health criteria. In the Medicare Modernization Act of 2003 (MMA), it included a sunset provision, effective January 1, 2006, that eliminates the state's authority to grant necessary provider of health designations. However, MMA did provide a grandfathering provision that allows any CAH that is designated as a necessary provider of health prior to January 1, 2006 to maintain its necessary provider designation.

The proposed rule endangers CAHs that are designated as a necessary provider of health because it proposes new parameters that will severely weaken the ability of CAHs to replace their current facilities. CMS is proposing that CAHs designated as a necessary provider may only retain their CAH status if they build a replacement facility within 250 yards of its current location or if the CAH can demonstrate their construction plans began before December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

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

The arbitrary date proposed by CMS is unrealistic and is a broad overreach of CMS authority. It puts in jeopardy many relocation projects that were started in the past 18 months since the passage of the MMA. This was clearly not the intent of Congress to prevent existing CAHs designated as a necessary provider to be perpetually prohibited from replacing or relocating their facility, which are often 40-50 years old. In addition, several Kansas CAHs are land-locked because they are located in residential areas. Therefore, these facilities will be forced to choose between building a replacement facility and jeopardizing their CAH designation or spending countless additional dollars in

improving and maintaining a deteriorating facility. This misguided policy does not make any reasonable sense. **KHA agrees with the suggested comments and recommendations of the AHA and would encourage CMS to remove the arbitrary date restrictions for relocation facilities and consider easing the proposed restrictions that discourage CAHs to relocate regardless of the improved benefits to beneficiaries.**

Pending Necessary Provider Status Applications:
The KHA and AHA are concerned about the hospitals that are currently in the process of converting to CAH status under the necessary provider program. Despite a hospitals best efforts and proactive planning, current circumstances surrounding an increase survey workload for state agencies and an increase in higher priority surveys, such as EMTALA complaints, may cause several hospital to miss the January 1, 2006 deadline. **Providers that have gotten to the stage of requesting a survey in advance of the January 1 deadline, but are unable to get the state to complete the survey have clearly demonstrated a good faith effort and should be considered as meeting the deadline**

SPECIALTY HOSPITALS
In the proposed Inpatient PPS rule CMS questioned whether certain specialty hospitals, defined as such in section 507 of Pub. L. 108-173 (MMA), met the Medicare statutory definition of a hospital. As stated in the proposed rule, CMS has identified that some "surgical and specialty hospitals may be primarily engaged in furnishing services to outpatients, and thus may not meet the definition of a hospital as contained in section 1861(e) of the Act".

The KHA and its members recognize and appreciate the complexity of CMS' task in applying the statutory definition of a hospital, especially the provision that requires the entity be primarily engaged in providing services to inpatients. The delivery of health care across the country, and in Kansas, has significantly changed since Medicare was enacted, with many hospitals and healthcare systems providing a wide range of inpatient and outpatient services. **KHA concurs with the AHA recommendation that CMS reviews a hospital's entire operation to ascertain whether the facility is *really* engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care.**

In addition, **KHA encourages CMS to apply the provider agreement and initial survey restrictions to all new specialty hospitals**. As reported by CMS, the suspension does not apply to those hospitals that have prior to June 9, 2005 submitted an enrollment application or have requested an advisory opinion from CMS concerning whether they were subject to the moratorium under section 507 of the MMA.

HOSPITAL REDESIGNATIONS AND RECLASSIFICATIONS

Urban Critical Access Hospitals Redesignated as Rural:

The KHA agrees with the AHA requests for CMS to provide clarification on the treatment of hospitals that are located in urban areas and apply for reclassification as rural. According to CMS statements in the proposed rule, "a hospital that is granted redesignation under section 1886(d)(8)(E) of the Social Security Act as added by section 401 of the Balanced Budget Act of 1997 (BBA), is treated as a rural hospital for all purposes of payment under the inpatient PPS, including the standardized amount, wage index and disproportionate share calculations as of the effective date of the redesignation." CMS makes this statement in the context of a proposed policy change on the wage index in an effort "to promote consistency, equity and to simplify our rules with respect to how we construct the wage indexes of rural and urban areas when hospital redesignations occur."

However, this same consistency in policy has not occurred when these redesignations occur for CAHs that are located in urban areas as of October 1, 2004 as a result of the use of the 2000 census data. Although the regulations were changed last fiscal year to allow CAHs in this situation to be temporarily reclassified as being located in a rural areas, CMS has not provided the same affirmative direction for CAHs in terms of treatment as rural for all purposes of Medicare payment. For example, the fiscal intermediary in one state has revoked the CRNA pass-through status for CAHs located in metropolitan areas as a result of the census change, citing the fact they are considered urban. Further, the FI has indicated the rural designation under section 1886(d) is only for provisions of 1886(d) and since the CRNA pass-through provision is outside of this section, the rural determination does not apply.

However, in examining the authority for the CRNA pass-through at 42 USCA §1395k note, the rural definition references section 1886(d) of the Social Security Act. In section 1886(d)(2)(D)(ii), "urban area" is defined as an area within a Metropolitan Statistical Area and "rural area" is defined as any area outside such an area or similar area. However, a further section of 1886(d) at 1886(d)(8)(E) allows a hospital to be treated as being located in a rural area if it meets the qualifications in this section. Since the annotated code refers broadly to section 1886(d), the rural determination made under 1886(d)(8)(E) does apply for the purposes of the CRNA pass-through as directed by the code.

There are three Kansas CAHs that have applied for and received redesignation from urban to rural. The KHA urges CMS to make an affirmative statement that all hospitals granted a redesignation should be treated rural for all purposes of Medicare payment.

Thank you for considering our comments on the proposed rules changes. Please contact Fred Lucky at 785-276-3128; flucky@kha-net.org or Chad Austin at 785-276-3127; caustin@kha-net.org if you have any questions regarding these comments.

Sincerely,

Thomas L. Bell
President

331

MILLER
HEFTER
HARTSTEIN

Submitter : Mr. Michael Lefevre **Date:** 06/23/2005

Organization : Gundersen Lutheran Medical Center

Category : Hospital

Issue Areas/Comments

WA/GEN

GENERAL

GENERAL

My comment is related to the Wage index section and is included on the attachment.

CMS-1500-P-627-Attach-1.DOC

June 23, 2005 Attachment 627

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

Physical Address:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam:

RE: Wage Index

In reviewing the IPPS Proposed Rule dated May 4, 2005, we have discovered a change in Computation of the Proposed FY 2006 Unadjusted Wage Index that we oppose. On page 23372 and 23373 is a description of the computation of the unadjusted wage index. Section F., Step 4 describes the formulas for allocating overhead salaries and wage related costs to excluded areas for removal from the wage index. This formula has been used for several years. However, there is a change in the formula in the Proposed Rule for FY2006 that is not explained in the text:

> FRVol.70, No. 85 page 23373
> "Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, **8, and 8.01**);"

The change in the formula reflects the addition of lines 8 and 8.01 to the denominator of the formula, thus lowering the denominator of the equation by the embedded subtraction from line 1, and increasing the ratio of overhead to revised hours. The higher ratio increases the amount of wage related costs removed from the wage index for excluded areas. The formula reported in the IPPS Final Rule dated August 11, 2004 reads as follows:

> FRVol.69, No. 154 page 49050
> "Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio

of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7)"

Thus, lines 8 and 8.01 do not appear in the denominator of the equation in the IPPS Final Rule for FY2005.

This change is not explained in the text of the IPPS Proposed Rule for FY2006. No impact study has been performed for the proposed change, which will particularly affect CBSA's with hospitals that have a large component of excluded area salaries.

We oppose the change in the Computation of the Proposed FY2006 Unadjusted Wage Index on the grounds that it was unexplained in the text of the Proposed Rule and it is inconsistent with the formula as it was applied in prior years.

Sincerely,

Michael S. Lefevre, CPA
Sr. Reimbursement Analyst
Gundersen Lutheran, La Crosse, WI

332

MILLER
COLLINS
MOREY
SMITH
KENLY
WALZ
HART
HEFTER
HARTSTEIN

Submitter :

Date: 06/23/2005

Organization : **Hackettstown Community Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-629-Attach-1.DOC

WI/OM
CAH/RELOC
HOSP REDES
TRANSFERS

Attachment 629

June 23, 2005

Dr. Mark McClellan
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
Room C5-14-03
Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1500-P

Dear Dr. McClellan:

Hackettstown Community Hospital (Hackettstown) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule,* 70 Federal Register (May 4, 2005).

The following comments/questions will apply to the various labeled sections from the aforementioned proposed ruling:

- **"Occupational Mix Adjustment":**
    1. It was stated in the preamble that the response rate to the occupational mix survey was 94.6 percent (3,563 out of 3,765 hospitals). This was an increase from last year's response percentage (89.4 percent); Last year approximately 425 hospitals did not submit data. This year CMS excluded data from hospitals that became designated Critical Access Hospitals (CAHs) since the original survey was collected (March 2004) and those hospitals for which there was no corresponding cost report data. The purpose of the occupational mix adjustment, as stated in the preamble, is to control for the effect of hospitals' employment choices on the wage index. The occupational mix adjustment, similar to FY 2005 remains at 10 percent for FY 2006. Does this achieve CMS' vision for the adjustment? Hackettstown continues to support a mechanism by which hospitals that submitted data would be rewarded for submitting timely data, such as varying the percentage of occupational data used. For those hospitals submitting data they would receive a higher percentage of the occupational mix data if the results were positive and a lower percentage if the results were negative. CMS should put this type of compliance benefit in place to improve compliance (similar to how the quality incentive

exists). Also critical access hospitals (CAHs) should not be excluded in the calculation unless they were CAHs in the base years that are used for the calculation of the wage index.

2. Being as the data used for the proposed occupational mix adjustment is essentially the same data, has CMS given any thought to adjusting the national average?

3. The chart listed on page 23369 of the preamble only listed 6 of the 7 general service categories and the national average table was not listed however was mentioned in the preamble.

4. It was further stated that the application of the occupational mix adjustment beyond FY 2006 will be determined and discussed in subsequent IPPS updates. It was also mentioned in the preamble that any improvement of the data collection process would be published in a Federal Register notice.

- **"508 Legislation":** For any hospital that is reclassified from April 1, 2004 through March 31, 2007 under section 508 from the Medicare Modernization Act. CMS should continue the legislation through the entire federal fiscal year. The legislation has an expiration date of March 31, 2007 that should be extended to the end of the fiscal year (September 30, 2007). The continuation to the end of the fiscal year will also allow hospitals to better budget their revenue and eliminate the guessing of whether they should remain in their reclassed CBSA or opt out to reclass into another. The 508 should also be continued as this will prevent large shifts in commuting patterns that will create great losses for hospitals.

  Additional reimbursement that Hackettstown has received from the section 508 legislation has enabled Hackettstown to provide much needed services to the community. A new radiation oncology center at Hackettstown was in process prior to the receipt of additional reimbursement through the section 508 legislation. After learning of the fact that Hackettstown qualified under section 508 management was able to add Positron Emission Tomography (PET) technology to the radiation oncology center. PET scanning has become a standard of care and it is now an integral part of the radiation therapy treatment planning process

  In addition, subsequent to learning of the qualification under section 508, Hackettstown has added a Wound Healing Center and has added Magnetic Resonance Imaging (MRI) technology to its campus. Both of these are much needed services in the community and may not have been possible if not for the additional reimbursement provided under the section 508 legislation.

Finally, with a shortage of quality nursing personnel throughout the country, Hackettstown has been able to remain competitive in the nursing market and has been able to provide competitive wage packages in its nurse recruiting efforts.

- **"Hospital Reclassifications":** Hackettstown agrees that hospitals in States that were impacted by the "imputed rural floor" benefited from the calculation; CMS should propose now to extend the imputed rural floor to coincide with the existence of a rural floor. This would then put all 50 States on a "level playing field." The remaining States, not involved with the imputed rural floor calculation, have been receiving the rural floor benefit for many years and will continue to benefit in the future.

- **"Post Acute Transfers":** The analysis of post acute transfers does not take into account patients that were admitted from a skilled nursing facility (SNF) and then discharged back to the same skilled nursing facility. A number of Medicare patients are residents of a SNF so regardless of their condition at time of discharge they will be discharged back to the SNF. The post acute transfer policy unfairly penalizes those hospitals that serve a large number of Medicare patients residing in a SNF. BESLER suggests excluding cases from the post acute transfer policy if the admission source is "Transfer from a SNF" and the discharge status is "Discharged/Transferred to a SNF". In reality the SNF is the sole residence for these patients so they are really being discharged to their home. These criteria should apply to *all* DRGs subject to the "transfer rule."

Thank you for this opportunity to comment.

Respectfully submitted,
Hackettstown Community Hospital

Stella M. Visaggio, CPA
Chief Financial Office/Administrative Director

333

BROOKS
FAGAN
GRUBER
KELLY
NUE
HEFTER
HARTSTEIN

Submitter :

Date: 06/23/2005

Organization : **The Heart Rhythm Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

DRG/GEN

GENERAL

Attachment comments

CMS-1500-P-631-Attach-1.DOC

Attachment 631

Heart Rhythm Society

June 23, 2005

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

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 (**CMS-1500-P)**
Section II 4a. Automatic Implantable Cardioverter / Defibrillators.

Dear Mr. Hartstein:

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the CMS Proposed Rule on the Medicare Hospital Inpatient Prospective Payment System for FY 2006, published in the May 4, 2005 Federal Register (CMS-1500-P). The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients and the primary information resource on heart rhythm disorders.

We believe that a prospective payment system has been an appropriate and successful means of controlling costs, encouraging efficiency, and simplifying payments for hospital services. An important requirement of any payment system, however, must be to pay appropriately for medical services so as not to limit access to care or diminish the quality of care. In addition, payments and the determination of such payments under the system must be reasonable and fair and based on accurate and complete data.

For FY 2006, we ask CMS not to remove 37.26 from the list of cardiac catheterization procedures that map to DRGs 535 and 536. We believe that 37.26 should be retained in DRGs 535 and 536 until definition and usage of 37.26 is clarified and adequate data is accumulated to determine whether a modification of the defibrillator DRGs is justified.

In previous DRG revisions CMS has stated that a full-scale electrophysiologic study (EPS) qualifies as a cardiac catheterization. However, the data do show that cardiac defibrillator cases with code 37.26 alone have lower average charges than those with other cardiac catheterization codes. This likely reflects coding problems in the use of 37.26, particularly in differentiating between device interrogations, noninvasive-programmed stimulation, intraoperative induction and testing, and full scale diagnostic EPS. We do not believe that removing 37.26 from the list of cardiac catheterization procedures that map defibrillator cases to DRGs 535 and 536 is warranted at this time. We believe that it is not appropriate to modify the DRGs based on charge data that includes such unequal procedures. The solution is to fix the coding, not to alter DRG assignment.

As noted in the proposed rule, the logic of DRG assignment for defibrillators rests partly on whether the patient received a cardiac catheterization during the stay. In the past, CMS has explained that cardiac catheterization is used to differentiate DRGs 535 and 536 from DRG 515 because "cardiac catheterization is generally performed to establish the nature of the patient's cardiac problem and determine if implantation of a cardiac defibrillator is appropriate" (Federal Register, August 1, 2004, p. 45356). CMS noted that cardiac catheterization is generally performed on an outpatient basis to establish the need for defibrillator implant prior to admission. Patients admitted with AMI, heart failure or shock who undergo cardiac catheterization during their stay are generally acute patients who require defibrillator implantation urgently. All of these statements are equally true for full scale diagnostic EPS.

Diagnostic cardiac catheterization involves threading catheters into the heart chambers to take pressure measurements. Among other things, diagnostic cardiac catheterization is used to determine the ejection fraction, a classic indicator associated with heart failure. In comparison, full scale EPS is also diagnostic. It also involves threading catheters into the heart chambers, this time to assess the electrical activity of the heart. The results of a full scale EPS, for example identifying inducible ventricular tachycardia, can be important in determining the need for a defibrillator as well as the appropriate device type and how it is programmed.

Full scale diagnostic EPS can be and often is performed on an outpatient basis to electively evaluate the need for a defibrillator. As with cardiac catheterization, EPS performed as an inpatient indicates an acute patient who requires urgent defibrillator implantation.

The problematic issue with the CMS data analysis is that code 37.26 is used for procedures other than full scale diagnostic EPS. This is an issue with the code, not with electrophysiologic studies or defibrillator implantation. During part of FY2004, the time frame for the MedPAR file used in the analysis, code 37.26 could be used to represent four different procedures:

- device interrogation without arrhythmia induction
- noninvasive programmed stimulation (NIPS)
- full scale diagnostic EPS

- intraoperative induction and device testing

While they share some features, these procedures differ considerably. Device interrogation can be performed bedside in the patient's room. Due to the risk to the patient, NIPS must be performed in a fully equipped electrophysiologic laboratory but is non-invasive. EPS must also be performed in an EP lab but is invasive and requires special disposable catheters. It was also noted in the proposed rule that the inappropriate use of 37.26 for intraoperative testing exists within the coding community. Given the broad scope of the code and the wide variation in hospital resources across the procedures, it is not surprising that defibrillator cases with 37.26 showed lower average charges than procedures with cardiac catheterization.

Effective November 1, 2003, coders were instructed to stop using 37.26 for bedside interrogations (Coding Clinic, Third Quarter 2003, p.23). Although this was early in FY2004, new guidelines take time to disseminate among coding staff and to be reflected in coding systems. Moreover, it was not until the FY2005 ICD-9-CM updates that notes were placed on codes 37.26, 89.45, and the newly created 89.49 clearly differentiating bedside interrogation without arrhythmia induction from NIPS and EPS. Thus, it seems likely that the FY 2004 MedPAR data for 37.26 is skewed by the presence of bedside interrogations, a low resource procedure that is no longer coded to 37.26.

Throughout FY 2004, code 37.26 was used for both NIPS and full scale diagnostic EPS, which remains the practice today. These procedures are similar in that both must be performed in an EP lab and both involve inducing arrhythmias. However, EPS is invasive and is truly diagnostic. In contrast, NIPS is non-invasive and is performed to test a previously implanted device.

The resource intensity of full scale diagnostic EPS on defibrillator DRGs cannot be properly assessed until these lesser procedures are no longer part of 37.26. Moving bedside interrogation out of 37.26 was a good step in the right direction. CMS should continue moving in this direction by separating NIPS and EPS within ICD-9-CM. This will result in a discrete code (37.26) to clearly identify full scale diagnostic EPS.

Instructing coders that 37.26 should not be used for intraoperative testing is equally important. In the short term, this can be accomplished through a clarification in the Federal Register, Final Rule that intraoperative testing is part of the procedure and is not reported separately as 37.26. The long-term solution is to provide coding clarification within the description of 37.94 which currently include "intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements."

Cardiac resynchronization therapy defibrillators improve the heart's pumping ability by delivering small electrical impulses that help synchronize contractions of the left ventricle. The left ventricle is the heart's main pumping chamber, and its ability to pump blood is enhanced when the muscular walls contract synchronously. In addition, cardiac resynchronization therapy defibrillators monitor the heart for potentially fatal rhythms. If

such a rhythm is detected, a lifesaving shock is delivered, restoring normal heart rhythm and preventing sudden cardiac death.

Cardiac resynchronization therapy with defibrillation meets the criteria for a new technology. This technology is still inadequately reimbursed under the current system and provides substantial diagnostic and treatment improvement relative to technologies previously available. We urge CMS to continue allowing for this higher payment in fiscal year 2006 for some Medicare-covered heart failure patients who receive a cardiac resynchronization therapy defibrillator device.

We hope that CMS will accept these recommendations from The Heart Rhythm Society and not remove code 37.26 from DRG 535 and 536. CMS should allow time for more accurate data to be collected with the removal of the unequal procedures out of code 37.26 and provide clear instruction regarding intraoperative testing. Thank for the opportunity to comment on the proposed inpatient rule. If you or CMS staff have questions please feel free to contact Brian Outland, Manager of Regulatory and Reimbursement Affairs at boutland@HRSonline.org or 202-464-3433

Sincerely,

Anne B. Curtis, MD
President, Heart Rhythm Society

Mark D. Carlson, MD
Chair – Health Policy Committee

334

COLLINS MOREY SMITH HEFTEL HARTSTEIN

Submitter : Mr. Barry Goettsch **Date:** 06/23/2005

Organization : Cherokee Regional Medical Center

Category : Critical Access Hospital

CAH/RELOC

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern,

We at Cherokee Regional Medical Center would like to express our disappointment in the proposed changes to plant replacements for Critical Access Hospitals. Who is coming up with this stuff? It should be our governments position to do what they can to make adequate health care available for all citizens, this includes those citizens in rural america, and sometimes adequate health care delivery can only be achieved by upgrading facilities. Why does CMS insist on continually throwing up barriers which make it difficult for rural hospitals to get the job done. Medicare has been a poorly run program since its implementation, and while many hospitals may have exploited the weaknesses of mismanagement, it is clear that hospitals in Iowa did not and have not. Leave critical access hospitals alone and let them serve the citizens, pay their bills, and afford to provide the facilities and technology that we have been blessed with to ease the pain and suffering of injury and illness. Also, what is the significance of the date December 8, 2003. Does this decision have any objective basis or is this yet another example of the misdirected bureaucracy that is CMS. Has anyone there ever considered working with hospitals instead of against them? Have you ever considered reimbursing hospitals on the basis of their quality, productivity, and efficiency? We emplore you to utilize a little common sense before proposing changes. One last question, what does CMS intend to do when thier efforts finally do start closing rural hospitals and benficiaries do not have access to the health care that has been guranteed to them by Medicare. Look around as it is happening. You finally did something right that could prevent this and now you are tinkering with it again. I guess when the tax-payer is paying the bills you don't need to learn from your mistakes. Again, leave critical access hospitals alone, help don't hurt, and decide on a common goal for direction as it would be a refreshing change for the better.

- Respectfully,

Barry Goettsch, Sr. VP/COO
Cherokee Regional Medical Center

335

BODDEN
KRUSHAT
HEFTER
HARTSTEIN

Submitter : Mrs. Deanette Russell **Date:** 06/23/2005

Organization : Stanly Memorial Hospital

Category : Hospital

9 DATA

Issue Areas/Comments

GENERAL

GENERAL

Hospital Quality Data

1. Optional measures should not be included in our validation scoring. This is not required data for us to abstract. The only elements that the CDAC staff should abstract for are the required data points to enable scoring for the specified quality indicators.
2. If an indicator requirement can be collected from 2 different diagnostics and the vendor develops a tool to allow skip logic to guide the data submission process, the CDAC system should also allow that skip logic methodology to apply in the validation process.
3. In the appeals process, the 10 days for the hospitals to respond is extremely limiting, and are these business days, or calendar days? If the hospitals have only 10 days to appeal a concern, CDAC should also be held to that same guideline and have to respond to that appeal in the same timeframe. If 30 days is more reasonable, then it should be 30 days for both. I feel that CDAC should be held to an equally limiting timeline.

336

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN
Walz
Treitel

Submitter : Dr. Richard Peress **Date:** 06/23/2005

Organization : Richard E. Peress MD

Category : Physician

DRG/GEN
NT

Issue Areas/Comments

GENERAL

GENERAL

Mr. Marc Hartstein

Deputy Director of the Division of Acute Care

Centers for Medicare and Medicaid Services

7500 Security Blvd.

Room C4-25-11

Mail Stop C4-03-06

Baltimore, MD 21244-1850

(410) 786-4539

marc.hartstein@cms.hhs.gov

There are additional factors besides age which must be considered in the decision to provide or deny Medicare coverage for surgery to implant an artificial disc.

1- There are a significant number of young, under 65 patients who are on Medicare as a result of Social Security Disability. This is their only insurance coverage, and by Medicare not covering disc replacement, they would be deprived of a treatment which their working, insured counterparts have access to as a treatment option with great potential of reversing their disability. This inequality is not medically justifiable.

2- Not all patients over 60+ are FEMALE !! Male patients into their 70's unless on steroids, or alcoholics, are generally are not afflicted by osteoporosis. The male Medicare population should not suffer denial simply because they are the same age as their osteoporotic female counterparts.-Again, there is no medical justification for a policy of discrimination resulting in denial equal access which younger male patients with the same indications have.

I have over my 18 years of practice as a spine surgeon on numerous occasions, performed spine surgical procedures on males over 65 years, who lead very active, athletic lives, as well as male and female patients under 65, trapped by their spine condition in a disabled state. Both of these groups would have, in my opinion, reaped far greater benefits if they had had access to the motion preserving process of lumbar artificial disc replacement.

This disabled, younger group often undergoes more than 2 procedures secondary to the elevated adjacent level stresses associated even with single level fusions. This phenomenon is well documented in the literature in terms of consuming excess healthcare resources.

It is time for spine fusion for disc related pain to take it's rightful place in surgical history alongside knee and hip fusions, and offer the option of an artificial disc replacement to all individuals meeting anatomic criteria, regardless of their age.

It is my hope, and the hope of my Medicare insured patients, who have-patiently awaited the release of the disc prosthesis in the US, enduring pain and disability and emotional and financial hardships, that you will approve coverage, and not discriminate against them further.

I look forward to your reply, and news of a decision to end their suffering and hopefully their disability, as well as the burden to society of the cost of their benefits.

Sincerely,

Richard Peress MD

Orthopedic Spine Surgery
Phelps Memorial Hospital Center
701 North Broadway
Sleepy Hollow, NY 10591

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

337 COLLINS MOREY SMITH HEFTER HARTSTEIN

Submitter : Ms. William Parrish
Organization : Parrish, Moody & Fikes,p.c.
Category : Critical Access Hospital

CAH/RELOC

Date: 06/23/2005

Issue Areas/Comments

GENERAL

GENERAL

This letter serves as a response to 'Proposed Policy Change Relating to the Designation of Critical Access Hospitals as Necessary Providers' published in the May 4, 2005 Federal Register.

Under the proposed rule, any CAH that is designated as a necessary provider under its state rural health plan prior to January 1, 2006 will not be allowed to maintain its necessary provider designation if it constructs a new facility, unless it meets stringent relocation requirements or submits an application to the State agency prior to January 1, 2006. We believe that these proposed requirements place undue restrictions on CAHs that are not within the intent of the Critical Access Hospital Program.

As hospitals look to replace aging facilities, they often find that it is more practical to build a new facility rather than to renovate an older building. Modern technology requires extensive retrofitting of older buildings, which is oftentimes, more complex and extensive than new construction. Additionally, innovative building materials and design used in new construction allow for savings in terms of energy, cost, and space. The proposed rules will make it difficult, if not impossible, for a CAH grandfathered under the 'necessary provider' designation to build a new facility to meet the needs of the community it serves in the most cost efficient manner.

Section VII(B)(3)(a) of the proposed rule states that if a CAH facility is constructing renovation of the same building in the same location, the renovation will be considered a replacement of the same facility and not a relocation. Construction of a new facility would be deemed a replacement if the construction were undertaken either within 250 yards of the current hospital building, or on land that is contiguous to the current CAH and owned prior to enactment of Pub. L. 108-173. Only a replacement facility would be able to maintain the 'necessary provider' designation; a relocated facility would lose its 'necessary provider' designation.

Many CAHs that are looking to replace their current facilities are unable to acquire land that is either contiguous or within 250 yards of their current facility. These hospital facilities may have been in place for many years and are 'land-locked' in their current locations. Acquiring property to satisfy these conditions may be either very expensive or impossible. Additionally, many CAHs are publicly supported hospitals and the high cost of acquiring adjacent land would be passed on to local taxpayers. These CAHs would continue to serve the same population whether the facility was reconstructed within 250 yards or relocated five miles from the existing facility. Allowing CAHs to relocate within a more reasonable distance of the original CAH seems more appropriate.

Section VII(B)(3)(b) provides that a CAH that does not satisfy the 250 yard criteria may still be able to maintain its 'necessary provider' designation if it files a relocation application with the State agency before January 1, 2006. CAHs are smaller, rural hospitals that struggle to acquire the necessary financial resources to even begin planning for replacement of their aging facilities. This proposal would require all facilities not meeting the 250-yard criteria to submit their intent before January 1, 2006 or be forever barred from relocating and maintaining their CAH status. Medical technology, populations, and economies are constantly changing; requiring that CAHs determine their future building needs and ability to meet those needs, by January 1, 2006 seems unreasonable.

The proposed rules essentially eliminate the ability for CAHs granted under the 'necessary provider' designation, to replace their existing facilities. Over time, this would result in the closure of existing CAHs due to the inability to replace their facilities. We believe the proposed rules must be modified to allow for reasonable replacement of existing CAH facilities.

338

Submitter : Mr. Theodore Giovanis

Organization : T. Giovanis & Company

Category : Hospital

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-555-Attach-1.DOC

Kahn - S/NF
WI / Gen

Helter
Hartstein
Knight
Kraemer
Lifset
Treitel
Miller

Tamara Jones

Attachment 555

T. GIOVANIS & COMPANY
Health Policy and Regulatory Consultants

P.O. Box 130
Highland, MD 20777
Phone: 301.854.2496
Fax: 301.854.2248
www.tgiovanis.com
tngiovanis@aol.com

June 22, 2005

Marc Hartstein
Deputy Director
Division of Acute Care
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS - 1500-P
P.O. Box 8010
Baltimore, Maryland 21244-1850

Re: Comments on the May 4, 2005 Proposed Rule for the Inpatient Prospective Payment System

Dear Mr. Hartstein:

We write on behalf of the Orange County, NY hospitals to provide comments on the Centers for Medicare and Medicaid Service (CMS) proposed rule for inpatient prospective payment for FY 2006 regarding two items. The details of our comments follow:

Labor Related Share

As a by-product of CMS' proposal to change the Market Basket components it is also proposing a change in the labor share proportion of the payment. Such a change would move from the present labor share proportion of 71.066% to 69.731%. CMS acknowledges that the present labor share comes from prior labor share proportion. However, the labor share that should theoretically being used at present is actually 72.495 %, which is the proportion from 1997. The labor share is important because it impacts the portion of the payment that is adjusted by the area wage index (AWI).

CMS made an evaluation in 2002 and proposed a 72.495% labor share, which it subsequently backed away from. Then Congress required that any hospitals with an area wage index of less than 1.0 receive a labor share of 62.0% if that was more beneficial. Decreasing the labor share proportion is predisposed to positively impact rural hospitals.

In CMS' analysis it related and compared the 1992 based labor share weights (71.066%) to the 2002 based labor share weights (69.731%). CMS does not draw any conclusions regarding the related shifts by line item. What CMS should be evaluating is why the proportions changed from 1997 data, which the agency decided not to use. This represents the true question. The real issue to be questioned is why the labor share went from 71.066% (1992) to 72.495% (1997) to 69.7315% (2002). These changes raise questions about 1) the veracity of the data, 2) the change in base cost data, 3) the effect of proxy changes on the trending, 4) consistency of CMS' methodology, and 5) other factors. CMS did not seem to analyze these issues or seems to have ignored them. CMS needs to address why it believes that the labor share proportion is fluctuating (regardless of whether the agency used the 1997 based labor share proportion). The agency needs to concern itself with why this fluctuation occurred and whether it was caused by any methodological or data change and whether such a change was appropriate. This type of analysis has not been performed - rather the agency has chosen to compare the 1992 weights to the 2002 weights which show the least amount of variation.

If CMS were to have compared the 2002 weighted labor share with the 1997 labor share it would have seen a greater variation among the elements. Some variations would have been 100% greater, which would have raised the question of why such variation occurred. CMS' discussion in the rule did not focus on the 1997 to 2002 variation. In fact, CMS was almost dismissive of the fact that the 1997 proportions existed.

The fact is that the 1997 data increased labor share proportions and in turn the impact of the AWI. This would have adversely impacted the rural providers. At that time CMS knew of the Senate's interest in protecting rural providers from this effect. Coincidentally, CMS pulled back from implementing this change. Subsequently, the Senate pushed to put in place the 62 % labor share for providers with AWIs less than 1.0. Thus, rural hospitals are now protected.

The current labor share proposal would generally provide a reduction to urban hospitals and would not fundamentally benefit the rurals because they are already protected by the 62% labor share requirement. Thus, CMS should not implement the revised labor share proportions.

In reading the rule, it is not clear that the budget neutrality adjustment incorporates CMS' revision to the labor share proportion. The budget neutrality adjustment for the area wage index and recalibration is a slightly positive number (greater than 1.0) while all of the other budget neutrality factors are negative. If the labor share adjustment as proposed were implemented, payments would decrease as a result because the higher AWI areas would receive lower payments. Because the majority of discharges and payments are paid at AWIs above 1.0, one would expect that a shift to paying a higher proportion of these discharges at 1.0, which a lower labor share would cause would reduce total payments. Due to these lower payments the system would lose aggregate dollars if there is no budget neutrality adjustment for this purpose. Thus a relative high budget neutrality factor (higher than presented in the rule) would apply.

It appears that CMS used the same base rates from FY 2005 then changed the labor non-labor share proportion. If there was no explicit adjustment to account for the fact that the labor share reduction reduced Medicare expenditures, because the AWI is applied to a lower portion, then there is a savings to the trust fund in the absence of a budget neutrality adjustment.

CMS should include an appropriate budget neutrality factor or at a minimum acknowledge that it has not accounted for this change in the standardized amounts. In addition to the absence of increasing rates for this anticipate decrease in payments, there is support for not implementing the new labor share proportions to the standardized amounts.

CMS needs to consider the impact of the proposed change in the labor share proportion (given the protections provided to rural hospitals through the 62.0% requirement) on urban providers. This is actually hidden somewhat in the rule's impact analysis. Essentially, urban hospitals lose about 1.0 percentage point as a result of CMS' proposed changes. While CMS acknowledges this, it does not discuss nor analyze whether this is tolerable by urban providers and what effects may be caused by its implementation. These are all reasons why CMS should not implement their proposed labor share change.

Provider 33-0209 Table 2 Area Wage Index

In the May 4, 2005 proposed rule provider 33-0209 (as well as other hospitals in Orange County, NY) is listed as having an AWI of 1.0767 - its home area AWI. In the corrected Table 2 released in late May/June 1 this provider is listed as having a AWI of 1.1327 which appears to be the AWI for its home MSA plus the Section 505 add-on on Table 4J. [The Orange County, NY hospitals are Section 508 reclassified to: 1) New York, NY - 33-0126 (and 33-0001 which was merged into 33-0126), 33-0135, and 33-0205; and 2) Nassau-Suffolk, NY - 33-0264 (and 33-0209 which was merged into 33-0264). Each of these mergers were addressed explicitly in the respective Section 508 reclassification application.]

Because provider number 33-0209 was merged into provider number 33-0264, both of these sites received a Section 508 reclassification and are reclassified to the Nassau-Suffolk, NY MSA. As a result provider number 33-0264 is appropriately listed in corrected Table 2 as having the AWI for Nassau-Suffolk, NY MSA of 1.2781.

In the rule in similar situations both sets of provider numbers (the survivor number and the merged number) have the reclassified area AWI reflected on Table 2 and not their home MSA. Accordingly, provider number 33-0209 should be assigned the reclassified AWI for Nassau-Suffolk, NY of 1.2781.

We understand that the effect of this change is moot in that the affected number is now inactive. Nevertheless this change should be made.

We appreciate the opportunity to make these comments. If you have any questions about our comments or otherwise need to discuss them further, please feel free to contact me.

Sincerely,

Theodore Giovanis

339

Submitter : Mr. David McClure

Organization : Tennessee Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

Date: 06/22/2005

GENERAL

GENERAL

See Attachment

CMS-1500-P-568-Attach-1.DOC

CAH/[illegible]
SCH/Gen
Transfers
MB/H
Paymt/Rates/outliers
Labor/S
WI/OM
WI/Gen
WI/Co
GeoReclas

Hefter
Hartstein
Collins
[illegible]
Smith
Phillips
Fagan
[illegible]
Kelly
[illegible]
Knight
Seifert
Treitel
Miller
Kenly

Attachment 568

June 22, 2005

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

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

Dear Sirs:

On behalf of the Tennessee Hospital Association (THA), we appreciate the opportunity to submit comments on the fiscal year (FY) 2006 inpatient prospective payment system (IPPS) proposed rule.

THA, established in 1938, serves as an advocate for hospitals, health systems and other healthcare organizations and the patients they serve. The association represents over 200 healthcare facilities, including hospitals, home care agencies, nursing homes, and health-related agencies and businesses, and over 2,000 employees of member healthcare institutions, such as administrators, board members, nurses and many other health professionals. THA is the premiere organization in Tennessee that promotes and represents the interests of all health careers, hospitals and health systems.

While THA is supportive of many of the provisions in the proposed rule, we are particularly concerned and oppose the potential negative impact of historic understatement of the market basket projection, the proposed expansion of the post-acute care transfer policy, and the proposed restrictions on critical access hospitals.

Attached are THA's detailed comments regarding CMS' proposed changes to the inpatient payment system, including those related to the wage index. THA comments on the critical access hospital proposals have been submitted under separate cover. THA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me or David McClure, THA vice president of finance, at 615-256-8240.

Sincerely,

Craig Becker, FACHE
President

Attachment

Attachment
Tennessee Hospital Association
Comments on FY 2006 Medicare Hospital Inpatient PPS
CMS-1500-P

Hospital Marketbasket - (*Federal Register* page 23384)

Background: The hospital update is based on a marketbasket factor that is intended to reflect the average change in the price of goods and services hospitals purchase in order to furnish inpatient care. To accomplish this, CMS selects wage and price proxies intended to reflect hospital costs. These proxies are primarily drawn from Producer Price Indexes (PPIs) and Consumer Price Indexes (CPIs). The price changes must be projected forward to estimate the increase for the subsequent year so an appropriate marketbasket update can be determined in advance of payment. CMS projects a hospital marketbasket increase of 3.2 percent for FFY 2006.

THA Comment:

The projected marketbasket increase provides an estimate of cost increases that is not reconciled to the actual increases for the proxies that are used. This is basic to the prospective nature of the PPS methodology. In some years, the projection is higher than the actual increase and in others, it is lower. Over the life of the PPS, the differences have balanced out and the cumulative error is small. However, in recent years, the projection has consistently been lower than the actual increase. The actual increase in FFY 2004 was 3.8 percent, compared to a projected increase of 3.4 percent. In the proposed rule, CMS reports that, based on the most recent data, the FFY 2005 marketbasket increase is now estimated to be 4.1 percent, compared to the estimated 3.3 percent increase that was projected for use in the update factor.

THA is very concerned that the methods being used to project the marketbasket increase are flawed and are failing to provide reliable results. Given a 4.1 percent cost increase for FFY 2005, a projected FFY 2006 increase of 3.2 percent does not seem consistent with evidence that inflation is increasing in the general economy.

Medicare Marketbasket Projection Differences 1998 - 2005								
	1998	1999	2000	2001	2002	2003	2004	2005
CMS Increase Projection	2.7%	2.4%	2.9%	3.4%	3.3%	3.5%	3.4%	3.3%
Actual Increase	2.9%	2.5%	3.6%	4.1%	3.0%	3.9%	3.8%	4.1%
Annual Shortfall	-0.2%	-0.1%	-0.7%	-0.7%	0.3%	-0.4%	-0.4%	-0.8%
Cumulative Shortfall	-0.2%	-0.3%	-1.1%	-1.9%	-1.6%	-2.1%	-2.7%	-3.8%

Based on the understatement for seven of the last eight years of the CMS projected marketbasket compared to the actual increase, we question the accuracy of the FFY 2006 marketbasket projection. We request that CMS review the methodology used to project the marketbasket and revise it for the FY2006 projection.

Post Acute Care Transfer (*Federal Register* page 23411)

Background: When a patient is transferred from one acute care facility to another acute care facility, the transferring hospital receives a per diem payment with total payment limited to the full diagnostic-related group (DRG) amount that would have been made if the patient were discharged without being transferred. Beginning in FFY 1999, the transfer policy was expanded to cover patients discharged to a post-acute care setting. Initially, this policy applied to cases assigned to one of 10 DRGs that had high volumes of cases discharged to post-acute care. The law gave CMS authority to expand the number of DRGs for FFY 2001 and subsequent years. CMS established criteria for determining the DRGs that should be included and extended in the policy to cover 29 DRGs in FFY 2004. In FFY 2005, CMS found that no additional DRGs met the criteria. However, CMS revised the list of DRGs to adjust for one post-acute transfer DRG current that was split into two new DRGs, resulting in 30 DRGs subject to the policy.

CMS Proposal: *As a result of our analysis, we considered two options for revising the current criteria. Option 1 is to include all DRGs within the postacute care transfer policy. ... Option 2 would expand the application of the postacute care transfer policy to 223 DRGs that have both a relatively high volume and a relatively high proportion of postacute care utilization. .... In this proposed rule, we are formally proposing Option 2 as presented above. However, we invite comments on both of these options.....*

In the proposed rule, CMS states: *The 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 transfer policy adjusts the payments to approximate the reduced costs of transfer cases.* The proposal results in expansion of the policy to many DRGs where there is no evidence that hospitals are changing behavior to take advantage of the payment system.

THA Comment:

THA strongly opposes the expansion of the post-acute transfer policy. In this proposal, CMS makes substantial revisions to the DRG selection criteria with little justification or evidence. The revised criteria do not address specific changes in hospital behavior that might indicate an attempt to take advantage of the payment system. Moreover, they would not result in more equitable payments. For all practical purposes, such an extensive expansion of the post-acute transfer policy acts as an across-the-board reduction in Medicare payments. As a result, hospitals would be penalized for providing efficient care in the setting that is most appropriate for the patient.

Hospital Quality Data (*Federal Register* page 23424)

Background: The MMA provides a full marketbasket update of 3.2 percent for hospitals that submit data on 10 quality measures data to CMS. This provision applies for three years (FFYs 2005-2007). Hospitals that fail to submit the necessary data or withdraw from the program will receive the marketbasket increase minus 0.4 percent.

***CMS Proposal**: CMS proposes to place the following additional requirements on hospitals for the data for the FY 2006 payment update.*

- *The hospital must have passed our validation requirement of a minimum of 80 percent reliability, based upon our chart-audit validation process, for the third quarter data of calendar year 2004 in order to receive the full market basket update in FY 2006.....*
- *The hospital must have two consecutive quarters of publishable data. The information collected by CMS through this rule will be displayed for public viewing on the Internet. Prior to this display, hospitals are permitted to preview their information as we have it recorded. In our previous experience, a number of hospitals requested that this information not be displayed due to errors in the submitted data that were not of the sort that could be detected by the normal edit and consistency checks. We acquiesced to these requests in the public interest and because of our own desire to present correct data. However, we still believe that the hospital bears the responsibility of submitting correct data that can serve as valid and reliable information.*

The rule requires that the accuracy of hospital submitted data be validated through chart re-abstraction. A sample of five charts will be reabstracted by the Clinical Data Abstraction Center (CDAC) and compared to the hospital's submission. CMS will require an 80 percent agreement rate between the original submission and the re-abstraction. If a hospital disagrees with the abstraction results from the CDAC, the hospital can appeal the results to their quality improvement organizations (QIOs).

THA Comment:

We strongly oppose any attempt by CMS to link the proposed validation process with the hospital update factor. CMS proposes to base the update on data from the third quarter of 2004. CMS audits of earlier periods in 2004 often were unreliable due to data problems and inconsistent definitions. These issues were not completely resolved by the third quarter of 2004. Hospitals should not suffer a payment reduction due to technical problems with the data submission and validation process.

Operating Payment Rates - (*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 called 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 every year based on CMS' projections of total outlier payments to make outlier reimbursement equal 5.1 percent of total 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.*

THA Comment:

The proposed $26,675 threshold for FFY 2006 represents an increase of 3.4 percent, compared to the FFY 2005 threshold of $25,800. CMS estimates that actual FFY 2004 outlier payments were 3.5 percent of total payments and projected FFY 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 the proposed 3.4 percent threshold increase will result in another year of underpayments. We recommend the outlier threshold be adjusted for the traditional shortfall in prior year outlier payments.**

Labor-Related Share (*Federal Register* page 23391)

CMS Proposal: CMS *proposes 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 we no longer believe that postage costs meet our definition of labor-related, we are excluding them from the labor-related share. Using this methodology, we calculated a labor-related share of 69.731.*

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.

THA Comment:

THA is concerned about the removal of postage from the labor-related categories. CMS' assertion in 2003 that additional analyses are needed still stands today. THA believes CMS should continue to consider this category labor-related until a broader look at the calculation of the labor-related share is taken. THA believes arbitrarily pulling out one item, such as postage, will unfairly penalize those hospitals in high wage areas.

Occupational Mix Adjustment (*Federal Register* page 23368)
CMS Proposal: *For the FY 2006 wage index, we are proposing to use the same CMS Wage Index Occupational Mix Survey and Bureau of Labor Statistics (BLS) data that we used for the FY 2005 wage index. For the proposed FY 2006 wage index, we are proposing to use the same methodology that we used to calculate the occupational mix adjustment to the FY 2005 wage index.*

CMS has not changed the calculation of the occupational mix adjustment and only has made minor changes to the data. Therefore, the proposed FFY 2006 adjustments do not differ materially from those applied to the FFY 2005 wage indexes.

THA Comment:
THA recommends that CMS release future data collection surveys in a timeframe that allows hospitals adequate time (4-6 months) to prepare for data collection and reporting.

Blended Wage Index - (*Federal Register* page 23375)
CMS Proposal: *For FY 2006, we are again proposing to adjust 10 percent of the wage index factor for occupational mix. In computing the occupational mix adjustment for the proposed FY 2006 wage index, we used the occupational mix survey data that we collected for the FY 2005 wage index. While we considered adjusting 100 percent of the wage index by the occupational mix, we did not believe it was appropriate to use first-year survey data to make such a large adjustment. As hospitals gain additional experience with the occupational mix survey, and as we develop more information upon which to audit the data we receive, we expect to increase the portion of the wage index that is adjusted.*

CMS found that the proposed wage index values for 30 percent of rural areas and 54 percent of urban areas would decrease as a result of the adjustment. CMS states that: *Although these results show that rural hospitals would gain the most from an occupational mix adjustment to the wage index, their gains may not be as great as might have been expected. Further, it might not have been anticipated that almost one-third of rural hospitals would actually fare worse under the adjustment.* This is another reason why CMS is not increasing the occupancy mix blend percentage.

THA Comment:
THA supports the current moderate implementation approach of the occupational mix adjustment.

Wage Data - (*Federal Register* page 23372)
Background: The wage index is calculated using data reported by hospitals in the Medicare cost report. The wage data includes salaries and hours, certain contract labor costs and hours, and fringe benefit costs, including pensions and other deferred compensation costs.

CMS Proposal: *Due to recent questions and concerns we received regarding inconsistent reporting and over reporting of pension and other deferred compensation plan costs, as a result of an ongoing Office of Inspector General review, we are clarifying in this proposed rule that hospitals must comply with the PRM, Part I, sections 2140, 2141, and 2142 and related Medicare program instructions for developing pension and other deferred compensation plan costs as wage related costs for the wage index.*

Beginning with the FY 2007 wage index, CMS will require that the fiscal intermediaries ensure that pension, post-retirement health benefits, and other deferred compensation plan costs for the wage index are developed according to provider reimbursement manual (PRM) instructions.

THA Comment:
THA recommends 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.

**** End of Comments****

DRG/Gen. 340

Submitter : Mrs. Kelley Lawson **Date:** 06/22/2005

Organization : Next Wave Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment: Comments on Table 6 A New Diagnosis Codes. These comments were forwarded to Dr David Berglund on May 20, 2005.

CMS-1500-P-561-Attach-1.DOC

Attachment 561

Department of Health and Human Services,
Attention: CMS-1500-P,
P.O. Box 8011,
Baltimore, MD 21244-1850.
6/22/2005

Via: E-mail

RE: Comments on File CMS-1500-P
Tables 6 A New Diagnosis Codes.

To Whom it May concern:

I spoke with Dr Berglund on May 6 regarding the announced changes to diagnosis code 996.4 – Mechanical Complication of Internal Orthopedic Device, Implant, and Graft. The purpose of this letter is to:

- state our concerns about the need for additional 996.4 code category in areas we did not think about when the proposed codes were published last fall,
- comment on the osteolysis code that was not part of the proposed codes published last fall, and
- offer suggestions for amending the category to include specific codes for more complications than just those of joint prostheses.

Concerns about new 996.4 codes

We agree that this code needs to be expanded to better reflect the various types of mechanical complications that are associated with the many different types of orthopedic devices, implants and grafts. However, the new codes do not do this adequately. Seven (7) of the new 996.4 codes represent different types of prosthetic joint failure, but only one code (996.49) is reserved for all the complications of all the other types of orthopedic devices implants and grafts. This is a concern since our review of the 2003 NYS SPARCS Data shows that 1708 of 5150 (33%) of the cases with 996.4 as principal diagnosis code had procedures for complications that had nothing to do with a joint prosthesis. All these cases would all be lumped into one code (996.49) under the new coding scheme, with no way to differentiate between them. This has always been the problem with code 996.4, and the new coding scheme does not improve the situation, except for cases involving joint prostheses.

I have included some examples of the different types of procedure codes submitted in the NYS SPARCS data to give you an indication of the wide variety of cases that would end up in 996.49. I have also included a mock up of a portion of the ICD9CM Disease Index for "complications" illustrating how most of the sub-terms for mechanical complications will have code 996.49 assigned to them. (See Attachments A and B)

The new 996.4 coding scheme does not even address all the issues that prompted the revisions. One issue that was brought up at Coding Maintenance Committee Meeting and mentioned in the Federal Register[1], was the failure of (bone) grafting material that is used in many spine and joint procedures to replace or build up bone defects caused by wear and tear, disease, injury, age, drug or radiation therapy. Grafting often fails in situations where the patients bone integrity is not good. Graft failure can lead to disability, pain, and cause additional complications with

[1] Wednesday, May 4, 2005 / Proposed Rules page 23325-23326

implanted orthopedic devices. If the codes are implemented as is, all of these significant grafting complications will be lost in the 996.49 code with all the "other" mechanical complications.

Code Modification Recommendations & Suggestions

Given the coding issues we discussed above, we offer the following recommendations and suggest the following structure for the mechanical complications of internal orthopedic devices, implants and grafts:

We recommend creating one code to identify graft failures, and a separate code to identify non-joint prosthetic orthopedic device complications. Causes, complications, risks and outcomes associated with graft failures are different than those associated with device (hardware) problems and should be captured separately for tracking and quality assessment.

We recommend having only one "other" mechanical complication code in the 996.4 category. Having one for other joint prosthesis complications and one for other internal orthopedic devices will be confusing to coders and users of the data.

We recommend not having a code for peri-prosthetic fracture or peri-prosthetic osteolysis in the mechanical complication code series. These are problems of the bone and not the prosthesis. These complications should have codes in the orthopedic chapter. This is in keeping with recent decisions to assign codes for atherosclerosis of a cardiac bypass graft to the circulatory chapter, and the "ostomy" complications to the affected body system chapters (i.e. tracheostomy complications to the respiratory chapter and colostomy complications to the digestive chapter.)

We suggest putting the peri-prosthetic osteolysis in the aseptic necrosis of the bone code category and assigning it code 733.45. We suggest putting the peri-prosthetic fracture around prosthetic joint in with the stress fracture codes and assign it code 733.96. Also, rather than associating these problems with the mechanical failure codes, they might better be classified with the 996.77 – Other complications of internal (biological)(synthetic) prosthetic device, implant and graft due to internal joint prosthesis. Other complications such as pain, stenosis, fibrosis, and hemorrhage due to an orthopedic device are already classified in 996.77. We are suggesting the code structure in Attachment C as a way to more adequately cover the mechanical internal orthopedic device, implant or graft complications.

We hope that these explanations and suggestions are helpful to you in determining the final structure of the mechanical complication codes. Please contact us if you have questions or would like further input regarding these codes.

Sincerely,

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Manager HIM/UR
Next Wave
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CC: Dr Berglund, NCHS

ATTACHMENT A

List of Procedures abstracted from 2003 SPARCS Data
Procedures performed other than arthroplasty knee/ hip with code 996.4 in PDx. These sites are not represented with new codes.

02.06 Other cranial osteoplasty
02.07 Removal of skull plate
02.94 Insertion or replacement of skull tongs or halo traction device
03.02 Reopening of a laminectomy site
76.43 Other reconstruction of mandible
76.76 Open reduction of mandibular fracture
76.94 Open reduction of temporomandibular dislocation
78.02 Bone graft of humerus
78.07 Bone graft of tibia and fibula
78.17 Application of external fixation device, tibia and fibula
78.42 Other repair or plastic operation on humerus
78.47 Other repair or plastic operations on tibia and fibula
78.52 Internal fixation of humerus without fracture reduction
78.57 Internal fixation of tibia and fibula without fracture reduction
78.59 Internal fixation of other bone, except facial bones, without fracture reduction
78.62 Removal of implanted device from humerus
78.65 Removal of implanted device from femur
78.67 Removal of implanted device from tibia and fibula
78.69 Removal of implanted device from other bone
79.05 Closed reduction of fracture of femur without internal fixation
79.06 Closed reduction of fracture of tibia and fibula without internal fixation
79.31 Open reduction of fracture of humerus with internal fixation
79.36 Open reduction of fracture of tibia and fibula with internal fixation
79.37 Open reduction of fracture of tarsals and metatarsals with internal fixation
79.39 Open reduction of fracture of other specified bone, except facial bones, with internal fixation
79.71 Closed reduction of dislocation of shoulder
81.91 Arthrocentesis
81.97 Revision of joint replacement of upper extremity
83.82 Graft of muscle or fascia
86.01 Aspiration of skin and subcutaneous tissue
86.04 Other incision with drainage of skin and subcutaneous tissue

ATTACHMENT B

Mock up of Index based on the published changes

Complications
arthroplasty 996.41-996.47
.....
external (fixation) device with internal component(s) NEC 996.78
infection or inflammation 996.67
mechanical 996.49
mechanical
device
fixation, external, with internal components 996.49
fixation, internal (nail, rod, plate) 996.49
orthopedic, internal 996.49
graft NEC 996.52
bone 996.49
cartilage 996.49
muscle 996.49
orthopedic, internal 996.49
tendon 996.49
implant NEC 996.59
orthopedic, internal 996.49
orthopedic device, implant, or graft
internal (fixation) (nail) (plate) (rod) NEC 996.78
infection or inflammation 996.67
joint prosthesis 996.77
infection or inflammation 996.66
mechanical 996.49
Failure, failed
device implant or graft—see Complications, mechanical
fusion (joint) (spinal) 996.49

ATTACHMENT C

TABLULAR MODIFICATIONS

996 Complications peculiar to certain specified procedures

996.4 Mechanical complication of internal orthopedic device, implant and graft
Mechanical complications involving:
External (fixation)device utilizing internal screw(s), pin(s) or other fixation
Grafts of bone, cartilage, muscle, or tendon
Internal (fixation) device such as nail, plate, rod, etc.

Use additional code to identify joint replaced by prosthesis (V43.60-V43.69)

Excludes: *complication of external orthopedic dices, such as:*
Pressure ulcer due to cast (707.00-707.09)

996.40 Unspecified, mechanical complication of internal orthopedic device, implant or graft

996.41 Mechanical loosening of prosthetic joint
Aseptic loosening

Excludes: *peri-prosthetic osetolysis (733.45)*

996.42 Dislocation of prosthetic joint
Subluxation of prosthetic joint

996.43 Prosthetic joint implant failure
Breakage of prosthetic joint

Excludes: *graft failure (996.46)*
failure of orthopedic devices other than joint prosthesis (996.47)

996.44 Articular bearing surface wear of prosthetic joint

996.45 Graft failure
Mechanical (functional) failure involving:
Autograft,
Allograft
morselized bone graft ,
BMP,
PMMA,
chondrocytes,
tendons,
muscle
and other grafting material

996.47 Mechanical failure of non-prosthetic internal orthopedic devices
screws, nuts, bolts, rods, plates,
pins and other internal fixation.

996.49 Other mechanical complication of internal orthopedic device, implant or graft

341

Submitter :

Date: 06/22/2005

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-565-Attach-1.DOC

Attachment 565

June14, 2005

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

Re: Comments on **WAGE DATA CORRECTIONS**

Dear Dr. McClellan:

We appreciate the opportunity to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, published in the Federal Register on May 4, 2005. We are commenting on the policy discussed at page 23384 of the May 4, 2005 Federal Register regarding retroactive changes to the federal fiscal year 2005 (FY 2005) wage index.

The policy discussed at page 23384 states that, pursuant to section 903(a)(1) of Pub. L. 108-173, which allows the Secretary to make retroactive changes to items and services if failure to apply such changes would be contrary to the public interest, the Centers for Medicare and Medicaid Services (CMS) is proposing a retroactive correction to the wage data used to compute the FY 2005 wage index for hospitals that meet certain criteria. The criteria are: 1) the fiscal intermediary or CMS made an error in tabulating a hospital's FY 2005 wage index data; 2) the hospital informed the fiscal intermediary or CMS, or both, about the error, following the established schedule and process for requesting corrections to the FY 2005 wage index data; and 3) CMS agreed before October 1 that the fiscal intermediary or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected by the beginning of FY 2005, but CMS was unable to publish the correction by that date. The discussion at page 23384 also states that CMS published a correction to its FY 2005 inpatient prospective payment final rule on December 30, 2004 that included the corrected wage data for four hospitals that meet the above criteria and that the corrections were effective January 1, 2005.

We very much agree that a retroactive correction to the FY 2005 wage index is appropriate and appreciate the Secretary exercising his authority to make that retroactive correction. For reasons discussed below, however, we request that the policy be amended to delete the requirement that CMS must have agreed before October 1, 2004 that it made an error in tabulating a hospital's data.

St. Joseph Hospital (provider no. 18-0010) and St. Joseph East (provider no. 18-0143) are both located in the Lexington, KY core-based statistical area ("CBSA"). For both hospitals, the fiscal intermediary made an error in tabulating the hospitals' FY 2005 wage index data (based on the hospitals' cost reports ending June 30, 2002), and the hospitals informed the fiscal intermediary and CMS of this error following the established schedule and process for requesting corrections to the FY 2005 wage data. Accordingly, both hospitals meet the first two criteria proposed by CMS for a retroactive correction to the FY 2005 wage index data.

The hospitals received a letter dated October 15, 2004 from James Hart, Deputy Director of the Division of Acute Care for CMS, stating that CMS had reviewed this wage data matter and that it agreed that it was necessary to correct the hospitals' wage data. The letter also states,"[t]he corrected wage data will be retroactive to October 1, 2004, and will be published in an upcoming correction notice and/or joint signature letter." Because this letter is dated October 15, 2004, it does not technically meet the third criterion proposed by CMS at page 23384. As a practical matter, we believe that CMS had determined prior to October 1, 2004 that the wage data for provider nos. 18-0010 and 18-0043 should be corrected, but did not issue its letter stating so until October 15, 2004. Note that prior to October 1, 2004 there were numerous conversations between CMS, PricewaterhouseCoopers (which was acting as the representative for the St. Joseph Hospitals on this matter) and the St. Joseph Hospitals. In these conversations, CMS verbally agreed that the fiscal intermediary had incorrectly tabulated the wage index data for the St. Joseph Hospitals' wage index data and the correction should be effective October 1, 2004.

We believe, however, that the circumstances described above justify a retroactive correction to the FY 2005 wage data pursuant to section 903(a)(1) of Pub. L. 108-173, because the failure to apply such changes would be contrary to the public interest. The fact that CMS agreed to make the wage data change retroactive to October 1, 2004 is sufficient reason to implement the change as of that date. Moreover, these wage data corrections should have been implemented as part of the established process for requesting corrections to the wage index data, which would have made them effective October 1, 2004. Accordingly, we suggest that the criteria published at page 23384 of the Federal Register be amended to delete the requirement that CMS must have agreed before October 1, 2004 to correct the wage data.

We also want to confirm our understanding that the wage data correction for provider nos. 18-0010 and 18-0143 will result in a retroactive wage index correction to October 1, 2004 for all acute-care hospitals in the Lexington, KY CBSA. In our opinion, a change to the wage data for provider nos. 18-0010 and 18-0143 that did not affect the wage index for the entire CBSA would be inequitable and contrary to the public interest.

Again, we very much appreciate the opportunity to comment on the proposed policy and CMS's effort to make retroactive corrections to the FY 2005 wage index when those corrections are in the public interest.

Sincerely,

William E. Hoffman, Jr.
V.P. for Government Programs

cc: Scott Raab, Office of Senator Mitch McConnell

342

Submitter : Mr. Eric Rugo

Organization : Stryker Corporation

Category : Device Industry

NT

Date: 06/23/2005

Hefter
Hartstein
Treitel
Walz

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1500-P-648-Attach-1.DOC

Attachment 648

stryker®

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

Orthopaedics

June 23, 2005

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

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

Dear Dr. McClellan:

On behalf of Stryker Orthopaedics, I appreciate the consideration and review you and your team gave to our New Technology Add-On Payment Application for the Trident® Ceramic Acetabular System. Stryker is a leader in the worldwide orthopaedic market and is one of the world's largest medical device companies. With its broad base of technologies, Stryker products are used in over 80 percent of the hip and knee replacement procedures performed each year in the United States.

We commend the Centers for Medicare and Medicaid Services' ("CMS") decision in the proposed rule to grant unique ICD-9-CM codes for hip bearing surfaces. The addition of these codes will allow outcomes to be tracked by bearing surface and allow for better data evaluation, which will ultimately lead to improvements in design and patient demand matching. These new codes also will permit the collection of charge data for these unique bearing surfaces, which we look forward to discussing further with your agency. The gathering of this data will allow for DRG assignment that appropriately matches the charge data these new codes reveal.

We have reviewed CMS's analysis of the Trident® application and rationale for the proposed denial of an add-on payment. ***We respectfully disagree with CMS's preliminary assessment that Trident® fails to meet the "newness" and "substantial***

improvement" criteria and thus request that CMS approve Trident® for an add-on payment in the final rule. Our comments in response to CMS's analysis follow below.

"Newness" Criterion

In the proposed rule, CMS proposes to deny add-on payments for Trident® because the agency no longer considers the device to be "new" under its interpretation of the Medicare statute. Specifically, the agency notes that Trident® was available on the market in April 2003 and thus "charges reflecting the cost of the device *may* have been included in the data used to calculate the DRG weights in FY 2005 and the proposed DRG weights for FY 2006" (emphasis supplied). This preliminary determination by CMS is inconsistent with the agency's past rulings on other technologies, which were available on the market for nearly identical lengths of time as Trident® and were approved by the agency for add-on payments.

Last year, CMS approved add-on payments for cardiac resynchronization therapy with defibrillator (CRT-D). One CRT-D device received Food and Drug Administration (FDA) approval in May 2002, and another received FDA approval in June 2002. Both of these devices were deemed "new" by CMS since the FY 2005 add-on payment year would represent the third year of the two-to-three year "new" window after the date of FDA approval. Moreover, as CMS states in this year's proposed rule in relation to last year's CRT-D favorable add-on payment decision, "We also noted that we would extend new technology add-on payments for the entire FY 2005 even though the 2-3 year period of newness ended in May 2005 for CRT-D since predictability is an important aspect of the prospective payment methodology and, therefore, we believe it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year."

CMS also approved add-on payments in FY 2005 for Bone Morphogenetic Proteins (BMP) for spinal fusions. This product received FDA approval in July 2002 and, according to CMS, "[the product] was still within the 2-year to 3-year period during which a technology can be considered new under the regulations."

There appears to be no meaningful distinction between the timeframe at issue in the case of Trident® and the timeframes that existed in the cases of the CRT-D and BMP technologies. Trident® was available on the market in April 2003 and is being considered for an FY 2006 add-on payment. As with the CRT-D and BMP technologies, Trident's® two-to-three year period of newness would end in the middle of the third and final year of eligibility for an add-on payment. Using CMS's interpretation of its own regulations, not only is Trident® still within the two-to-three period during which a technology can be considered "new," it is eligible for an add-on payment for the full fiscal year. It also is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

Stryker recommends that CMS continue to determine the end-point to the add-on payment eligibility period in the same manner in which the agency did in FY 2005 and thus find that Trident® meets the "newness" criterion.

Substantial Clinical Improvement Criteria

CMS additionally asserts that Trident® represents only an "incremental advance" over similar technologies, despite the fact that there are no peer-reviewed, published studies of prospective, randomized, controlled clinical trials demonstrating improved performance by the "similar" products to which the agency alludes. Unlike these other products, Trident® has been subjected to an extensive prospective, randomized, controlled clinical study that meets CMS's high standards for evidence collection.

The randomized, controlled clinical trial, described in the Journal of Bone and Joint Surgery (JBJS) as Level of Evidence 1,[1] is recognized today as the gold standard for evidence-based practice. Wright et al, stated that surgeons intuitively recognize that a rigorous research design provides more convincing and dependable results.[2] In order to provide comment on a proposed FDA guidance document to standardize clinical study design, orthopaedic surgeon members of the Hip Society identified four variables that must be included in study designs and reports in order to determine "study success" for hip replacement surgery. The four variables are as follows: complications, clinical outcomes (Harris Hip Score), revision surgeries, and radiographic failures. The peer-reviewed publications related to current ceramic-on-ceramic articulations present examples of the study design that incorporate these success criteria and JBJS Level of Evidence 1 (highest quality) reporting.[2] These studies provide compelling clinical evidence that the new technology, designs, and manufacturing processes associated with ceramic devices utilized in total hip arthroplasty perform as intended.[3-6] The study results separate the new designs from older technology that often reported less than desirable results.

Other contemporary alternative bearings such as metal-on-metal and highly cross-linked polyethylene have not had published clinical trial data with the same completeness and consistency as ceramic bearings and often have not focused on a consecutive series of patients. As a result, conclusions as to the clinical performance of these devices may not be clear. FDA regulatory considerations are partly responsible for this difference. Since ceramic bearings are considered Class III devices, robust study designs with a defined statistical justification of sample size and clear study endpoints were requirements for approval of the products. In comparison to the FDA approval process, the path to publication is less challenging, as journals may more readily accept study data of lesser quality.

While metal-on-metal bearings are Class III devices, they were introduced into the marketplace through the 510(k) process demonstrating substantial equivalence to products already on the market. However, as Class III devices, clinical data were provided to support some submissions. There are published reports of randomized controlled clinical studies for metal-on-metal bearings[7-9], at least one of which was an IDE study.[7] The results of the IDE study contained study success information but did not

seem to clearly distinguish the metal-on-metal results from the ceramic/polyethylene control group. This study also limited the recommendation for continued use to patients who do not have abnormal renal function. Other reports of randomized trials for the metal-on-metal articulations tend to focus on the statistically higher serum and urine metal ion concentrations in the metal-on-metal group and do not report study success parameters such as hip scores, other complications, and radiographic results.[8, 9]

Highly cross-linked polyethylene bearings are Class II products and require the 510(k) process without clinical data to establish substantial equivalence to previous polyethylene devices for market clearance. Post-market randomized and non-randomized studies of highly cross-linked polyethylene tend to focus on polyethylene wear measurement comparisons of a selected population and do not report other standard study success criteria, such as failure for reasons other than wear.[10-12] Results from these studies provide preliminary evidence that highly cross-linked polyethylene may reduce the incidence of wear when compared to previous designs. However, the authors generally caution that the follow-up period is short and the results are preliminary. Overall clinical performance and survivorship of the device with mating components are not presented. Other authors have raised concerns that the cross-linking process may affect the mechanical strength of the implant. There also is evidence that osteolysis is associated with impingement between the femoral neck and the rim of the polyethylene liner with highly cross-linked polyethylene, as well as with traditional polyethylene.[13] Long-term follow-up of randomized clinical trials is necessary to address these issues.

Stryker's ceramic-on-ceramic bearing clinical trial was the first IDE study to be approved by the FDA and the only ceramic study to be presented to the FDA Panel. The Panel members – and the panel statistician in particular – commended the study design, statistical report, and patient follow-up. A post-market study of a subset of the original study patients continues to demonstrate excellent patient outcomes as reported this year at the annual meeting of the American Academy of Orthopaedic Surgeons (AAOS). D'Antonio, Capello, and Hozack reported at the Hip Society and individual symposia that there were excellent clinical results with three to seven years' (mean of 5.2 years) follow-up.[14-16]

This new generation of ceramic implant design eliminates the ion issues of metal-on-metal bearing surfaces and completely avoids polyethylene debris – a problem that cross-linking has failed to solve. Ceramic-on-ceramic design features, combined with the rigor of the ceramic clinical study and the excellent results of the ongoing post-market study, substantially separate the ceramic-on-ceramic bearings for total joint arthroplasty from alternative bearing technologies.

Stryker strongly disagrees with CMS's assessment that Trident® is an "incremental advance" over existing hip bearing surfaces. We urge CMS to take a closer look at all available clinical evidence related to hip bearing surfaces. If the agency takes this step, we are confident that CMS will determine that Trident® represents a "substantial improvement" over existing hip replacement technologies.

Charge Threshold Criteria

In the proposed rule, CMS does not disagree with Stryker's assessment that Trident® exceeds the charge threshold. Nonetheless, Stryker wants to be certain that the modeling provided is clear. The current hip arthroplasty procedure code associated with use of the Trident® Ceramic implant maps to DRG 209. The correlating CMS-assigned new technology add-on charge threshold for DRG 209 is $34,195. To demonstrate that the Trident® Ceramic Acetabular System meets the established threshold, Stryker provided two data sets:

1. The Lewin Group, a nationally recognized policy research and management consulting firm specializing in health care, performed an assessment using 2002 MedPAR data, the 2001 Standard Analytical File of inpatient claims, and the invoice price for the Trident® Ceramic Acetabular System with associated implant mark-up.

2. Thomas Jefferson University Hospital provided charge data for 203 patients that underwent total hip replacement surgery using the Trident® Ceramic Acetabular System in the first half of 2004.

In conducting its assessment, the Lewin Group performed the following analysis:

Step One: Extracted the approximately 100,000 relevant cases from the 2002 MedPAR data file by ICD-9-CM procedure code 81.51.

Step Two: Adjusted charges for Indirect Medical Education (IME), Disproportionate Share (DSH), and local area wages to obtain standardized charges and calculate the mean and median charges for DRG 209, ICD-9-CM 81.51.

Step Three: Extracted the relevant cases from the 2001 Standard Analytic File to determine the device charge per case and determined the proportion of the charge represented by the device.

Step Four: Applied the hospital market basket increase for years 2003, 2004, and 2005.

Step Five: Calculated the charge for DRG 209, ICD-9-CM 81.51, without the device. Substituted the invoice price for the device, recalculated the mean and median charges for the procedure with the Trident® Ceramic Acetabular System.

Step Six: Tabulated results, including fields for (1) the mean and median 2002 MedPAR charges (standardized), (2) ratio of implant to DRG payment, (3) MedPAR charge without the implant, (4) mean and median charges using the Trident® Ceramic Acetabular System invoice price with relevant percentage mark-ups.

The final analysis demonstrated an average charge per case of $34,230 with an associated hospital mark-up of 28%. The use of the Trident® Ceramic Acetabular System therefore exceeds the CMS established DRG charge threshold of $34,195. (See Appendix A for the full data set.)

To prove this 28% mark-up is appropriate and, in fact, may be lower than standard hospital implant mark-ups, Thomas Jefferson University Hospital provided data from 203 patients treated with the Trident® Ceramic Acetabular System in 2004. In this data set, the total average charge per case is $46,540. When fully standardized, the average charge per case is $43,935. This charge exceeds the CMS established DRG threshold by $9,740 and further validates the cost model developed by the Lewin Group. (See Appendix B for the full data set.)

We are therefore confident that the Trident® Ceramic Acetabular System meets the CMS-established cost threshold to be eligible for a new technology add-on payment.

Conclusion

We appreciate CMS's review of this additional information that is material to a re-assessment by the agency of its preliminary conclusions in the proposed rule.

CMS should continue to determine the end-point to the add-on payment eligibility period in the same manner as it did last year and thus find that Trident® meets the "newness" criterion. CMS also should take a closer look at all available clinical evidence related to hip bearing surfaces and find that Trident® represents a "substantial improvement" over existing hip replacement technologies.

If you have any questions regarding this information or would like to discuss any aspects of Stryker's application, please feel free to contact me.

Sincerely,

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Director of Reimbursement
Stryker Orthopaedics
T: 201-831-5684
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References

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Appendix A

MedPAR 2002				Mean	STD	Range Low	Range High	25%	50%	75%	95%	99%
	DRG	209	Total Charges	28,904	16,915	2,222	627,805	19,863	25,029	32,810	54,867	91,858
	ProcCode	81.51	Covered Charges	28,772	16,904	-	627,805	19,806	24,960	32,726	54,670	91,503
	Observations*	99,772	Amount Reimbursed	9,119	3,405	-	164,990	7,784	8,603	9,865	13,765	18,297

MedPAR 2002 STANDARDIZED^^	DRG		Mean	STD	Range Low	Range High	25%	50%	75%	95%	99%
		Total Charges	26,892	13,798	1,618	565,086	17,884	22,821	29,878	47,536	74,725

5% SAF Inp 2001				Mean	STD	Range Low	Range High	25%	50%	75%	95%	99%
	DRG	209	Total Charges	24,445	10,504	2,906	122,996	17,970	22,011	27,761	43,882	63,596
	ProcCode	81.51	Medicare Payment	9,025	2,467	-	26,554	7,898	8,681	9,772	13,213	16,490
	Observations	2,871	Total Payment	9,756	2,462	-	29,346	8,656	9,407	10,519	13,964	14,123

5% SAF Inp 2001 STANDARDIZED^^			Mean	STD	Range Low	Range High	25%	50%	75%	95%	99%
		Total Charges	24,152	9,491	2,793	104,092	18,214	22,174	27,787	41,766	57,066

Percentage	Device to Total Charges											
				33%				29%	34%	38%	38%	41%
	Observations			Mean	STD	Range Low	Range High	25%	50%	75%	95%	99%
	2782		DEVICE CHARGE	8,085	4,769	6	48,009	5,201	7,650	10,585	15,887	23,433
	1703		0270 or 0274 or 0278	8,652	4,549	86	48,009	5,745	7,801	10,681	16,456	25,091
	742	General	Revenue Center 0270	7,036	5,194	11	27,360	1,653	7,297	10,718	15,739	20,726
	49	Ortho Device	Revenue Center 0274	9,117	7,490	6	41,122	4,410	7,807	11,290	19,773	41,122
	288	Implant	Revenue Center 0278	7,268	3,609	43	21,314	4,755	6,953	9,396	13,463	19,357

			Increase	Total Charges	Device Charge
Hospital Market Bskt	Rate of Change	2002-2003	4.2%	26,771	8,425
Hospital Market Bskt	Rate of Change	2003-2004	3.2%	27,628	8,694
Hospital Market Bskt	Rate of Change	2004-2005	3.1%	28,484	8,964

Markup			10%	15%	20%	25%	28%	
Stryker Device Cost		11,492	12,641	13,216	13,790	14,365	14,710	
Projected 2005	Total Charges	28,484	32,161.72	32,736.32	33,311	33,886	34,230	
Projected 2005	Device Cost	8,964						

Outliers removed base on CMS methods for trimming

^Global freight projections at www.cms.gov Market Basket Homepage

^^Standardization of total charge calculated at the hospital level is ((0.711 x total charges) / Wage Index + (0.289 x total charges) / cost of living adjustment) / (1+ indirect medical expense + disproportionate share))

Appendix B

Hospital	Date of Surgery	Ave Total Charge per case	IME Value	DSH Value	Wage Index
Jefferson University	2004	$ 46,540.00	0.995922	0.141877	1.0855
Calculation Model					
Step 1	$ 46,541.14				
Step 2	$ 30,484.34				
Step 2 b	$ 43,934.73	Fully Standardized Charge Per Case			

343

Submitter : Mr. Charles Owens

Date: 06/23/2005

Organization : Georgia State Office of Rural Health

Category : State Government

CAH/Reloc

Hefter
Hartstein
Morey
Collins
Smith

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-649-Attach-1.DOC

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Attachment 649

Tim Burgess, Commissioner

Sonny Perdue, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.communityhealth.state.ga.us

Charles F. Owens, Executive Director
Office of Rural Health Services
502 Seventh Street South, Cordele, Georgia 31015-1443
Main Number: (229) 401-3090
Faxes: (229) 401-3077(General) or 401-3084 (Administration)
cowens@dch.state.ga.us

June 23, 2005

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

Dear Sir:

I am writing today to express 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. Georgia has thirty-five CAHs serving our rural citizens. Most CAHs were built during the Hill-Burton years and are in dire need for modernization. The overwhelming majority of the CAHs are prohibited from major renovation or expansion of services due to the limited space surrounding the current facilities. Over the years the vast majority of our facilities have been surrounded by housing, local businesses or industry which limits the available land necessary for construction. Other obstacles include the availability of land for development, availability of public utilities as well as the desirability of the area.

The modernization of our CAHs is essential for them to secure a competitive edge with larger modern facilities. A modern facility will attract our traditional patients as well as those with insurance. The generation of revenue from other sources rather than Medicare and Medicaid allows the hospital to reduce the cost of providing services reducing the expenses to Medicare and Medicaid programs. Additionally being able to build a modern facility conducive to the current market would allow the hospital to more efficiently organize itself to maximize the use of the skilled staff, which can result in significant costs savings.

Placing the limitation on CAHs creates a major disadvantage for the CAH. Citizens served by CAHs deserve care in modern facilities equal to that of the larger hospitals. A modern well-designed facility will provide the CAH a setting to deliver a higher quality of health care as well as a safer environment for our patients and employees alike. Not only will a modern facility improve the health care delivery it will also be an economic force to aide the development of the communities they serve.

The law allows existing CAHs with construction projects under development before December 8, 2003 to continue. However the majority of CAHs within Georgia have only recently secured themselves financially allowing them to begin the development of a new construction project. This decision has major implications for virtually every CAH within the United States.

CMS should allow CAHs to relocate within their service area which would allow them to serve their current population plus the additional market they could potentially attract. CAHs deserve the ability to construct cost efficient modern facilities that will allow them to meet the needs of the citizens of their communities. Many states have Certificate of Need Programs, which limit the location of health care facilities. 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.

Sincerely,
Charles F. Owens

344

Submitter : Mr. Mick Hagwell **Date:** 06/22/2005

Organization : Keweenaw Memorial Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-558-Attach-1.DOC

CAH/Reloc. Hefter Hartstein Collins Money Smith

Attachment 558

June 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P

To Whom It May Concern:

The recently released Inpatient Prospective Payment System (IPPS) proposed rule only provides continued Critical Access Hospital status for necessary providers that are building replacement facilities at another location and can demonstrate their construction plans began before December 8, 2003. This proposed rule represents a drastic over-reaction to a perceived problem, is unnecessarily restrictive and arbitrary, and will result in greater costs and inefficiencies for the hospitals that it effectively "land-locks." There are many reasons why it is appropriate and cost efficient for an aging health facility to relocate more than 250 yards from its current location. In the case of Keweenaw Memorial Medical Center we are in the process of currently committing $350,000 in unexpected repairs just to keep our bed units functioning. These repairs are being made primarily to our HVAC system in a building constructed in 1920. We have significant environment of care concerns that need to be addressed such as ventilation in our pharmacy, fire safety codes, and in general the overall deterioration of the building itself. Renovating and retrofitting an 85 year old building for efficient patient flow; heating; ventilation, air conditioning; and information technology will cost more than constructing a new hospital. Such increased costs will inevitably be passed on through formula to both federal and state payers.

The CMS proposed rule, as it currently stands will not allow us to build a new, more efficient facility due to the fact that we would be forced to relocate more than 250 yards from our current landlocked location. Please consider the impact this proposed rule will have on hospitals such as ours. In closing we would ask you to review Michigan's Certificate of Need regulations that may provide an alternative to the proposed rule regarding necessary providers such as ourselves as we consider the option of rebuilding. Michigan's CON process provides ample oversight to assure a hospital's relocation is appropriate from a cost, quality, and access perspective.

Thank you for taking the time to consider our comments.

Sincerely,

Charles Nelson, CEO
Mick Hagwell, CFO
Keweenaw Memorial Medical Center

205 Osceola Street
Laurium MI 49913

345

Submitter :

Date: 06/16/2005

Organization :

Category : **Hospital**

NT
DRG/GEN

Hefter
Hartstein
Brooks
Gruber
Fagan
Kelly
Hue
Walz
Treitel

Issue Areas/Comments

Issues

New Technology Applications

See attached document regarding Charite Artificail Disc

CMS-1500-P-376-Attach-1.RTF

Attachment 376

Morristown Memorial Hospital 100 Madison Avenue, Morristown, NJ 07962

Jeff Newman
Business Advisory Services
P: 973-656-6951# F: 973-290-8627
jeff.newman@ahsys.orgl

June 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention:CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1840

To Whom It May Concern:

I am writing to you as a representative of Atlantic Health System, a three-hospital system in north central New Jersey. Two of our hospitals, Morristown Memorial Hospital in Morristown, New Jersey and Overlook Hospital in Summit, New Jersey intend to begin providing spinal fusion procedures through their respective orthopedic surgery departments during 2005 utilizing the CHARITE artificial disc manufactured by Depuy Spine Inc. a division of Johnson and Johnson of New Brunswick, New Jersey.

I am writing to ask that CMS give consideration to grouping these procedures for Medicare eligible patients into DRGs 497/498 rather than DRGs 499/500. We feel it is more appropriate that DRGs 497/498 are utilized since they reflect the more clinically complex and costly procedures associated with a spinal fusion as opposed to a back/spine procedure where no fusion is done. As you know the CHARITE implant is used in lieu of harvested bone or other material in fusing a patient's spine in the lumbar region. Each implant costs the hospital approximately $12,000/unit and we are concerned about the hospital's ability to provide this new technology without provision for adequate reimbursement to cover the cost of the device.

The procedure using the CHARITE device has been shown to have a lower incidence of morbidity and pain management problems associated with the more traditional spinal fusion using harvested bone or the use of spinal hardware such as plates, screws, and cages.

Also, while it is true that there may be relatively few Medicare eligible patients who actually get the CHARITE implant for spinal fusion, I would like to mention that commercial insurers frequently arrange their reimbursement based on what CMS implements when new technologies are introduced.

If a permanent designation cannot be made at this time, AHS asks that CMS give consideration to a temporary assignment of this procedure into DRGs 497/498 be done, pending further study. Thank you for your time and consideration in this matter.

Sincerely,

Jeff Newman
Contracts Manager-Atlantic Health System
Cc: D. Petronio
J. Dipaolo

Thomas Jefferson University Hospital
Jefferson Health System®

346

Thomas J. Lewis
President and
Chief Executive Officer

Labor/s

Hefter
Hartstein
Knight
Seifert
Treitel

June 23, 2005

Thomas Jefferson University Hospitals

Thomas Jefferson University Hospital

Methodist Hospital Division

Jefferson Hospital for Neuroscience

Ford Road Campus

Methodist Hospital Nursing Center

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

Subject: Labor-Related Share

To Whom it May Concern:

I am writing on behalf of Thomas Jefferson University Hospital (TJUH) to express our opposition to the changes that the Centers for Medicare & Medicaid Services (CMS) has proposed in the FY 2006 Medicare inpatient PPS regulation governing the labor-related share of Medicare payments to hospitals. Together with our academic partner, Thomas Jefferson University, TJUH is an academic and regional medical center and is one of the largest employers in Philadelphia. TJUH is a proud member of the Jefferson Health System. The proposed regulation calls for reducing the labor-related share from 71.1 percent to 69.7 percent for hospitals located in areas with a wage index greater than 1.0 and would cost TJUH approximately $150,000 in lost Medicare revenue.

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

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

Since this change will decrease Medicare revenue for all affected hospitals – those whose wage index is greater than 1.0 – CMS proposes achieving budget neutrality by redistributing this money by increasing the standardized amount for all hospitals. This approach will result in a financial windfall for *all* hospitals with a wage index of 1.0 or less – that is, for most rural hospitals.

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

In an industry in which a positive operating margin of four percent is considered necessary to operate effectively, a 2003 study by the National Association of Urban Hospitals found that among hospitals that qualify for Medicare DSH payments, the collective financial performance of urban hospitals nation-wide is 25 times worse than that of rural hospitals. Collectively, the operating margins of urban Medicare DSH hospitals in the U.S. are *minus* 5.7 percent. That same study found that large urban hospitals that provide at least 15 percent of their services to Medicaid patients have an average operating margin of *negative* 8.52 percent.

It has become increasingly difficult to meet the health care needs of the community as these types of proposed reductions in payments deteriorate our ability to provide high quality health care. We urge CMS not to reduce the labor-related share of the Medicare wage index.

Sincerely,

Thomas J. Lewis
President and Chief Executive Officer

TJL:g

347

Kentucky Hospital Association

Representing Kentucky Health Care Organizations

MB/H
QData

June 24, 2005

TRansfers
Geo reclas
CAH/Reloc

Hefter
Hartstein
Seifert
Knight
Boden
Krusnat
Walz
Hart
Kenly
Collins
Morey
Smith

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

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

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.

2501 Nelson Miller Parkway
Post Office Box 436629
Louisville, Kentucky 40253-6629
502-426-6220
FAX 502-426-6226

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

such data for the proposed transfer expansion has been provided. In fact, many cases with a shorter length of stay are very costly because the level of services provided during the initial days of hospitalization is more intensive and expensive.

Finally, we believe that CMS's proposal is contrary to the statute. In section 1886(d)(4)(J) of the Social Security Act, CMS is directed 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, as the 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to a post-acute care setting in FY 2004. Moreover, CMS is capturing DRGs that are not high volume.

Recommendation: KHA strongly opposes any expansion of the post-acute care transfer policy, and urges CMS to withdraw it from the final rule.

Countywide Rural Hospital Reclassification Criteria

CMS defines hospital labor market areas based on the definitions of statistical areas established by OMB. In December, 2000, OMB announced its new standards which provided for the identification of the following statistical areas:

- Metropolitan Statistical Areas
- Micropolitan Statistical Areas
- Metropolitan Divisions
- Combined Statistical Areas
- New England City and Town Areas
- New England City and Town Area Divisions
- Combined New England City and Town Areas

Metropolitan Statistical Areas are defined as having at least one urbanized area of 50,000 or more population, plus adjacent territory that is socially and economically integrated. Mircropolitan areas – which are new areas – have at least one urban cluster of at least 10,000 but less than 50,000 population. If specified criteria are met, adjacent metropolitan and micropolitan statistical areas may become the components of a new set of areas called Combined Statistical Areas.

In its 2005 IPPS rule, CMS adopted the revised OMB Metropolitan Statistical Areas (MSAs). This change resulted in the creation of two new MSAs in Kentucky and the reconfiguration of the Louisville and Lexington MSAs.

Madison County, Kentucky, adjoins Fayette County (which contains the city of Lexington) and, since the inception of IPPS, the two hospitals located

there have been classified and paid using the Lexington MSA wage index. The new OMB definitions now remove Madison County from the Lexington MSA because it is defined as a micropolitan area. Madison County, however, has grown considerably over the last ten years and is more populated, urbanized and integrated with Lexington than when it was part of the MSA. Despite these factors, Madison County's designation as "micropolitan" results in the application of the rural Kentucky wage index which greatly lowers payment to these hospitals.

Under the revised OMB area definitions, OMB defines the Lexington-Fayette-Frankfort-Richmond "Combined Statistical Area" (CSA) to include the Lexington MSA along with the city of Richmond (located in Madison County), and two other micropolitan areas. When OMB issued its new area classifications, it specifically advised that, in some cases, several new metropolitan and micropolitan areas have been created from a previously designated MSA and, where these separate areas form a CSA, they should be combined and the CSA used for analytic and program purposes since it is equivalent to the old MSA.

Although CMS has proposed a three-year hold harmless before these wage index reductions would go into place, we believe it is improper to fundamentally redesignate the hospitals located in Madison County as rural.

The regulations setting forth criteria for redesignation of all hospitals in a county utilize location in a Consolidated Statistical Area (CSA) for urban hospitals ***but not for rural hospitals***. In fact, the current criteria for rural countywide reclassification is useless because, to our knowledge, there have never been any such reclassifications. In order for the criteria to be meaningful and allow rural hospitals to qualify under the same criteria as urban hospitals, the regulation should be changed to allow for the rural countywide reclassification of hospitals if the rural county is in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation. If this provision is extended to rural hospitals, the two facilities located in Madison County could be reinstated back to the Lexington MSA to prevent a significant loss of Medicare payments.

Recommendation: KHA strongly urges CMS to amend the criteria for the rural countywide reclassification of hospitals, as outlined below, which would apply the same criteria that currently exists for urban hospitals also to rural hospitals, to allow reclassification if the rural county is in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation.

Section 412.232 Criteria for all hospitals in a rural county seeking urban designation.

(b) Metropolitan character.

(1) For fiscal years prior to FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are

located meets the standards for redesignation to an MSA or an NECMA as an outlying county that were published in the Federal Register on March 30, 1990 (55 FR 12154) using Bureau of the Census data or Bureau of Census estimates made after 1990.

(2) For fiscal years ***2006 and thereafter*** [~~beginning with FY 2005~~], ***hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation qualify as meeting the metropolitan character requirement for reclassification*** [~~the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an outlying county that were published in the Federal Register on December 27, 2000 (65 FR 82228) using Census Bureau data or Census Bureau estimates made after 2000~~].

Critical Access Hospitals – Necessary Provider Status Relocations

Currently, a governor may certify a hospital as a "necessary provider" to allow a hospital to become a critical access hospital (CAH) if it meets all CAH criteria except that it is located closer than 35 miles from a PPS hospital or another CAH. 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.

KHA believes that CMS is exceeding its authority and is undercutting the intent of Congress, as expressed in the MMA, by independently establishing criteria that conflicts with the law and would have the effect of removing CAH status to "necessary provider" hospitals specifically grandfathered under the MMA. CMS would undermine this by allowing hospitals to rebuild only within 250 years of their existing site or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For a hospital that moves any further, the hospital would have to show that it serves the same community, was under development as of December 8, 2003 and filed for relocation with the state before January, 2006. These date restrictions are unreasonable. The December 8, 2003 date CMS proposes as the time for hospitals to have purchased property or begun development bears no relationship to the statute and would be particularly impossible for any hospital that converted to CAH status in 2004 or later.

In Kentucky, there are 25 critical access hospitals, most of which converted as a "necessary provider" of care. The physical plants of these facilities are old and in desperate need of updating and repair. The hospitals that have converted to CAH did so because they were operating at a financial loss. Conversion has brought financial stability to these hospitals and preserved access to care throughout many rural Kentucky communities. It is only now that their financial condition has improved, and they are credit worthy, that these hospitals can plan and finance the construction of replacement facilities. Allowing the rebuilding of these outdated hospitals is beneficial to the patients they serve and economical because new facilities will be designed to accommodate the efficient delivery of outpatient, emergency and short stay inpatient care – the focal point of CAH services - which cannot be accomplished merely from renovating old hospitals designed primarily for delivering inpatient services. While we agree that CAHs should serve the same community, they should not be barred from relocating within the same general area to build on a site that provides better patient access or, for other reasons, will provide better services. If the CMS proposal is not withdrawn, many Kentucky CAHs and their patients will be locked into inferior facilities.

Recommendation: KHA endorses the recommendations of the AHA in opposing CMS's relocation proposal. We specifically recommend that CMS rescind this proposal, reconsider its criteria, and publish new criteria in advance for review and comment. With respect to the criteria, CMS should automatically consider any CAH that moves within five miles to be rebuilding and not relocating, and thus, the same provider. With respect to relocation, CMS should eliminate arbitrary dates by which hospitals would have to purchase property or be "under development", and include more flexibility in evaluating specific relocations which would allow for hospitals to be relocated on sites more than five miles from their existing location if more cost effective or if it would be more accessible to the population served.

KHA appreciates the opportunity to submit these comments on behalf of all of Kentucky's hospitals, and we hope they will be reflected in changes to the final rule. Please feel free to contact me at 502-426-6220 if you have any questions or desire additional information.

Sincerely,

Nancy C. Galvagni

Nancy C. Galvagni
Senior Vice President

Transfers
CAH Reloc
SpH
Hosp. Redes
CAH Lujar

Hefter
Hartstein
Walz
Hart
Collins
Morey
Smith
Romano
Kenly

KANSAS HOSPITAL ASSOCIATION

Thomas L. Bell
President

June 22, 2005

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

RE: CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates; Published May 4, 2005

On behalf of the membership of the Kansas Hospital Association, we appreciate the opportunity to comment on the above referenced proposed changes to the Inpatient Prospective Payment System (PPS) for federal fiscal year 2006.

POST-ACUTE CARE TRANSFER POLICY

In the proposed rule, CMS states "*the 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 transfer policy adjusts the payments to approximate the reduced costs of transfer cases.*" While, if supported with empirical evidence, this would in some ways justify a change in policy, the rule failed to substantiate this claim. We are, therefore, only left to surmise that the proposed change was nothing more than an attempt to reduce otherwise merited reimbursement.

The estimated impact of this proposed change on Kansas' PPS hospitals is a negative $4.926 million for FFY 2006. In FFY 2002, Kansas' PPS hospitals combined for a negative 4.3 percent Medicare margin, a negative 2.3 percent for inpatient services. Given a proposed net market basket update factor of only 2.5 percent after all technical and budget neutrality factors are applied, and that current estimates of the actual market basket increase is 4.1 percent, this "stealth" payment reduction only serves to exacerbate an already negative margin situation.

KHA urges CMS to abandon this proposed change in payment policy until such time as reliable data can substantiate a need.

CRITICAL ACCESS HOSPITALS

Relocation of a CAH Using a Necessary Provider Designation:

There are 82 community hospitals that are designated and operating as CAHs in Kansas. Several of these CAHs were grandfathered into the CAH program from the earlier EACH/RPCH program. The remaining CAHs were designated based upon the necessary provider of health criteria. In the Medicare Modernization Act of 2003 (MMA), it included a sunset provision, effective January 1, 2006, that eliminates the state's authority to grant necessary provider of health designations. However, MMA did provide a grandfathering provision that allows any CAH that is designated as a necessary provider of health prior to January 1, 2006 to maintain its necessary provider designation.

The proposed rule endangers CAHs that are designated as a necessary provider of health because it proposes new parameters that will severely weaken the ability of CAHs to replace their current facilities. CMS is proposing that CAHs designated as a necessary provider may only retain their CAH status if they build a replacement facility within 250 yards of its current location or if the CAH can demonstrate their construction plans began before December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

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

The arbitrary date proposed by CMS is unrealistic and is a broad overreach of CMS authority. It puts in jeopardy many relocation projects that were started in the past 18 months since the passage of the MMA. This was clearly not the intent of Congress to prevent existing CAHs designated as a necessary provider to be perpetually prohibited from replacing or relocating their facility, which are often 40-50 years old. In addition, several Kansas CAHs are land-locked because they are located in residential areas. Therefore, these facilities will be forced to choose between building a replacement facility and jeopardizing their CAH designation or spending countless additional dollars in

improving and maintaining a deteriorating facility. This misguided policy does not make any reasonable sense. **KHA agrees with the suggested comments and recommendations of the AHA and would encourage CMS to remove the arbitrary date restrictions for relocation facilities and consider easing the proposed restrictions that discourage CAHs to relocate regardless of the improved benefits to beneficiaries.**

Pending Necessary Provider Status Applications:
The KHA and AHA are concerned about the hospitals that are currently in the process of converting to CAH status under the necessary provider program. Despite a hospitals best efforts and proactive planning, current circumstances surrounding an increase survey workload for state agencies and an increase in higher priority surveys, such as EMTALA complaints, may cause several hospital to miss the January 1, 2006 deadline. **Providers that have gotten to the stage of requesting a survey in advance of the January 1 deadline, but are unable to get the state to complete the survey have clearly demonstrated a good faith effort and should be considered as meeting the deadline**

SPECIALTY HOSPITALS
In the proposed Inpatient PPS rule CMS questioned whether certain specialty hospitals, defined as such in section 507 of Pub. L. 108-173 (MMA), met the Medicare statutory definition of a hospital. As stated in the proposed rule, CMS has identified that some "surgical and specialty hospitals may be primarily engaged in furnishing services to outpatients, and thus may not meet the definition of a hospital as contained in section 1861(e) of the Act".

The KHA and its members recognize and appreciate the complexity of CMS' task in applying the statutory definition of a hospital, especially the provision that requires the entity be primarily engaged in providing services to inpatients. The delivery of health care across the country, and in Kansas, has significantly changed since Medicare was enacted, with many hospitals and healthcare systems providing a wide range of inpatient and outpatient services. **KHA concurs with the AHA recommendation that CMS reviews a hospital's entire operation to ascertain whether the facility is *really* engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care.**

In addition, **KHA encourages CMS to apply the provider agreement and initial survey restrictions to all new specialty hospitals**. As reported by CMS, the suspension does not apply to those hospitals that have prior to June 9, 2005 submitted an enrollment application or have requested an advisory opinion from CMS concerning whether they were subject to the moratorium under section 507 of the MMA.

HOSPITAL REDESIGNATIONS AND RECLASSIFICATIONS

Urban Critical Access Hospitals Redesignated as Rural:

The KHA agrees with the AHA requests for CMS to provide clarification on the treatment of hospitals that are located in urban areas and apply for reclassification as rural. According to CMS statements in the proposed rule, "a hospital that is granted redesignation under section 1886(d)(8)(E) of the Social Security Act as added by section 401 of the Balanced Budget Act of 1997 (BBA), is treated as a rural hospital for all purposes of payment under the inpatient PPS, including the standardized amount, wage index and disproportionate share calculations as of the effective date of the redesignation." CMS makes this statement in the context of a proposed policy change on the wage index in an effort "to promote consistency, equity and to simplify our rules with respect to how we construct the wage indexes of rural and urban areas when hospital redesignations occur."

However, this same consistency in policy has not occurred when these redesignations occur for CAHs that are located in urban areas as of October 1, 2004 as a result of the use of the 2000 census data. Although the regulations were changed last fiscal year to allow CAHs in this situation to be temporarily reclassified as being located in a rural areas, CMS has not provided the same affirmative direction for CAHs in terms of treatment as rural for all purposes of Medicare payment. For example, the fiscal intermediary in one state has revoked the CRNA pass-through status for CAHs located in metropolitan areas as a result of the census change, citing the fact they are considered urban. Further, the FI has indicated the rural designation under section 1886(d) is only for provisions of 1886(d) and since the CRNA pass-through provision is outside of this section, the rural determination does not apply.

However, in examining the authority for the CRNA pass-through at 42 USCA §1395k note, the rural definition references section 1886(d) of the Social Security Act. In section 1886(d)(2)(D)(ii), "urban area" is defined as an area within a Metropolitan Statistical Area and "rural area" is defined as any area outside such an area or similar area. However, a further section of 1886(d) at 1886(d)(8)(E) allows a hospital to be treated as being located in a rural area if it meets the qualifications in this section. Since the annotated code refers broadly to section 1886(d), the rural determination made under 1886(d)(8)(E) does apply for the purposes of the CRNA pass-through as directed by the code.

There are three Kansas CAHs that have applied for and received redesignation from urban to rural. The KHA urges CMS to make an affirmative statement that all hospitals granted a redesignation should be treated rural for all purposes of Medicare payment.

Thank you for considering our comments on the proposed rules changes. Please contact Fred Lucky at 785-276-3128; flucky@kha-net.org or Chad Austin at 785-276-3127; caustin@kha-net.org if you have any questions regarding these comments.

Sincerely,

Thomas L. Bell
President

Docket Management Comment Form

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

Temporary Comment Number: 17864

Submitter: Mr. Thomas Bell **Date:** 06/23/05

Organization: Kansas Hospital Association

Category: Health Care Professional or Association

Issue Areas/Comments

General

See Attachment

Attachments

CMS-1500-P-T17864-Attach-1.doc

Print | Comment on Another Docket | Exit

Print - Print the comment
Exit - Leave the application

3419

CAH RC

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

Story
county
MEDICAL CENTER

630 Sixth Street
Nevada, Ia 50201

Phone: 515-382-2111
Fax: 515-382-6617

Dear Dr. McClellan;

After reviewing the proposed CMS guidelines regarding "relocation of a CAH hospital" I must express my deep concern with the negative impact these proposed rules would have on the future of Story County Medical Center.

Story County Medical Center was opened in 1951. Our facilities are located on one square block (323 x 323 feet) in an older residential area of Nevada, Iowa a rural agricultural community of 7,000 people. Our building is aging and in need of significant replacement of its operating plant. Moreover, because our hospital was built in the 1950's it is poorly designed to efficiently handle the growing outpatient volumes of today's modern facilities. Finally, our problems are exacerbated because we are land locked and there is not space available to expand our much needed medical office space or expansion or replacement of the hospital. We have attached a schematic of the footprint of the hospital on our present site for your review.

As part of the Medical Center's ongoing strategic planning process we have identified our current location and facility as a significant barrier to future growth. In discussing our future with healthcare architects, they have recommended that we build a replacement hospital as a major renovation project would not be practical. Any renovation project would devote a significant portion of the projects funding to merely bringing our existing facility into compliance with current building codes and would not result in desired operating efficiencies or quality improvements. Our current facility does not even meet the minimal expectations of today's patients or physicians. Given the unavailability of land at our current location, building a replacement hospital would involve relocation.

The ideal site for a replacement hospital would be approximately 2 miles southeast of our current location near a major highway, which would increase the accessibility of our services for those in the surrounding communities (please see attached map).

Architects have told us that it will cost as much to renovate our existing facility as it will to relocate and replace it. Prospective lenders have told us that they would prefer relocation insofar that a lenders collateral position is improved with a new modern facility with room to grow. We fully expect that our cost of capital will be lower and more accessible with a relocated replacement facility than if we are forced to remain in our present site.

Story County Medical Center operates as a Critical Access Hospital under the necessary provider exemption. Based on our interpretation of the proposed CMS guidelines governing relocations, Story County Medical Center would not meet the proposed requirements for relocation. We are respectfully requesting that CMS modify its proposed requirements that *"construction plans were under development as of 12/8/03 and that the 12/8/03 deadline for purchase of land adjacent to the CAH"*

be removed from the policy. We do believe that the 75% tests are reasonable and can comply with them.

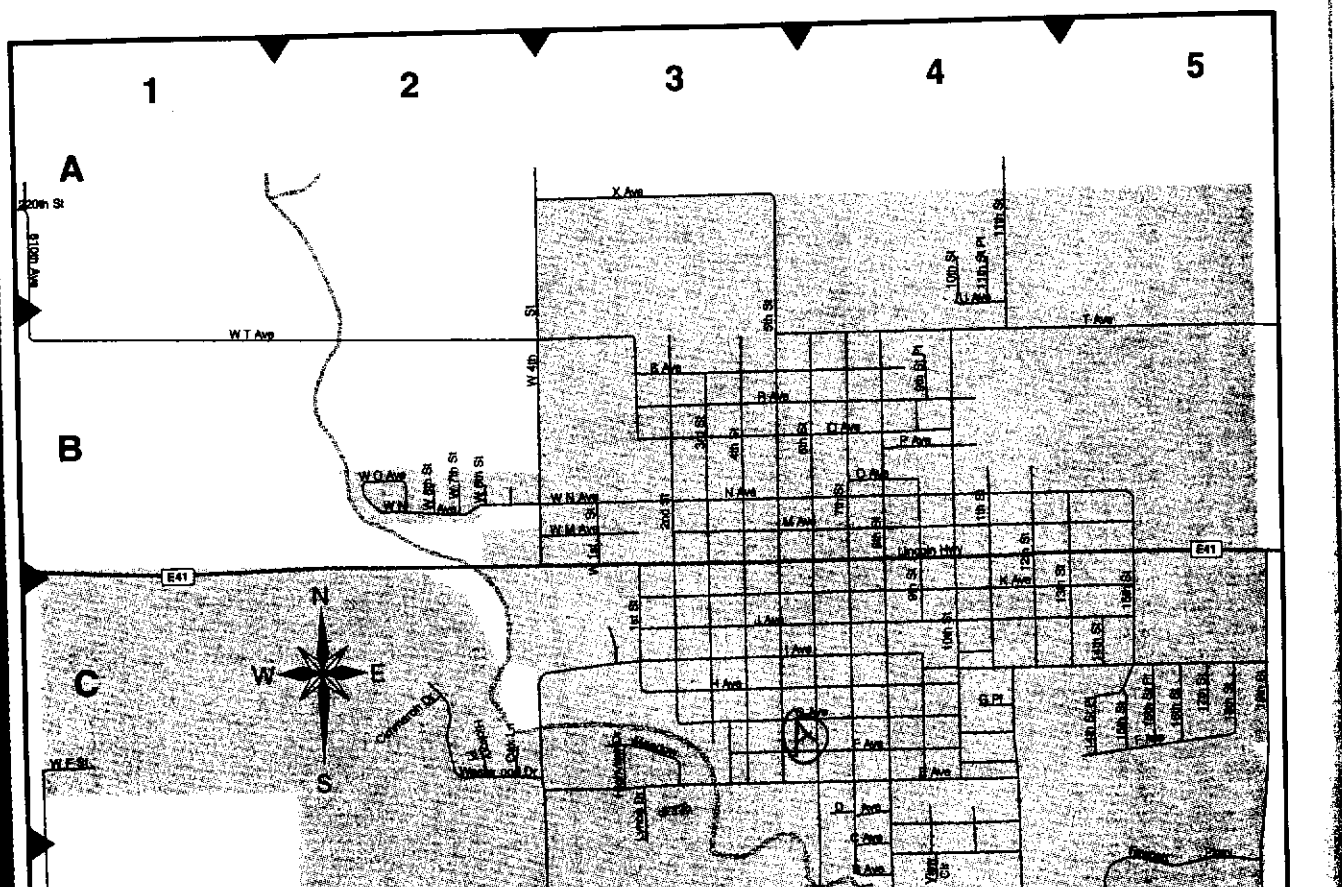
Story County Medical Center was recognized as a CAH on December 1, 2001. This program had allowed us to grow and meet more of the needs of our population. We are at a point where we need to expand our facility and operate in an efficient, cost-effective manner. Relocation of the hospital would be the most economical option, however the proposed regulations would prohibit us from doing this.

Thank you in advance for your consideration of these comments.

Respectfully,

Todd M. Willert
Administrator

= Story County Medical Center



(A) = current Hospital

(B) = proposed relocation

CARILION
Health System

June 24, 2005

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

RE: CMS-1500-P Postacute Care Transfers, from *2006 Proposed Changes to the Hospital Inpatient Prospective Payment Systems*

Dear Dr. McClellan:

Carilion Health System appreciates the opportunity to provide comments to CMS on the fiscal year 2006 proposed changes to hospital inpatient prospective payment systems.

Carilion Health System is a not-for-profit system based in Roanoke, Virginia with hospitals in Roanoke and throughout southwest Virginia. We provide the area's only Level 1 Trauma, tertiary care center, as well as maintaining a teaching hospital. Carilion is the only provider of certain key services for this area. Without Carilion's intervention, residents of Virginia and parts of West Virginia would experience significant barriers to access for many of these services. Demographically, our area runs a higher Medicare population than Virginia as a whole.

The American Hospital Association estimates that over 50% of hospitals have negative Medicare inpatient margins. Based on our demographics, Carilion's high Medicare population makes us vulnerable to these types of losses, and we do in fact run a negative margin on Medicare inpatient care.

Our comments focus on one specific area of the proposed change: the expansion of the postacute care transfer policy.

We estimate that proposed changes in the postacute care transfer policy will cost us well in excess of $1.5 million annually.

Just as importantly, we believe the policy expansion undermines the averaging concepts that underpin the basic principles of the Medicare prospective payment system. Medicare inpatient PPS generally assumes an optimal length of stay, with cases exceeding that LOS more likely to pay less than cost and those with a shorter LOS having a greater chance of receiving payment to cover costs. The postacute care transfer policy expansion would make it extremely hard to break even on a transferred case since the hospital is at risk both for keeping the patient less than the average LOS and the hospital is at risk for keeping the patient more than the average LOS. It would seem to penalize greater-than-expected efficiency in moving a patient to the next appropriate level of care.

P.O. Box 40032 Roanoke, VA 24022

We disagree with any premise that hospitals are actively managing transfers to maximize payment under the current system. Our hospitals are actively managing patients towards the right care setting at the appropriate time to provide the best level of care for each patient. Ironically, the expansion of the policy would seem to provide the very motivation CMS is trying to avoid: by narrowing further the breakeven payment corridor, hospitals may be more likely to try to manage to an optimal length of stay. That serves no one's interests, particularly those of the patient.

Finally, one of the advances in health care facilitated by the prospective payment system is the recognition that there are discrete phases to a patient's recovery: in modern medicine, not all care has to take place in the acute hospital setting. Alternative, post-acute settings are often more cost-effective and more clinically advantageous to the patient's recovery. CMS policy has supported and promoted this view. As a result, inpatient stays have dropped over time as patients move to the next appropriate care setting. As it has on the inpatient side, CMS has already taken effective action to stabilize costs in those postacute settings. Previous policy has reduced costs while generally supporting clinical decisions that provide the right level of care at the right time for the next, discrete stage in a patient's illness. Expansion of the postacute care transfer policy muddles that picture and effectively makes it difficult for providers to break even whether they keep the patient or whether they transfer the patient: penalties apply either way. There is no clear policy motivation for this change beyond reducing payments to providers.

Carilion Health System is proud to serve the growing Medicare population in Southwest Virginia, and strives to provide cost-effective quality care. To continue that mission, we urge your consideration of our comments. We believe the proposed expansion of DRGs covered by the postacute care transfer policy will have a detrimental impact on Carilion's hospitals and our ability to serve our patients to both our standards and yours. We respectfully request that CMS remove the provisions of the 2006 rules that would expand the postacute care transfer policy.

Thank you.

Donald E. Lorton
CFO, EVP