500

Submitter : Dr. Barry Arbuckle

Date: 06/24/2005

Organization : MemorialCare Medical Centers

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-796-Attach-1.DOC

Transfers
SpH
Q Data

Hafter
Hartstein
Walz
Hart
Romano
Bodden
Hammel

MEMORIALCARE®
Memorial Health Services

Attachment to #796

June 24, 2005

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

Via: Electronic Mail

Attention: CMS-1500-P

Dear Dr. McClellan:

As President and Chief Executive Officer of MemorialCare Medical Centers (MemorialCare) a five-hospital, not-for-profit health system in Los Angeles and Orange Counties, I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "Medicare Inpatient Prospective Payment System (PPS): The Proposed Rule for Fiscal Year 2006".

MemorialCare is an integrated health care system founded on the traditional values of not-for-profit community service. Our projected adjusted patient days for fiscal year 2005 are 497,000 on a base of 112, 000 patient discharges. With over 185,000 visits to our Emergency Departments, including one Level II trauma center, we also served our communities by performing 50,000 surgeries and delivering 13,000 babies.

We feel it critical to our future that you address a number of important issues that will affect hospital financing in the coming year. I will give our view on the Post-Acute Transfer Policy (PAC), then comment on the consequences if there is further proliferation of physician-owned, limited service hospitals. Finally, I'd like to discuss the proposed criteria for the reporting of hospital quality data.

Post-Acute Care Transfer Policy (pages 23411-58)

The proposed rule will expand the post-acute care transfer policy from 30 Diagnosis Related Groups (DRGs) to 223 DRGs in FFY 06. Using the MEDPAR 2006 data file, created by CMS on 6/1/05, and the Revised Table 5-DRG Relative Weights (CMS, 6/1/05), this rule change will cost MemorialCare over $2 Million in federal reimbursement. As a community-based system, the potential loss of these critical dollars presents a new unfunded mandate and is unacceptable in an environment in

which the actual costs of care continue to rise. CMS believes that the proposed change will expand the application of PAC transfer policy to DRGs that have both a relatively high volume and a relatively high proportion of PAC utilization. In reality, this rule will prove to be another barrier to MemorialCare serving its communities.

MemorialCare is committed to ensuring that its Medicare patients receive care in the most appropriate setting, e.g. acute care as long as needed, with transfer to a lower level of care as soon as the individual patient's care warrants same and with the goal of ensuring maximum individual functioning into the future. One of the long-standing principles behind PPS is that some cases will cost more than the DRG payment, while other will cost less. On average, we expect the payments to be adequate over the entire affected population. As proven by the calculations of our losses as noted above, this rule change is clearly detrimental and harmful to community-based hospitals.

MemorialCare is fully committed to quality care based on best practice, evidence based medicine. Expanding the DRG's affected by the PAC transfer policy will compromise clinical decision-making and penalize those providers of care such as MemorialCare for providing efficient care, at the most appropriate time, and in the most appropriate setting.

MemorialCare respectfully requests CMS reverse its support of this proposed rule change, and retain the current 30 DRGs. We believe that the people for whom we provide care and you provide coverage will be best served accordingly.

Limited Service Hospitals (page 23447)

In the proposed rule change, CMS has stated that certain limited service hospitals do not qualify under the Medicare stated definition of a "hospital" – that they be engaged primarily in furnishing services to hospital inpatients. MemorialCare commends CMS for taking this step.

Community based hospitals, guided by EMTALA and other licensing requirements are mandated to serve all patients presenting in the emergency department. Our mission commands us to provide service to our community without regard to a patient's ability to pay. Physician-owned, limited service hospitals operate under no such guidelines. Any physician referring a patient to a hospital in which he/she holds a financial interest clearly has a conflict of interest.

The impact of the limited service hospitals on the communities in which they now exist is not yet fully appreciated and the potential to disrupt the availability of comprehensive medical services in these communities remains an important and unanswered question. It is critical that the expansion of limited service hospitals be curtailed until the impact of these hospitals on access to comprehensive health services in their communities can be accurately assessed.

While MemorialCare is in general support of CMS's position, at the same time, we must respectfully request that all Medicare applications submitted by these physician-owned, limited service hospitals during the recently expired moratorium, be denied. We further request that the six-month freeze imposed on June 8, 2005 by CMS on new applications be held fast.

Reporting of Hospital Quality Data (pages 23424-426)

Pursuant to the proposed rules, CMS will be utilizing Clinical Data Abstraction Contractors (CDAC) to validate quality data submitted to the Clinical Data Warehouse. MemorialCare voluntarily participates in the Hospital Quality Alliance, a public-private collaboration to improve the quality of healthcare by the monitoring and public disclosure of quality outcomes. This collaboration includes the CMS and the American Hospital Association. Further, it is supported by other organizations such as the Agency for Healthcare Research Quality (AHRQ), the National Quality Forum (NHF) and the Joint Commission on Accreditation of Healthcare Organizations JCAHO).

MemorialCare is supportive of any effort to streamline the data collection and submission process, and to decrease the financial burden to hospitals which is associated with participation in this and other quality initiatives.

Thank you for the opportunity to present our views on this very important issue. The final disposition of the proposed rules will have a long lasting affect on MemorialCare and thousands of other not-for-profit hospitals. Our mission is to improve the health and well-being of individuals, families and our communities through innovation and the pursuit of excellence in all that we do. As proof of our commitment to serving our communities, MemorialCare contributed over $63,400,000 in total quantifiable community benefits in FY 2004. Any losses to our reimbursements for the care given to our Medicare patients will have a devastating affect on our ability to take care of those most in need.

MemorialCare will be happy to work with CMS on these and any other issues discussed above, or any other topics that relate to the complexities of hospital financing.

If you have any questions concerning these comments, please feel free to contact me at (562) 933-1833, or Peter J. Mackler, Director of Government Relations and Policy at (562) 933-1836.

Sincerely,

Barry Arbuckle, Ph.D.
President and Chief Executive Officer

501

Submitter : Ann Gosier
Organization : Guidant Corporation
Category : Device Industry
Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1500-P-797-Attach-1.DOC

Date: 06/24/2005

DRG/GEN
CC list
NT
WI/GEN
MedPAC
ICD-9-CM
DRG weights

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue
Walz
Treitel
Miller

GUIDANT

Attachment to #797

June 23, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Room 445-G Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Hospital Inpatient Prospective Payment System, Proposed Rule, CMS-1500-P

Dear Administrator McClellan:

Guidant Corporation welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the FY 2006 Medicare inpatient prospective payment system.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research and development facilities in the states of Minnesota, California and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leading designer and manufacturer of medical technologies used primarily to treat cardiovascular and vascular illnesses. Guidant's products save and enhance lives.

SUMMARY OF GUIDANT RECOMMENDATIONS

Automatic Implantable Cardioverter/Defibrillator (ICD) ("DRG Reclassifications")

1) Currently, code 37.26 (cardiac electrophysiologic stimulation and recording studies (EPS)) represents up to four separate and distinct medical procedures. Coding changes needed to eliminate the confusion surrounding code 37.26 were submitted to CMS on February 11, 2005, and should be on the agenda at the September 29, 2005, meeting of the ICD-9-CM Coordination and Maintenance Committee. A coding problem should be addressed with a coding solution through the Committee, not a change in payment structure.

2) Due to coding issues, the FY 2004 MedPAR charge data for cases with code 37.26 are inadequate and should not be used as the basis for modifying the payment structure. CMS should im plement the previously described coding correction and then collect charge data that do not combine cases with full-scale EPS, bedside interrogations, NIPS, and intraoperative device testing.

3) If, following the collection of charge data, CMS finds that a change in payment structure is needed, the agency first should perform robust data analysis with the intent of decreasing over- or underpayments.

Guidant Corporation
1310 G Street, NW, Suite 770, Washington, DC 20005
Tel 202.508.0800 Fax 202.508.0818
www.guidant.com

4) If CMS believes that removing code 37.26 from DRGs 535 and 536 is warranted based on charge differences, then for similar reasons the agency should consider splitting DRG 515 into two DRGs based on the principal diagnosis of heart failure, acute myocardial infarction, and shock.

5) To ensure the integrity of estimating procedure costs and confirm that hospitals are appropriately reporting device charges, CMS should use external data to validate device charges within the MedPAR database.

6) CMS should share in the costs of collecting and managing ICD Registry data. CMS also should leave open the issue of provider reimbursement for ICD data reporting so that the agency can reconsider it once more details about Registry data become available.

Carotid Artery Stent ("DRG Reclassifications")

1) CMS should capture all available recent data and, at a minimum, include at least six months of data prior to performing its DRG analysis in the final rule. Without proper analysis of the most recent CAS data, hospitals will be forced either to shoulder the burden of the additional costs not reimbursed by Medicare for another 12 months, or to deny Medicare beneficiaries access to this cutting-edge procedure.

2) Given the significant difference in charges, CMS should create a new DRG pair for carotid stenting cases in FY 2006, split based on the presence or absence of complications and co-morbidities (CC). If CMS is unable at this time to create a new DRG pair for carotid stenting, then – consistent with our earlier positions – we recommend that CMS move all carotid stenting cases into DRG 533 until such time as the agency can take this important step.

Coronary Artery Stents ("DRG Reclassifications")

1) CMS should move forward with its proposal to establish new DRG pairs for bare metal stent procedures with AMI and drug-eluting stent procedures with AMI based on the presence or absence of CCs.

2) CMS should move forward with its proposal to establish new ICD-9 codes to identify the number of stents inserted and the number of vessels treated in both the coronary and non-coronary vasculature.

Complications and Comorbidities (CC) Exclusions List for FY 2006 ("DRG Reclassifications")

CMS should proceed with its examination of the CC list. However, since the revision of the CC list would have an extensive impact on hospital revenue streams, any review and revision should be conducted and implemented cautiously, systematically, and thoroughly using external expertise and with complete transparency and stakeholder involvement.

Proposed Add-On Payments for New Services and Technologies ("New Technology Applications")

1) CMS should attempt to assign a new technology to an appropriate, clinically similar DRG, in which the average costs of care most closely approximate the costs of care using the new technology.

2) CMS should increase the level of the add-on payment from 50 to 80 percent to provide a reasonable payment to hospitals and ensure patient access to new technology therapies.

3) To maintain a coherent and consistent policy, CMS should continue to determine the end-point to the add-on payment eligibility period in the same manner as done in FY 2005. In the final rule, CMS therefore should reconsider any technologies that were denied add-on payments in the proposed rule due to the agency's change in policy.

4) The determination of whether a technology is "substantially similar" to another technology should not be used as a disqualifying criterion for add-on payment eligibility. CMS should not adopt or undertake an ad hoc clinical assessment during the eligibility phase of the new technology application process.

5) CMS should revise its stated position on eligibility for add-on payments and clarify that a subsequent date of FDA approval for "substantially similar" technologies will have no bearing on whether such products are eligible for add-on payment if the initial applicant is approved.

Frequency of Release of MedPAR Data

CMS should invest in the staff resources necessary to release the most current MedPAR data on a quarterly basis.

Acceptance of External Data

CMS should broaden its utilization of U.S. market external data in order to facilitate the establishment of adequate inpatient payment for new technology procedures at the time of FDA marketing approval. In line with its approach to updating outpatient payment rates, we also urge CMS to accept external data as part of the annual inpatient payment update process in order to address problems in the MedPAR database, including charge compression affecting certain technologies.

CMS Response to MedPAC Recommendations

Guidant shares CMS's concerns about MedPAC's recommendations related to the replacement of DRG charge-based weights with cost-based weights, the use of hospital-specific relative weights, the replacement of DRGs with severity-based APR-DRGs, and DRG-specific outlier reductions. We believe that any attempt to significantly modify the inpatient system should move forward only after a measured, studied, and fully transparent analysis of the implications of such action.

DETAILED RECOMMENDATIONS

Automatic Implantable Cardioverter/Defibrillator (ICD)
("DRG Reclassifications")

1) Code 37.26

CMS has proposed removing code 37.26 (cardiac electrophysiologic stimulation and recording studies (EPS)) from the list of cardiac catheterization procedures that map defibrillator system implants to either DRG 535 or 536. CMS justifies the modification by stating: 1) hospital coders have expressed confusion to both CMS and the American Hospital Association (AHA) regarding the current use of code 37.26; and 2) on average, the subset of DRG 535 and 536 cases with only an EPS have lower standardized charges than other DRG 535 and 536 cases, and thus fit more appropriately into DRG 515.

The coding confusion is due to the fact that code 37.26 has represented several separate and distinct clinical procedures. Currently, code 37.26 covers both a full-scale diagnostic EPS and a noninvasive-programmed stimulation, or NIPS. Similar to a cardiac catheterization, a full-scale EPS involves threading disposable catheters into the heart to monitor the heart's electrical activity. The results of the EPS, such as the induction of ventricular tachycardia, can be used to determine whether a defibrillator is needed and assist in selecting the appropriate device. NIPS also is used in the induction or termination of arrthymias but is performed using a device already implanted in the heart. Unlike EPS, NIPS does not involve the invasive procedure of threading catheters through the heart, nor does it require the use of disposable catheters.

In addition, until November 1, 2003, coders were instructed to use 37.26 for bedside device interrogations without arrhythmia induction. Bedside interrogations share some similarities with the NIPS procedure but can be performed in a patient's room, eliminating the need to take the patient to a fully equipped EP lab. CMS also indicated that intraoperative device testing may be inappropriately coded as 37.26, even though this procedure is included in the ICD system implant code (37.94). The confusion in coding is understandable as these procedures are clinically different and require very different resource utilization.

Guidant Recommendation

While we understand that there is coding confusion, it does not warrant a payment structure modification. Instead, the coding problem should be addressed with a coding solution. Coding changes needed to eliminate the confusion surrounding code 37.26 were submitted to CMS on February 11, 2005, and should be on the agenda for the September 29, 2005, meeting of the ICD-9-CM Coordination and Maintenance Committee. Any payment structure changes made before new codes are in place and reliable data are collected and analyzed could have unintended consequences.

2) FY 2004 MedPAR Charge Data

Current MedPAR data do not differentiate charges for cases with bedside interrogations, NIPs, intraoperative device testing, full-scale diagnostic EPS, or any combination of these procedures. This lack of differentiation creates difficulties in understanding the true charges related to cases with a full-scale diagnostic EPS. Not only are implants with NIPS not differentiated from cases with a full scale diagnostic EPS, but it is quite probable that many cases reported in FY 2004 were coded 37.26 based on the presence of the significantly less resource intensive bedside

interrogation. Since the bedside interrogation coding change did not take place until November 1, 2003, and because it can take time for coding changes to disseminate and become standardized, both the NIPS cases and those with bedside interrogation are likely affecting the analysis used to justify CMS's latest modification. As explained above, these four procedures are distinct and vary widely with regard to hospital resource utilization, and their combined inclusion results in misleading MEDPAR data elements.

Guidant Recommendation

FY 2004 MedPAR charge data contain misleading elements and should not be used as the basis for modifying the payment structure. CMS should implement the previously described coding correction and then collect charge data that do not combine cases with full-scale EPS, bedside interrogations, NIPS, and intraoperative device testing.

3) Potential Increase in Over- or Underpayments

If there is a problem with the payment structure as CMS suggests, then alternative payment structures should be considered and the impact of change on each analyzed carefully. An initial examination of the proposed structure indicates that the change might create a greater dispersion of charges within DRG 515. We believe a greater dispersion of charges would increase the likelihood of either underpaying or overpaying for a particular case. For example, removing code 37.26 from the list of cardiac catheterization procedures that map to either DRG 535 or 536 would exacerbate an underpayment issue for many CRT-D system implants. Evaluating the estimated FY 2006 payment rates for providers with a DRG 515 payment in FY 2003, we find that more than half of these providers would not receive payments sufficient to cover the average CRT-D device cost. CMS's proposed modification to the payment structure would drastically increase the number of cases subjected to this underpayment. If there is a need to change the payment structure, CMS first should consider various alternatives and perform robust data analysis.

Guidant Recommendation

If CMS finds that a change in payment structure is needed, the agency should consider alternatives to its proposal and perform robust data analysis with the intent of decreasing occurrences of over- or underpayments.

4) Splitting DRG 515

For FY 2004, Guidant requested that CMS restructure the DRGs for ICD system implants – DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization) – by separating more costly cases with a principal diagnosis of heart failure, acute myocardial infarction, or shock to ensure more appropriate payment across all ICD system cases. Specifically, Guidant requested that CMS create four DRGs in order to separate cases with additional, non-operating room procedures and also those cases with a primary diagnosis of heart failure, acute myocardial infarction, or shock. In line with the Guidant proposal, CMS split DRG 514 into two new DRGs, DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction, Heart Failure, or Shock) and DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction, Heart Failure, or Shock). CMS did not, however, split DRG 515 in a similar manner. For FY 2005, Guidant again submitted a request to split DRG 515. CMS responded that it did not believe the number of cases within DRG 515,

or the differential in charges and length of stay for cases with and without a primary diagnosis of heart failure, acute myocardial infarction, or shock, was sufficient to merit the creation of two separate DRGs.

In this year's proposed rule, CMS proposes to remove code 37.26 from the list of cardiac catheterization procedures that map to either DRG 535 or 536 based on coding confusion and charge differences. Table 1 shows that DRG 535 cases have an average standardized charge of $112,500, whereas DRG 535 cases coded with 37.26 and no other cardiac catheterization secondary procedure codes have average standardized charges of $98,273, a 12.6 percent decrease from the DRG 535 average standardized charges. Table 1 also shows that DRG 536 cases have an average standardized charge of $93,644, whereas DRG 536 cases coded with 37.26 and no other cardiac catheterization secondary procedure codes have average standardized charges of $84,433, a 9.8 percent decrease from the DRG 536 average standardized charges. Based on CMS's proposal, it appears that the charge differential is sufficient to warrant a split in payment.

A similar trend is evident in DRG 515 cases with a principal diagnosis of heart failure, acute myocardial infarction, or shock. Table 1 shows that DRG 515 cases have an average standardized charge of $83,052, whereas DRG 515 cases with a principal diagnosis of heart failure, acute myocardial infarction, or shock have average standardized charges of $90,069, an 8.4 percent increase from the DRG 536 average standardized charges. The DRG 515 cases with a principal diagnosis of heart failure, acute myocardial infarction, or shock also represent almost 40 percent (10,773) of all DRG 515 cases. It therefore would seem that if removing code 37.26 from the list of cardiac catheterization procedures – which map implantable defibrillator system implants to either DRG 535 or 536 – is necessary, it also is necessary to split DRG 515 into two separate DRGs based on the principal diagnosis of heart failure, acute myocardial infarction, or shock.

TABLE 1: FY 2004 MedPAR – Detailed Information for DRG Average Standardized Charges

DRG	Subgroup	FY 2004 MedPAR data		
		# of cases	Avg Std Charges	% Difference in Avg Std Charges
DRG 535	All	13,044	$112,500	
DRG 535	With 37.26 only	5,626	$98,273	- 12.6%
DRG 536	All	19,654	$93,644	
DRG 536	With 37.26 only	11,577	$84,433	- 9.8%
DRG 515	All cases	27,440	$83,052	
DRG 515	With AMI, HF, or Shock	10,773	$90,069	8.4%

Guidant Recommendation

Based on the data and precedent being set in the proposed rule with respect to changing DRG structures, DRG 515 should be split into two DRGs based on the number of cases assigned to DRG 515 and the difference in hospital charges associated with cases with and without the principal diagnosis of heart failure, acute myocardial infarction, or shock. The split would ensure more appropriate payment for all ICD cases and better align the DRG payment logic across ICD cases based on important differences in hospital resource requirements.

5) Use of External Data

CMS uses the charges included on hospital inpatient claims to estimate procedure cost, including the cost of technologies. To reduce charges to estimated costs, CMS applies a hospital-specific, department-specific cost-to-charge ratio (CCR). The CCR represents an average of the hospital mark-ups for a wide variety of items and services. The estimated costs are then used to establish the DRG weight for the procedure.

This approach to estimating procedure cost fundamentally understates the cost of procedures involving advanced technologies such as ICDs, which represent the majority of procedure cost. The CCR for such technologies often is substantially higher than a hospital's overall or departmental CCR. In other words, hospitals tend to assign lower mark-ups to advanced technologies compared with mark-ups assigned to other items and services. To the extent that hospitals' CCRs for advanced devices like ICDs are systematically higher than hospitals' overall and department-specific CCRs, the estimated cost of procedures utilizing such devices is significantly understated, resulting in the assignment of inadequate DRG weights. This effect on the DRG is especially pronounced when the charge for a device accounts for a high percentage of the total charges, as is the case with ICD procedures. Inpatient and outpatient studies have been conducted and shared with CMS that clearly confirm the existence of such charge compression for ICD procedures.

Guidant Recommendation

To ensure the integrity of estimating procedure costs and confirm that hospitals are appropriately reporting device charges, CMS should use external data to validate device charges within the MedPAR database.

6) Compensation for ICD Registry Data Management

The draft guidance on "Factors CMS Considers in Making a Determination of Coverage with Evidence Development" indicates that the agency will limit data collection requirements to instances in which additional data is needed to answer specific questions, thereby avoiding unnecessary costs. In the proposed rule, CMS also states that since the data elements required for the ICD Registry "are commonly found in patient medical records," the agency does not see the need for increased reimbursement to compensate providers for reporting the data. However, it seems premature to make judgments about the economic burden providers will incur due to ICD Registry data management until more specific information regarding the Registry is available.

Guidant Recommendation

Guidant recommends that CMS share in the costs of collecting and managing ICD Registry data. Taking this step would ensure that the agency has a stake in holding the resulting costs of data collection to a reasonable level. CMS also should leave open the issue of provider reimbursement for ICD data reporting so that the agency can reconsider it once more details about Registry data become available.

Carotid Artery Stent ("DRG Reclassifications")

1) New ICD-9 Codes and the Need for Subsequent Data Collection

As the agency notes in the proposed rule, CMS established codes for carotid artery stenting procedures (CAS) on October 1, 2004. Guidant commends CMS and the ICD-9-CM Coordination and Maintenance Committee for working with industry to create these new procedure codes to properly identify and track this breakthrough therapy.

Given the care that CMS took to create these new codes, we are particularly disappointed by CMS's decision not to analyze the data captured by the codes. Instead, the agency states that it used "proxy codes [39.50 and 39.90 with principal diagnosis code 433.10] to evaluate the costs and DRG assignments for carotid artery stenting because codes 00.61 and 00.63 were only approved for use beginning October 1, 2004, and because MedPAR data for this period are not yet available." Therefore, the costs analyzed by the agency include clinical trial data but not hospital charges for a commercialized device or procedures performed under a broader coverage policy.

Because CAS procedures have received expanded coverage since October 1, CMS's analysis is unfortunately out of date. The October 2004 coverage policy announced by CMS added coverage for post-approval studies, and the March 2005 coverage policy added coverage for a subgroup of patients outside of clinical studies. We thus expect that FY 2005 and FY 2006 will show an increase in volume to as much as 12 percent of cases in DRGs 533 and 534, in contrast to the 3.4 percent in CMS's analysis.

Guidant Recommendation

CMS should capture all available recent data and, at a minimum, include at least six months of data prior to performing its DRG analysis in the final rule. Without proper analysis of the most recent CAS data, hospitals will be forced either to shoulder the burden of the additional costs not reimbursed by Medicare for another 12 months, or to deny Medicare beneficiaries access to this breakthrough procedure.

2) Create New DRG Pair for Carotid Stenting Cases

For the proposed rule, CMS completed an analysis using FY2004 MedPAR data to determine charges and length of stay associated with carotid artery stenting in DRGs 533 and 534 by using procedure codes 39.50 and 39.90 in combination with diagnosis code 433.10. This code combination is an excellent proxy to identify carotid stenting cases given that the new ICD-9 codes were not in effect for the FY2004 MedPAR data. The analysis of FY2004 MedPAR indicates that carotid artery stenting cases have average charges of $29,737 and $22,002 for DRG 533 and 534, respectively, compared to average charges of $24,464 and $15,873 for all

cases within DRG 533 and 534, respectively, resulting in charge differentials of $5,273 (22%) and $6,129 (39%).

In analyzing the FY2004 MedPAR data, we noted an even greater difference in average charges between carotid stent cases and the average charge for the entire DRG as evidenced in the table below:

DRG	With or without 39.50 and 39.90	Discharges	Average Length of Stay	Average Charge	Average Standardized Charge
533	All Cases	35,730	3.1	$ 23,910	$ 21,286
533	DRG without codes 39.50 and 39.90	33,992	3.1	$ 23,294	$ 20,845
533	DRG with codes 39.50 and 39.90	1,738	3.1	$ 35,961	$ 29,903
534	All Cases	37,457	1.7	$ 17,012	$ 15,166
534	DRG without codes 39.50 and 39.90	35,911	1.7	$ 16,580	$ 14,870
534	DRG with codes 39.50 and 39.90	1,546	1.5	$ 27,042	$ 22,065

Based on our analysis of the MedPAR data, the increase in charges between carotid stent cases and DRGs 533 and 534 is $8,617 (40%) and $6,899 (45%), respectively, indicating the potential for significant underpayment for carotid stenting cases in these DRGs. This potential underpayment for carotid stenting procedures is likely understated as the 2004 MedPAR data reflect the time prior to FDA approval for carotid devices and thus only include discharges for patients participating in clinical trials. As a result, it is likely that few, if any, hospitals included the full cost (or any significant cost) of the carotid stenting devices in their FY 2004 charges. The differential between carotid and non-carotid cases will likely grow more pronounced in the FY 2005 MedPAR data as hospitals begin to include the charges for the FDA-approved carotid stent cases in their claims to CMS.

Guidant Recommendation

Given the significant difference in charges, we recommend that CMS create a new DRG pair for carotid stenting cases in FY 2006, split based on the presence or absence of complications or co-morbidities. In the analysis, the volume of carotid artery stent cases appears to be small. However, due to the recent availability of FDA approved devices, new and ongoing clinical trials, ongoing and anticipated post-market registries, and expanded Medicare coverage, the volume of carotid stent cases is increasing and will continue to do so. The increase in patient volume and inadequate payment for carotid artery stent cases will create a financial hardship for facilities providing this technology, potentially resulting in decreased beneficiary access to a valuable therapy.

If CMS is unable at this time to create a new DRG pair for carotid stenting, then – consistent with our earlier positions – we recommend that CMS move all carotid stenting

cases into DRG 533 as an interim measure until such time as the agency can take this important step.

Coronary Artery Stents ("DRG Reclassifications")

1) Restructuring of Percutaneous Cardiovascular Procedure DRGs

In the proposed rule, CMS states its intent to restructure the percutaneous cardiovascular procedure DRGs (DRGs 516, 517, 518, 526, and 527) by deleting DRG 516 and 526 and replacing them with two new DRG pairs split by CCs (proposed DRGs 547, 548, 549, and 550). Guidant appreciates CMS's willingness to continuously evaluate the DRG structure to ensure that DRGs remain clinically coherent and payment appropriately addresses the resource utilization. Based on the analysis presented in the proposed rule, we support the proposed new DRGs for coronary stenting in patients with Acute Myocardial Infarction (AMI) and believe it is an appropriate first step to ensuring coronary procedures are reimbursed appropriately.

Guidant Recommendation

CMS should move forward with its proposal to establish new DRG pairs for bare metal stent procedures with AMI and drug-eluting stent procedures with AMI based on the presence or absence of CCs.

2) New ICD-9 Codes for Stent Insertion and Number of Vessels Treated

Guidant commends CMS for proposing to create new ICD-9-CM codes to identify the number of stents inserted (codes 00.45, 00.46, 00.47, and 00.48) and the number of vessels treated (00.40, 00.41, 00.42, and 00.43) in both the coronary and non-coronary vasculature. These codes would enable hospitals to specify the amount of resources used in treating coronary artery and peripheral artery disease. They also would provide CMS with a more complete picture of the resource variations in the myriad types of stent cases.

We appreciate the transparent and iterative process through which CMS developed these new codes, which included input from industry and clinicians. The process set the stage for the creation of this logical and informative new code structure.

Since these codes would be effective October 1, 2005, we request that CMS review the MedPAR data from October 2005 through March 2006 prior to releasing the FY 2007 inpatient proposed rule. Such a timely review would enable the agency to revise the DRGs pertaining to percutaneous coronary interventions (DRGs 518, 517, and 527 and proposed DRGs 547, 548, 549, and 550) if they no longer remain clinically coherent and provide adequate reimbursement for these cases.

Guidant Recommendation

CMS should move forward with its proposal to establish new ICD-9 codes to identify the number of stents inserted and the number of vessels treated in both the coronary and non-coronary vasculature. Under CMS's proposal, the code structure would contain two empty spaces (00.44 and 00.49), which would be very beneficial as new stent technologies that may not fit the current technology paradigm come forward.

In addition, after the new codes become effective this fall, CMS should review the MedPAR data through March 2006 so that any necessary DRG revisions can be made in the FY 2007 inpatient proposed rule.

Complications and Comorbidities (CC) Exclusions List for FY 2006 ("DRG Reclassifications")

Guidant agrees with CMS that changes in resource utilization and inpatient hospital care, coupled with a CC list that has changed only incrementally over the last two decades, may be resulting in a CC list with reduced ability to differentiate patients' resource needs. We also agree that it may be valuable to conduct a substantive and comprehensive review of the CC list for the FY 2007 inpatient proposed rule. However, we strongly urge the agency to conduct this review with complete transparency and broad stakeholder involvement. Clinicians, hospitals, researchers, and other providers will be able to provide significant insight into the dynamics of CCs and their potential impact on resource utilization and patient severity. The agency also would benef it s ignificantly f rom en gaging o utside p rofessionals t o as sist in dev eloping t he standards for determining which conditions appropriately constitute CCs, particularly if statistical algorithms o r c ertain o ther m odels w ill be em ployed. T hese professionals s hould inc lude experts in data analysis, hospital coding, and medical resource utilization.

In the proposed rule, CMS provides several examples of how the standards for determining the list of CCs might be revised. We recommend that CMS analyze several methodologies and publicly disseminate both the methods tested and the results of the analysis for comment. The final m ethodology, s tandards, and CC list also should be s ubject t o public comment with sufficient time to allow for significant changes if needed before implementation in the final rule. We encourage CMS to evaluate the potential impact a secondary diagnosis may have on length of stay and hospital charges, as well as a comparison of the CC list to the lists used within other DRG systems. All of these analyses should then be reviewed by both CMS's own medical experts and outside medical experts.

Guidant Recommendation

Guidant agrees that CMS should proceed with its examination of the CC list. However, since the revision of the CC list would have an extensive impact on hospital revenue streams, it must be conducted and implemented cautiously, systematically, and thoroughly, using external expertise and providing for full transparency and stakeholder involvement.

Proposed Add-On Payments for New Services and Technologies ("New Technology Applications")

1) Initial DRG Assignment

The "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (MMA) requires that CMS first seek an appropriate temporary DRG assignment before establishing a new technology add-on payment for a qualifying technology. In the proposed rule, CMS correctly notes that section 1886(d)(5)(K) of the Social Security Act (as amended by the MMA) requires that, p rior t o es tablishing an add- on p ayment f or a new t echnology, t he S ecretary o f the Department of Health and Human Services "seek to identify one or more DRGs associated with the new technology, based upon *similar* clinical or anatomical circumstances and the cost of the technology and assign the new technology into a DRG where the average costs of care most

closely approximate the costs of care using the new technology. Within such groups the Secretary shall assign an *eligible* new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care using the new technology..." (emphasis added). Unfortunately, CMS does not seem to have acknowledged this statutory requirement when responding to specific requests for DRG reassignment.

Guidant Recommendation

We urge CMS to follow its statutory mandate by first seeking an appropriate, clinically similar and cost coherent DRG on a temporary basis into which the eligible technology could fit, prior to considering the technology for an add-on payment. While we recognize that it may not be possible to assign all eligible new technologies to existing DRGs, we believe CMS should more rigorously analyze whether a technology meets the test for the temporary DRG assignment in the proposed rule.

2) Add-On Payment Level

The MMA's conference report urged CMS to consider increasing the level of the add-on payment available for qualifying new technology procedures from 50 to 80 percent of the difference between the standard DRG payment and the cost of the new technology procedure. This change would align payment under the new technology add-on payment system with the 80 percent payment available under the inpatient outlier payment system. To date, CMS has not provided an indication of whether it plans to adopt the MMA conference report recommendation.

Guidant Recommendation

Guidant recommends that CMS increase the level of the add-on payment from 50 to 80 percent to provide a reasonable payment to hospitals and ensure patient access to new technology therapies.

3) End-point to Add-On Payment Eligibility

CMS has been inconsistent in the manner in which it recognizes the reimbursement period for new technology, particularly when the payment eligibility period overlaps calendar years. It is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

Guidant Recommendation

To maintain a coherent and consistent policy, CMS should continue to determine the end-point to the add-on payment eligibility period in the same way done in FY 2005. In the final rule, CMS therefore should reconsider any technologies that were denied add-on payments in the proposed rule due to the agency's change in policy.

4) CMS Should Not Use "Substantially Similar" as a Disqualifying Criterion

A new technology applicant must meet three criteria ("eligibility criteria") to be eligible for the add-on payment. The criteria at 42 C.F.R. § 412.87(b)(2) and (b)(3) – related to newness and adequate reimbursement under existing DRG payments – have been described in the past by

CMS as "threshold criteria." The newness and cost threshold criteria must be met before CMS will analyze whether the technology is a substantial clinical improvement over existing technologies, as required by 42 C.F.R. § 412.87(b)(1).

The threshold criteria neither include criteria for determining whether a technology is "substantially similar" to existing technology, nor do they even address that issue. Nonetheless, in the proposed rule, CMS states that several new technology applicants are "substantially similar" to existing technology, in the absence of any clinical assessment. Guidant is concerned that CMS is using the determination of "substantial similarity" as a basis to support a preliminary determination that these technologies are not "new," and therefore not eligible for the add-on payment, when no such requirement exists in the threshold criteria, and even when the products fall within the two- to three-year window to be considered "new" by CMS's criteria.

Guidant Recommendation

The determination of whether a technology is "substantially similar" should not be used as a disqualifying criterion. Instead, add-on payment eligibility determinations are more properly conducted within 42 C.F.R. § 412.87(b)(1), which states that "[a] new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." CMS should not adopt or undertake an ad hoc clinical assessment during the eligibility phase of the new technology application process.

5) Eligibility of Add-On Payments for Subsequently Approved Products

There is an apparent inconsistency in CMS's application of the "substantially similar" provision regarding the eligibility of competing products for add-on payments. In numerous instances, CMS has stated that "an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology" (May 4, 2005 Federal Register, page 23363). Guidant remains broadly supportive of this policy and believes it advances the goal of earlier patient access to new technology (despite our concerns with CMS's usage of "substantially similar" as noted above).

Guidant is therefore surprised by CMS's statement that a device approved by the FDA subsequent to the FDA's approval of another device – which submitted the new technology application – may only be considered as eligible for an add-on if the product receives FDA approval prior to publication of the FY 2006 final rule (May 4, 2005 Federal Register, page 23363). It appears that imposing a requirement of FDA approval for subsequent products prior to an arbitrary date, such as the publication of the final rule, contradicts CMS's goal of not bestowing an advantage on the first product to reach the market.

Guidant Recommendations

CMS should revise its stated position on eligibility for add-on payments and clarify that the subsequent date of FDA approval for "substantially similar" devices will have no bearing on whether such products are eligible for add-on payment if the initial applicant is approved.

Frequency of Release of MedPAR Data

CMS uses the most current MedPAR data file in drafting the inpatient rules and releases current MedPAR data on a semi-annual basis. Guidant remains concerned about the lack of public access to current MedPAR data during crucial public comment periods. In the past, and during the course of this year's inpatient proposed rule, CMS has made the MedPAR data available to the public two to three weeks prior to the close of the comment period. We recommend that CMS make the MedPAR data available to the public for the *entire* comment period. Releasing the MedPAR data to coincide with the release of the requests for comments for the proposed rule would enable more complete responses to the issues raised and more meaningful dialogue between CMS and the public.

Guidant Recommendation

CMS should release the most current MedPAR data on a quarterly basis to ensure that all stakeholders can engage fully throughout comment periods on inpatient proposed rules.

Acceptance of External Data

CMS has indicated that it will consider external data submitted by manufacturers and other stakeholders in order to determine appropriate initial DRG assignments for new procedures and eligibility for a new technology add-on payment. To date, however, CMS has used external data to determine initial DRG assignments in only a very limited number of cases.

External data also could be used to validate charges in the MedPAR database as part of the annual recalibration of relative weights. Such validation is particularly important in cases where MedPAR charges do not accurately reflect the cost of the procedure. For example, the use of external data would help to ensure adequate payment for technology procedures subject to charge compression. Charge compression, linked to the tendency of hospitals to assign relatively low charges to higher cost technology and other items, results in DRG payments that do not reflect the full cost of performing a procedure. We note that in the outpatient payment system, CMS used external technology price data supplied by manufacturers to update 2003 and 2004 payment rates for ICD implants and other technology procedures. CMS should use external data in a similar manner to update payment rates in the inpatient system.

Guidant Recommendation

Guidant encourages CMS to expand its utilization of U.S. market external data submitted by manufacturers in order to facilitate the establishment of adequate initial inpatient payment for new technology procedures at, or as close as possible to, the time of FDA marketing approval. In line with its approach to updating outpatient payment rates, we also urge CMS to accept external data as part of the annual inpatient recalibration and payment update process.

In determining whether external data provides an acceptable basis for making a new DRG assignment or otherwise adjusting DRG payments, CMS should apply reasonable standards that take into account the amount of data that may be available for new technologies, the difficulties involved in collecting such data, and the need to protect patient privacy and the confidentiality of proprietary data.

CMS Response to MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) recently made a number of recommendations focused on the hospital inpatient prospective payment reimbursement system. In the section of its recommendations related to the issue of specialty hospitals, MedPAC also makes broader recommendations, including suggesting the replacement of DRG charge-based weights with cost-based weights, the use of hospital-specific relative weights, the replacement of DRGs with severity-based APR-DRGs, and DRG-specific outlier reductions.

These proposed changes, if implemented, would have a significant impact on the inpatient reimbursement system. CMS mentions several potential issues associated with implementation, including difficulties in obtaining current cost-to-charge data, as well as charge compression if hospital-specific weights are adopted.

CMS has indicated that it intends to conduct a comprehensive and systematic review of the CC list for the 2007 inpatient proposed rule, and also may undertake a selective review of specific DRGs that are cited by MedPAC as problematic. Guidant encourages CMS to complete these projects before considering whether to implement the MedPAC proposals.

Guidant Recommendation

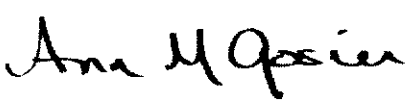
Guidant concurs with CMS's concerns about MedPAC's recommendations related to the replacement of DRG charge-based weights with cost-based weights, the use of hospital-specific relative weights, the replacement of DRGs with severity-based APR-DRGs, and DRG-specific outlier reductions. We agree that any effort to significantly modify the inpatient system should move forward only after CMS takes a measured, studied, and fully transparent approach to addressing these issues.

CONCLUSION

As noted above, to ensure timely patient access to medical innovations and the advancement of quality care, Guidant Corporation recommends specific changes to the proposed rule associated with the inpatient payment structure for ICD implants, carotid stenting, and drug-eluting stent insertion. More generally, we also believe revisions are needed to provisions in the proposal related to the initial DRG assignment and new technology add-on payment processes.

We look forward to continuing to work with CMS in an effort to integrate new technologies into the Medicare inpatient payment system on a timely basis. Should you have questions with regard to our recommendations for revision to the proposed rule or need additional information, please contact me at 202-508-0800.

Sincerely,



Ann Gosier
Vice President, Government Affairs

502

Submitter : Mr. Lawrence Nowak
Organization : Kaleida Health
Category : Hospital
Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-798-Attach-1.DOC

Transfers
Wilcom
Pymt/Outliers
IQ Data
DRG/GEN

Hefler
Hartstein
Walz
Hart
Miller
Treitel
Bodden
Hammel
Brooks
FASAN
Gruber
Kelly
Hue

Attachment to #798

KALEIDA
HEALTH

June 24, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, *Federal Register* 70, no. 85 (May 4, 2005): 23306–23673. [CMS-1500-P]

Dear Dr. McClellan:

On behalf of Kaleida Health, I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2006 inpatient prospective payment system (PPS). Kaleida Health is the largest acute care provider in Western New York State with 1,006 acute care beds within five hospital campuses. Medicare acute inpatient payments for Kaleida Health were over $150,000,000 for 2004.

Our principal recommendations are:

1. Post-acute care transfers. We strongly oppose CMS's proposal to expand the post-acute care transfer policy. We believe that the entire policy is wrong and that there is absolutely no justification for decreasing aggregate Medicare payments as a result.

2. Wage index. We strongly agree with CMS's decision to use only 10% of the occupational mix adjustment in the computation of the FY 2006 wage index.

3. Outliers. We are very disturbed that CMS has not been able to estimate the cost outlier threshold to a reasonable degree of accuracy, noting that the Agency estimates it did not spend 31% of the outlier pool in FY 2004.

4. Hospital quality data. We believe that the current flaws in the data validation process are so fundamental that CMS should not tie the full payment update to that process in FY 2006.

5. DRG reclassifications. We support CMS's proposals for DRG refinement and request that the agency also create new DRGs for a) ischemic stroke treatment with a reperfusion agent, which would only include strokes that were caused by clots and treated with tissue plasminogen activator, and b) cardiac defibrillator implant without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies.

More detailed comments about these issues are provided below.

Post-acute Care Transfers

During the 1990s, the national average length of stay decreased by about 2% per year, coincident with the expansion of managed care. One of the mechanisms hospitals used to decrease length of stay was to discharge patients to post-acute care. CMS and the Medicare Payment Advisory Commission (MedPAC) became concerned that the Medicare program was being exploited because spending was increasing rapidly for post-acute care services, but hospital payments were not adjusting fast enough to sufficiently offset some of the post-acute care increase. This was because diagnosis-related group (DRG) weights are based on two-year-old data.

Therefore, through the Balanced Budget Act of 1997 (BBA), Congress directed CMS to begin reimbursing short-stay discharges to post-acute care in 10 DRGs as transfer cases. Transfer cases receive only partial DRG payment. In hindsight, this directive was too late because length of stay stabilized early in this decade. Therefore, the DRG weights based on two-year-old data are no longer imbalanced. Nonetheless, in FY 2004, CMS extended its post-acute care transfer (PACT) policy to 29 DRGs and now, for FY 2006, the Agency is proposing to fully implement the policy by extending it to 231 DRGs, which are virtually all the DRGs to which the policy could reasonably be applied.

We strongly opposed the FY 2004 expansion of the PACT policy and more strongly oppose it now because the patients to whom it applies cannot legitimately be construed as transfer cases. The cases to which the policy is now—and would be—applied are merely cases with a shorter-than-average length of stay. Therefore, reducing the payment for these cases should be recognized as a form of case-mix refinement and, if it were done, should be budget-neutral. There is absolutely no justification for CMS taking savings from this policy, whether it is expanded or not.

The question then becomes whether this form of case-mix refinement is desirable. We feel strongly that this policy is inappropriate because it characterizes a low

length of stay as an indicator of a clinically inappropriate discharge, which conflicts with the more contemporary and more prevalent characterization of a low length of stay as an indicator of efficiency. In fact, length of stay is probably the most common measure of efficiency. We have worked very hard to reduce length of stay through better care coordination. Deeming a stay incomplete merely because the length of stay is shorter than the geometric mean minus one day is arbitrary and undermines our efforts. Furthermore, refining the DRGs to pay less for shorter-stay cases also undermines the incentive built into the case payment methodology, which is that hospitals would be rewarded for efficiency.

Hospital Wage Index: Occupational Mix Adjustment

We strongly support your decision to include the occupational mix adjustment at only 10% for Federal Fiscal Year 2006. The implementation of the occupational mix survey was a very confusing process for providers, resulting in a wide variation in int erpretations o f ho w t o r eport o ccupational m ix da ta a nd t he r esulting da ta forwarded to CMS. To adjust the wage index and payments to providers based on 100% inclusion of the occupational mix adjustment would be simply irresponsible.

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Outliers

CMS estimates that outlier payments in FY 2004 made up only 3.5% of total inpatient PPS payments, which is 31% less than the amount of funding that the hospitals contributed to the pool. We are c ompelled to express, once a gain, our concern about the Agency's inability to estimate the outlier threshold to a reasonable degree of accuracy.

Hospital Quality Data

The health care industry is in the very early stages of implementing electronic health records and the national health information infrastructure. Moving forward is analogous to a baby learning to walk because the systems—and financing—are very weak and the path is strewn with obstacles. Therefore, we agree with Congress and CMS that the appropriate way to implement "pay-for-performance" at this stage is to pay for data submission.

For FY 2006, however, CMS has proposed to make full payment of the annual Medicare inpatient PPS update also contingent on hospitals passing a data validity test. We believe that data validity is very important and appreciate the opportunity to work with IPRO (our quality improvement organization) and CMS on the data validation process. However, we believe that the current data validation process is, itself, no t yet s ufficiently valid t o b e t ied t o t he p ayment. T he p roblems a re s o fundamental that we believe they must be resolved before CMS penalizes hospitals financially. Therefore, we recommend that CMS not yet tie the full payment update to data validity.

The Greater New York Hospital Association has thoroughly catalogued the flaws in the data validation process and we fully support the Association's series of recommendations to correct these flaws.

DRG Reclassifications

We believe that continuous DRG refinement is very important because it allows hospitals to implement new technologies, pharmaceuticals, and treatment protocols while minimizing systematic risk. Therefore, we support CMS's proposed DRG refinements for FY 2006, with two modifications.

First, with respect to the stroke DRGs, 14 and 15, we support the second suggestion made by the representatives of several hospital stroke centers with which CMS consulted regarding recognition of the high cost of tissue plasminogen activator (tPA). This suggestion was to create a new DRG entitled "Ischemic Stroke Treatment with a Reperfusion Agent," which would only include strokes that were caused by clots and treated with tPA, as identified through the procedure code 99.10. Furthermore, we recommend that CMS implement the new DRG in FY 2006 rather than waiting for more data to accumulate, since the incremental cost and effectiveness of this thrombolytic agent are well documented.

Second, with respect to the DRGs involving the implantation of an automatic implantable cardioverter/defibrillator, CMS is proposing to regroup cases without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies (EPS), from DRGs 535 and 536 to DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization. CMS's data show that the average cost of cases with EPS is significantly higher than the cost of cases without EPS and that the volume of cases with EPS is also significant. Therefore, we recommend that CMS create a new DRG for cases with cardiac defibrillator implant without cardiac catheterization, but with EPS.

Thank you for considering these comments.

Sincerely,

Lawrence E. Nowak
Manager, Revenue Analysis

503

Submitter : Mr. Joel Perlman
Organization : Montefiore Medical Center
Category : Hospital
Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-799-Attach-1.DOC

Transfers
WI/Gen
CBSAs
WI/Bd
Labor/S
Q Data
DRG/GEN
GME/IRP
WI/OM
Pymt/ Quality
MedPAC

Hefter
Hartstein
Miller
Kenly
Seifert
Knight
Bodden
Nammel
Brooks
Fagan
Gruber
Kelly
Hue
Lefkowitz
Ruiz
Truong
Treitel
Kraemer

Attachment to #799

MONTEFIORE MEDICAL CENTER
The University Hospital
for the Albert Einstein
College of Medicine
Henry and Lucy Moses Division

111 East 210th Street
Bronx, New York, 10467-2490
718 920-7602
718 652-2161 Fax

Joel Perlman
Senior Vice President

MONTEFIORE

June 24, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, *Federal Register* 70, no. 85 (May 4, 2005): 23306–23673. [CMS-1500-P]

Dear Dr. McClellan:

On behalf of Montefiore Medical Center (Montefiore), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2006 inpatient prospective payment system (PPS). Montefiore is currently the largest nonprofit provider of healthcare and related services to individuals residing in New York's borough of the Bronx. We operate an extensive healthcare system that includes two acute care hospitals with a total of 1,062 beds; a network of 21 community-based primary care centers, three specialty care centers and physician practices; the nation's largest hospital-based homecare program; extensive programs of medical education and research; and a vast array of community service programs.

The remainder of the letter describes more detailed findings and observations supporting each recommendation. Our principal recommendations this year are summarized below:

1. Post-acute care transfers. We strongly oppose CMS's proposal to expand the post-acute care transfer policy. We believe that the entire policy is wrong and that there is absolutely no justification for decreasing aggregate Medicare payments as a result.

2. Wage index. We oppose CMS's decision to discontinue the blend of the metropolitan statistical areas (MSA) and core-based statistical areas (CBSA) wage indices for hospitals that were disadvantaged by the change to CBSAs, and recommend that the Medicare Geographic Classification Review Board (MGCRB) develop criteria that would allow areas within CBSAs to qualify as core urban areas and for all providers located in those areas to

receive their own wage indices. We also urge CMS to implement 100% of the occupational mix adjustment.

3. Labor share. We believe that CMS should not update the cost category weights in the hospital market basket unless it also designates professional liability insurance as a labor-related cost.

4. Outliers. We are very disturbed that CMS has not been able to estimate the cost outlier threshold to a reasonable degree of accuracy, noting that the Agency estimates that it did not spend 31% of the outlier pool in FY 2004.

5. Hospital quality data. We believe that the current flaws in the data validation process are so fundamental that CMS should not tie the full payment update to that process in FY 2006.

6. DRG reclassifications. We support CMS's proposals for DRG refinement and request that the agency also create new DRGs for 1) ischemic stroke treatment with a reperfusion agent, which would only include strokes that were caused by clots and treated with tissue plasminogen activator, and 2) cardiac defibrillator implant without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies.

7. Direct graduate medical education. For residents whose first year of training is completed in a program that provides a general clinical year of training, we recommend that the initial residency period be based on the specialty that the resident enters in the second year of training, regardless of whether, or when, the resident matches to the advanced specialty program.

Our more detailed comments about these issues are provided below.

Post-acute Care Transfers

During the 1990s, the national average length of stay decreased by about 2% per year, coincident with the expansion of managed care. One of the mechanisms that hospitals used to decrease length of stay was to discharge patients to post-acute care. CMS and the Medicare Payment Advisory Commission (MedPAC) became concerned that the Medicare program was being exploited because spending was increasing rapidly for post-acute care services, but hospital payments were not adjusting fast enough to sufficiently offset some of the post-acute care increase. This was because diagnosis-related group (DRG) weights are based on two-year-old data.

Therefore, through the Balanced Budget Act of 1997 (BBA), Congress directed CMS to begin reimbursing short-stay discharges to post-acute care in 10 DRGs as transfer cases. Transfer cases receive only partial DRG payment. In hindsight, this directive was too late because length of stay stabilized early in this decade. Therefore, the DRG weights based on two-year-old data are no longer imbalanced. Nonetheless, in FY 2004, CMS extended its post-acute care transfer (PACT) policy to 29 DRGs and now, for FY 2006, the Agency is proposing to fully implement the policy

by extending it to 231 DRGs, which are virtually all the DRGs to which the policy could reasonably be applied.

We strongly opposed the FY 2004 expansion of the PACT policy and more strongly oppose it now because the patients to whom it applies cannot legitimately be construed as transfer cases. The cases to which the policy is now—and would be—applied are merely cases with a shorter-than-average length of stay. Therefore, reducing the payment for these cases should be recognized as a form of case-mix refinement and, if it were done at all, should be budget-neutral. There is absolutely no justification for CMS taking savings from this policy, whether it is expanded or not.

The question then becomes whether this form of case-mix refinement is desirable. We feel strongly that this policy is inappropriate because it characterizes a low length of stay as an indicator of a clinically inappropriate discharge, which conflicts with the more contemporary and more prevalent characterization of a low length of stay as an indicator of efficiency. In fact, length of stay is probably the most common measure of efficiency.

Montefiore has worked very hard to implement protocols that minimize the period of hospitalization. We are proud of the fact that we have reduced our average length of stay by 11% during the past five years despite an increase in acuity. Deeming a stay incomplete—and thereby subject to partial payment—merely because the length of stay is shorter than the geometric mean minus one day is arbitrary and unfair, and it undermines our efforts. In fact, reducing length of stay has actually increased our per diem costs due to the fixed cost inherent in every patient stay. Therefore, we strongly urge CMS to roll back its current PACT policy and certainly not to expand it.

Hospital Wage Index: Core-Based Statistical Areas

After the 2000 census, the Census Bureau and the Office of Management and Budget (OMB) changed the definition of many of the nation's MSAs and renamed them CBSAs. Most MSA boundaries were not affected; however, some were tightened and others were expanded. CMS proposed to use the new CBSAs in place of the old MSAs as wage index labor markets starting in FY 2005, which would have generated gains for some hospitals and huge losses for other hospitals, including Montefiore.

Montefiore operates in a distinct labor market, which is driven by economic forces that are simply not present throughout our Medicare wage index labor market. Our average hourly wage rate is among the highest in New York City, so that the dilution of our wage index caused by including New York suburbs—and now New Jersey suburbs—in our Medicare wage index labor market has greatly disadvantaged us. Therefore, we, along with many other disadvantaged facilities, opposed CMS's proposal to adopt the new CBSAs on policy and fiscal impact grounds. In response, CMS agreed to compute area wage indices based upon a blend of the old and new labor market definitions for disadvantaged hospitals during FY 2005.

Since then, CMS has proposed to implement the new boundaries for its other prospective payment systems without a transition, and has proposed to end the blend in the inpatient PPS in

FY 2006. Ending the blend will cost Montefiore approximately $500,000, which is quite significant in the context of the huge volume of uncompensated services we provide. The disproportionately negative impact that CMS's action would have on our community is particularly unjust in light of the fact that other government agencies, including the U.S. Government Accountability Office and MedPAC, have criticized the indiscriminate use of MSAs (and, by extension, CBSAs) as hospital labor markets because some are obviously too large to effectively discriminate between separate hospital labor markets.

Therefore, just as CMS has used the MGCRB in the past to correct flaws in the hospital labor markets as defined by MSAs, we now urge CMS to use the MGCRB to correct flaws in the hospital labor markets as defined by the new CBSAs. In particular, we recommend that CMS develop and propose MGCRB criteria through which hospitals located in counties within CBSAs could apply for designation as a "core urban area" within the CBSA. Such criteria should include:

1. The county is located in an old MSA whose wage index was diluted because of an expansion of the Medicare wage index labor market when the CBSAs were adopted.

2. The county has a population of at least one million.

3. The three-year average hourly wage rate of the county must be at least 5% higher than the three-year average hourly wage rate of the CBSA.

The wage index applied to hospitals located in a core urban area would be based solely on their wage index data. In addition, the core urban area wage indices would apply to other providers located in the core urban areas, including inpatient rehabilitation facilities (IPFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities (IPFs), skilled nursing facilities (SNFs), and certified home health agencies (CHHAs).

We strongly recommend that CMS continue to provide the blended MSA/CBSA wage index to hospitals disadvantaged by their location in MSAs that were expanded when the CBSAs were adopted as hospital labor markets. The blend should continue until the process is in place for hospitals to reclassify into a core urban area. This policy should also apply to IRFs, LTCHs, IPFs, SNFs, and CHHAs.

Hospital Wage Index: Occupational Mix Adjustment

CMS conducted its first occupational mix survey in a highly compressed time frame in early 2004 and did not have confidence in the validity of the results. For that reason, the agency implemented a 90%-10% blend of the unadjusted area wage index and the occupational mix-adjusted area wage index, respectively, in FY 2005. For the past year, hospitals have had the opportunity to correct any mistakes they may have made in their original submissions, so CMS should have greater confidence in the validity of the current occupational mix adjustments. Nonetheless, CMS has proposed to continue the blend in FY 2006 in the same proportion as the blend used in FY 2005. We do not believe that continuing the blend is appropriate and urge CMS to fully implement the occupational mix adjustments in FY 2006.

Hospital Market Basket

The sum of the labor-related hospital market basket cost category weights represents the portion of the standardized amount that is wage-adjusted. The current labor share is 71.1% and it is based on FY 1992 data. CMS would have updated the weights in FY 2003 based on FY 1997 data, but declined to do so because the update would have increased the labor share to 72.5%, which would have hurt rural and other relatively low-wage hospitals. Now CMS is proposing to update the weights based on FY 2002 data, which would reduce the labor share to 69.7% and hurt high-wage urban hospitals. This change would not materially help rural and other low-wage hospitals because their labor share was fixed at 62% in the Medicare Modernization Act of 2003.

We can make a good case on behalf of Montefiore and other relatively high-wage hospitals that CMS should not update the cost component weights in FY 2006 to make up for not updating the weights in FY 2003. However, we would support CMS updating the weights in FY 2006 *if* the Agency also designated professional liability insurance as a labor-related cost. These costs are clearly wage-related—indeed, they are reported in the wage index—and are clearly locally determined. Furthermore, their share of total costs has grown considerably in recent years, at least in our market. Montefiore's professional liability rates have increased by 44% over the past two years.

We believe that the failure to include professional liability insurance in the wage-adjusted portion of the standardized amount in the past was a grave oversight. Including this important cost component in the labor share would bring it up to 71.3%, which is virtually the same as the current labor share of 71.1%.

Outliers and MedPAC Recommendations

CMS estimates that outlier payments in FY 2004 made up only 3.5% of total inpatient PPS payments, which is 31% less than the amount of funding that the hospitals contributed to the pool. We are highly disturbed by the Agency's continuing inability to estimate the outlier threshold to a reasonable degree of accuracy. This has drained precious funding from the Medicare program to the extent that Montefiore, an academic medical center with a high volume of extraordinarily costly cases, is now losing money from the outlier program. That is, our outlier payments represent less than 5.1% of our total payments, which is the amount we contribute to the outlier pool.

MedPAC's proposal to exclude payment outliers (in addition to statistical outliers) from the computation of the DRG weights would only exacerbate this problem, which is why we strongly oppose it. Rather than incorporating flaws in the outlier program into the structure of the DRGs, we recommend that CMS consider alternatives to the outlier program, including shrinking the outlier pool and further DRG refinement.

Hospital Quality Data

The health care industry is in the very early stages of implementing electronic health records and the national health information infrastructure. Moving forward is analogous to a baby learning to walk because the systems—and financing—are very weak and the path is strewn with obstacles. Therefore, we agree with Congress and CMS that the appropriate way to implement "pay-for-performance" at this stage is to pay for data submission.

For FY 2006, however, CMS has proposed to make full payment of the annual Medicare inpatient PPS update also contingent on hospitals passing a data validity test. We believe that data validity is very important and appreciate the opportunity to work with IPRO (our quality improvement organization) and CMS on the data validation process. However, we believe that the current data validation process is, itself, not yet sufficiently valid to be tied to the payment. The problems are so fundamental that we believe they must be resolved before CMS penalizes hospitals financially. Therefore, we recommend that CMS not yet tie the full payment update to data validity in FY 2006.

The Greater New York Hospital Association has thoroughly catalogued the flaws in the data validation process and we fully support the Association's series of recommendations to correct these flaws.

DRG Reclassifications

We believe that continuous DRG refinement is very important because it allows hospitals to implement new technologies, pharmaceuticals, and treatment protocols while minimizing systematic risk. Therefore, we support CMS's proposed DRG refinements for FY 2006, with two modifications.

First, with respect to the stroke DRGs, 14 and 15, we support the second suggestion made by the representatives of several hospital stroke centers with which CMS consulted regarding recognition of the high cost of tissue plasminogen activator (tPA). This suggestion was to create a new DRG entitled "Ischemic Stroke Treatment with a Reperfusion Agent," which would only include strokes that were caused by clots and treated with tPA, as identified through the procedure code 99.10. Furthermore, we recommend that CMS implement the new DRG in FY 2006 rather than waiting for more data to accumulate, since the incremental cost and effectiveness of this thrombolytic agent are well documented.

Second, with respect to the DRGs involving the implantation of an automatic implantable cardioverter/defibrillator, CMS is proposing to regroup cases without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies (EPS), from DRGs 535 and 536 to DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization. CMS's data show that the average cost of cases with EPS is significantly higher than the cost of cases without EPS and that the volume of cases with EPS is also significant. Therefore, we recommend that CMS create a new DRG for cases with cardiac defibrillator implant without cardiac catheterization, but with EPS.

Graduate Medical Education

Medicare direct graduate medical education (GME) payments are provided on behalf of every full-time equivalent (FTE) resident. Residents are counted as one FTE during the number of years required for them to achieve first board eligibility, known as the initial residency period (IRP). No resident can be counted as a one full FTE for more than five years. For any training beyond the IRP, residents are counted as 0.5 FTEs.

In the FY 2005 inpatient PPS final rule, CMS stated that starting with portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident "simultaneously matched" for one year of training in a particular specialty program and for a subsequent period of training in a different specialty program, then the resident's IRP would be determined based on the period of board eligibility associated with the second program. The FY 2006 proposed rule broadens CMS's policy by allowing that if a hospital can document that a resident matched to an advanced residency program beginning in the second year prior to the commencement of any training, then the resident's IRP will be determined based on the advanced specialty, even if the resident had not matched for a clinical base year program. We appreciate and support this proposal.

However, for residents whose first year of training is completed in a program that provides a general clinical year of training, we continue to believe that the IRP should be based on the specialty that the resident enters in the second year of training, regardless of whether, or when, the resident matches to the advanced specialty program. Not only would this be a much more straightforward—and administratively less burdensome—solution, it also would reflect Congress's statutory intent regarding initial residency periods, as reiterated by the Conference Committee agreement accompanying section 712 of the Medicare Modernization Act (P.L. 108-173):

> 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.

Therefore, we recommend that CMS amend its policy as it pertains to residents whose first year of training is completed in a program that provides a general clinical year of training to deem that the IRP for such residents be based on the specialty that the resident enters in the second year of training, regardless of whether, or when, the resident matches to the advanced specialty program.

Follow-Up

We are grateful for the opportunity to provide comments and appreciate the care that CMS staff bring to bear on these issues. If you or your staff have any questions or would like to discuss our comments further, please do not hesitate to contact me at (718) 920-7602 or at jperlman@montefiore.org.

Very truly yours,

Joel Perlman
Senior Vice President-Finance
Montefiore Medical Center

504

Submitter : Ms. Susan Hollander

Organization : Catholic Healthcare West

Category : Hospital

Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-800-Attach-1.DOC

TRANSFERS
& DATA
Pymt/Outliers
DSH

Hefler
Hartstein
Walz
Hart
Bodden
Hammel
Treitel
Smith
Kraemer

Catholic Healthcare West
CHW

185 Berry Street
Suite 300
San Francisco, CA 94107-1739
(415) 438-5500 *Telephone*
(415) 438-5724 *Facsimile*

Attachment to #800

June 24, 2005

SUBMITTED ELECTRONICALLY

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

RE: CMS 1500-P – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Payment Rates; Proposed Rule *(Federal Register, Vol. 70, No. 85)*, May 4, 2005

Dear Dr. McClellan:

Catholic Healthcare West (CHW), on behalf of our 40 hospitals in Arizona, California and Nevada, is pleased to submit the following comments on the notice of proposed rulemaking (NPRM) for the Medicare Hospital Inpatient Prospective Payment System for Fiscal Year 2006, as published in the May 4, 2005 *Federal Register* (Vol. 70, No. 85, page 23306). In addition to proposing rates of increase for hospital payments and updates to Diagnosis Related Group (DRG) weights and calibrations for FY 2006, the proposed rule includes potential changes to regulations governing several important areas affecting the care our hospitals provide to Medicare beneficiaries.

While Catholic Healthcare West is supportive of many of the provisions in the proposed rule, we are particularly concerned about the following proposals, for which we will provide comments and recommendations:

1. Expansion of the post-acute care transfer policy
2. Reporting of hospital quality data for annual hospital payment update/processes for data submission and validation
3. Increase in the Medicare fixed-loss cost outlier payment threshold
4. Payments to Disproportionate Share Hospitals (DSH)

In addition to these comments, we also support the comments and recommendations of the American Hospital Association, the Catholic Health Association, Premier, Inc. and the California Hospital Association.

1. POST-ACUTE CARE TRANSFERS

Catholic Healthcare West opposes the expansion of the post-acute care transfer policy as outlined in the proposed rule. The proposed significant expansion of the transfer policy weakens the basic principles and objectives of the Medicare Prospective Payment System (PPS), which is a system based upon averages. It undermines clinical decision-making, and penalizes hospitals for providing efficient care at the most appropriate time and in the most appropriate setting. We believe that this change could have profound effects on the stability of the overall payment system.

CHW is very concerned with CMS' continued effort to expand the post-acute care transfer policy in a manner that appears to be more budget-driven than based on sound policy rationale. In the proposed rule, CMS proposes to expand the policy from 30 to 231 DRGs. Specifically, CMS proposes to expand the application of the post-acute care transfer policy to any DRG that meets the following criteria:

- The Diagnosis Related Group (DRG) has at least 2,000 post-acute care transfer cases;
- At least 20 percent of cases in the DRG are discharged to post-acute care;
- At least 10 percent of the cases discharged to post-acute care occur before the geometric mean length of stay (LOS) for the DRG;
- The DRG has a geometric mean LOS of at least three days; and
- If a DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are subject to the transfer policy if either meets the first three criteria above.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. As stated above, the Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

Hospitals are disproportionately penalized in California and other regions of the country where managed care has yielded lower lengths of hospital stays for all patients, meaning that they are more likely to discharge or transfer prior to the geometric mean. Therefore, hospitals in these states are more likely to receive reduced payments as a result of the transfer rule, and expanding the rule will only exacerbate this inequity.

In situations where hospitals do not significantly change their discharge practices involving the use of post-acute care services, requiring such facilities to assume post-acute care costs would be unfair and arbitrary. Given that virtually all post-acute services are paid on the

basis of a prospective payment system rather than at reasonable cost, it matters little when the patient is discharged to a post-acute setting or how long the patient is there.

Further, the proposal significantly expands hospitals' liability for decisions not within their control. Patients and their physicians typically order and arrange post-acute care, often without the knowledge of the hospital. Yet, because hospitals must code a claim as a "transfer" or "discharge," they could be subject to erroneous allegations of fraud under the False Claims Act in an investigation of transfers incorrectly paid as discharges.

Finally, the post-acute transfer policy is not necessary. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Also, Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Ironically, this policy could ultimately be more costly to the Medicare program. Patients that are kept in the inpatient setting longer may not be discharged to skilled-nursing care or rehabilitation care, but may receive home health and additional physician services in both the inpatient and outpatient settings that increase the costs of care.

It is also important to note that CMS is not mandated by Congress to expand this transfer provision, nor has Congress indicated to CMS its interest in seeing this policy expanded.

Catholic Healthcare West has conducted an analysis of the impact of this policy change on our hospitals. The expansion of the post-acute transfer policy would reduce Medicare payments to CHW hospitals by $17.4 million in FY 2006, and at least $87 million over the period of FY 2006 – 2010. While CMS has estimated that the impact on overall payments will be a 1.1% reduction, the impact of this policy change on CHW hospitals in FY 2006 would be a 1.6% reduction in Medicare inpatient payments. Losses of this magnitude divert scarce resources away from patient care services, and compromise our ability to maintain our safety net hospitals that serve the poor.

In light of all of the above arguments, CHW makes the following recommendation with regard to the expansion of the post-acute transfer policy:

CHW strongly opposes any expansion of the post-acute care transfer policy, which is not in the best interests of patients or providers. It would fundamentally weaken the incentives inherent in the inpatient prospective payment system, and disrupt the continuum of care that is typical of quality delivery. It undercuts the basic principles and objectives of the Medicare PPS, undermines clinical decision-making and penalizes hospitals by limiting their reimbursement for providing efficient care at the most appropriate time and in the most appropriate setting. We strongly urge that this provision be withdrawn in the final rule.

2. HOSPITAL QUALITY DATA

To determine if a hospital qualifies for its full Medicare market basket update in FY 2006, CMS must determine if a hospital has submitted data on the 10 measures of heart attack, heart failure, and pneumonia care that were the starter set for the Hospital Quality Alliance. The proposed rule for FY 2006 states several requirements for data to be considered submitted for purposes of receiving the full market basket update. These requirements include the hospital's continuous submission of quarterly data on the 10 measures; the submission of the data for patients discharged through the 4th quarter of 2004 by May 15, 2005; and the validation of the hospital's 3rd quarter 2004 data. However, the ability of hospitals and their vendors to comply with the requirements for timely and accurate data submission is challenged by miscommunication, technical ambiguities, and other issues.

Therefore, we believe that the final FY '06 inpatient PPS rule should establish a clear documentation and communications process for data submission and validation. Further, we believe that hospitals should not be penalized when technical issues outside their control, specific to the CMS or Quality Improvement Organizations (QIOs), hinder their ability to meet specific data requirements. Until such time as the data submission/validation processes become more reliable, we oppose the proposed link between hospitals' meeting the validation requirements and receiving the full market basket update. We offer the following comments and recommendations regarding the quality reporting process.

Processes For Data Submission:

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

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

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Consequently, if hospitals that do not sample elect to submit all of their qualifying cases for a given study and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that every one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so

long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

Processes For Data Validation:

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

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

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

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

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

3. OPERATING PAYMENT RATES

Outlier Payments

Catholic Healthcare West strongly opposes CMS' proposed increase in the fixed-loss cost outlier threshold. CMS is proposing to establish a fixed-loss cost outlier threshold equal to the Inpatient PPS (IPPS) rate for the DRG, plus any indirect medical education (IME), disproportionate share hospital (DSH) and new technology add-on payments, plus $26,675. While the proposed increase over the FY 2005 payment threshold of $25,800 is not as large as prior year proposals, CHW remains, as it has in previous years, concerned that the increase is still too high. This increase will continue to make it even more difficult for hospitals to qualify for outlier payments, and will put them at greater risk when treating high-cost cases.

CHW has analyzed the impact of the proposed $26,675 outlier threshold on payments for our hospitals. If this threshold had been in place in the 12-month period from April 2004 – March 2005, CHW hospitals would have lost approximately $1.5 million.

The statute requires that outlier payments for any year are projected to be no less than 5 percent nor more than 6 percent of total operating inpatient PPS payments. Since the inception of the inpatient PPS, outlier payments as a proportion of total operating payments has varied above and below this standard, sometimes significantly. CMS took two main steps in 2003 to reduce this variability – one addressed the problem stemming from how a hospital-specific cost-to-charge ratio was determined, and the second provided a more timely methodology for determining the outlier threshold.

According to CMS, the actual 2005 outlier payments are estimated to be 4.4 percent of total DRG payments, or 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. Payments in 2004 were 1.6 percentage points lower than the funds withheld. The American Hospital Association (AHA) estimates that in FY 2005, CMS will have under-spent the funds set aside for outliers by an estimated $610 million, and by $1.3 billion for FY 2004.

In the proposed rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2003 and the first quarter of 2004 to the first quarter of 2005 to establish an average rate of increase. We appreciate that CMS is proposing this methodology in an effort to avoid using data prior to the major changes made to the outlier policy. However, using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. We strongly oppose using this methodology to estimate the outlier threshold.

The American Hospital Association (AHA) conducted a series of analyses to identify a more appropriate methodology that incorporates both cost inflation and charge inflation. They determined that the use of more than one indicator may make the threshold calculation more accurate and reliable. AHA's estimated fixed loss amount that would result in 5.1 percent

outlier payments under this methodology is $24,050. We strongly urge CMS to adopt AHA's methodology.

If CMS leaves the threshold at $26,675, rather than dropping it to $24,050, AHA estimates that CMS will under-spend by at least $510 million in FY 2006.

Therefore, CHW respectfully recommends the following with regard to the Medicare Inpatient PPS outlier payment threshold:

CHW strongly urges CMS to utilize AHA's recommended methodology, which would lower the outlier threshold from the proposed $26,675 to approximately $24,050, to both reflect CMS' substantial changes in outlier payment policy implemented in FY 2004, and to ensure that policy changes are neutral with regard to maintaining the statutorily required range of five to six percent of inpatient PPS payments being spent on outliers. Hospitals should receive the full 5.1 percent of payments that will be withheld from base inpatient payments in FY 2006 to cover extremely high-cost Medicare patients.

4. DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT DATA

Section 951 of the Medicare Modernization Act (MMA) required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. We believe that this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data, given that all are used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine whether the data based on the federal fiscal year or their own fiscal year is advantageous. **CHW supports CMS' plans to release a MedPAR limited data set for both SSI and Medicare, and to allow hospitals to determine whether they prefer to utilize their own fiscal year or the Federal fiscal year in the calculations of the Medicare fractions.**

CHW, however, strongly objects to CMS' decision not to make available Medicaid information. Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA, states that the Secretary of Health and Human Services must arrange to provide information that hospitals need to calculate the Medicare DSH payment formula. This same section in the version of the MMA passed by the House of Representatives states specifically that the Secretary is required to provide the information to hospitals so that they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital field has brought this issue regarding the problems of obtaining Medicaid information from the state programs to the attention of CMS for a number of years. Efforts were made through the Medicare Technical Advisory Group to find ways to remedy this problem. CMS has not as yet addressed this problem.

CMS states in the rule that it believes hospitals are best situated to provide and verify Medicaid eligibility information and that the mechanisms are currently in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting, and justifying the Medicaid days is problematic in many states. While some improvements have been made in the process for obtaining Medicaid eligibility and payment information from the states, there is still wide variation in the breadth of information provided as well as its accessibility and its reliability. In addition, the information from the states still must be processed to match claims data with eligibility data and then manipulated to develop reports that are acceptable to the fiscal intermediary.

This is a complex process that is time-consuming and labor intensive. As a result, hospitals often find it necessary to hire consultants that have the required expertise and computer programs. Moreover, the penetration of Medicaid managed care can add an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals. With increased interest in the Medicaid program at both federal and state levels, as well as expansion of Medicaid managed care programs and general concerns regarding the DSH calculation that CMS not only continue to monitor this process, but to also involve hospitals in future decision-making discussions.

Therefore, CHW recommends the following:

- **CMS should move forward with plans to release a MedPAR limited data set for both SSI and Medicare.**

- **CMS should allow hospitals to determine whether they prefer to utilize their own fiscal year or the Federal fiscal year in the calculations of the Medicare fractions in the DSH formula.**

- **CMS should impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information.**

- **Further, CHW recommends that CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state, and that the state make this information available to the providers and contractor audit staff.**

In closing, thank you for your review and consideration of these comments. Catholic Healthcare West would welcome the opportunity to discuss our comments with you or your staff, as well as to provide additional input as you make further refinements to the proposed rule. If you or your staff have any questions regarding these comments, please feel free to contact me at (626) 744-2268 or shollander@chw.edu.

Sincerely,

Susan D. Hollander
Vice President, Public Policy and Advocacy

~~[chw letterhead]~~

505

Submitter :

Date: 06/24/2005

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

DRG | GEN
DSH

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue
Smith

GENERAL

GENERAL

see attachment

CMS-1500-P-801-Attach-1.DOC

CMS-1500-P-801-Attach-2.DOC

Attachment 1 to #801

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

Re: File Code CMS-1500-P – Other DRG Issues

Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (Federal Register, Vol 70 No. 85 23305 - 23774)

Dear Dr. McClellan:

Sarasin Consulting welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Inpatient Prospective Payment System (PPS) and calendar year 2006 Rates, as published in the May 4, 2005 Federal Register.

Our comments are as follows:

We request clarification from CMS with regard to "admission" date. We have encountered some confusion over this issue in the following situations:

- Patient is seen in the emergency room on day one. Patient spends the night in the emergency room. Physician's order to admit to inpatient received on day two. Should the admission date be reflected as day one or day two?

- Patient is seen in the emergency room on day one and admitted to observation on day two, admit to observation order is written after midnight. Patient stays in observation until day three when the order to admit to inpatient is given. Which day is reflected as the admission date for this visit, day one, day two or day three?

- Patient is seen in the emergency room on day one. Physician's order to admit to inpatient is received on day one but an inpatient bed does not become available until day two (or possibly day three). What day is reflected as the admission date for this visit, day one, day two or day three?

- Patient is admitted for outpatient procedure on day one and encounters a complication. Patient is admitted to observation. On day two the physician orders admission to inpatient. What day is reflected as the admission date for this visit, day one or day two?

Additional Comments:
We realize that these situations may impact the Lifetime reserve days which provide each Medicare beneficiary a lifetime reserve of 60 additional days of inpatient hospital services after using 90 days of inpatient hospital services during a spell of illness. It is possible that some bill type 111s would show emergency room and observation day charges have been backed out in

"error," and dates of admission have been changed resulting in a greater number of covered days being charged against beneficiaries banks of covered days.

CMS needs to clearly define the exact day of inpatient admission for patients who initially are seen in the emergency room or observation and subsequently admitted to inpatient status on a different day. It would seem appropriate to assign the initial date presentation of the patient in the emergency room or observation as the inpatient admit date since the hospital is providing all of the acute services necessary and these services are being included in the hospital charges for DRG payment. It would seem that credit for the hospital day(s) prior to admission to inpatient status should apply. The date of inpatient admission can have a significant impact on a variety of issues including the post acute care transfer policy and SNF three day inpatient window.

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Hospital Inpatient PPS. If Sarasin Consulting can provide any further information, or if there are any questions or concerns with regard to this letter, please contact either Anita McAuley, RHIA (210) 590-8688 or Needacoder@aol.com.or myself Christi Sarasin, CCS at (410) 286-8678 or CDSarasin@aol.com, or
Sincerely,

Christi Sarasin, CCS
President and CEO Sarasin Consulting

Attachment 2 to #801

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

Re: File Code CMS-1500-P – DRG Reclassification

Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (Federal Register, Vol 70 No. 85 23305 - 23774)

Dear Dr. McClellan:

Sarasin Consulting welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Inpatient Prospective Payment System (PPS) and calendar year 2006 Rates, as published in the May 4, 2005 Federal Register.

Our comments are as follows:

We request CMS review DRG assignments for patients who require the insertion of vascular access devices (VADs) ICD-9-CM procedure code 86.07. Hospitals currently receive compensation for the provision of these devices **only** when the DRG assigns to

- DRG 315 Renal failure;
- DRG 269 Skin, subcutaneous tissue and breast procedures with a CC and
- DRG 270 Skin, subcutaneous tissue and breast procedures without a CC

It is our observation that the insertion of VADs is warranted for other conditions (such as cancer) and that hospitals are not currently compensated for the resource consumption associated with the procedure because the diagnosis is neither renal failure or a procedure associated with the skin, subcutaneous tissue or breast.

In addition, the surgical DRG that corresponds with a diabetic renal failure patient should be revised to include the VAD procedure. Currently, only nondiabetic renal failure patients group to a surgical DRG when both diabetic and nondiabetic renal failure should group the VAD to a surgical procedure.

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Hospital Inpatient PPS. If Sarasin Consulting can provide any further information, or if there are any questions or concerns with regard to this letter, please contact either Anita McAuley, RHIA (210) 590-8688 or Needacoder@aol.com.or myself Christi Sarasin, CCS at (410) 286-8678 or CDSarasin@aol.com, or
Sincerely,

Christi Sarasin, CCS
President and CEO Sarasin Consulting

506

Submitter : Christi Sarasin **Date:** 06/24/2005

Organization : Christi Sarasin

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-802-Attach-1.DOC

DRG | GEN
ICD-9-CM

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Attachment to #802

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

Re: File Code CMS-1500-P – DRG Reclassification

Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (Federal Register, Vol 70 No. 85 23305 - 23774)

Dear Dr. McClellan:

Sarasin Consulting welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Inpatient Prospective Payment System (PPS) and calendar year 2006 Rates, as published in the May 4, 2005 Federal Register.

Our comments are as follows:

We would like CMS to review the appropriateness of the AHA's Coding Clinic decisions on principal diagnosis sequencing without CMS input or consideration of the DRG impact from sequencing guideline decisions. We believe that over the past 10 years Coding Clinic sequencing guidelines have inappropriately driven the DRG payment system and distorted hospital case mix index and payment data. This has occurred most recently with Coding Clinic advice on sequencing of sepsis as well as their guidelines for sequencing of respiratory failure. Following are specific conditions that have been affected by sequencing guidelines provided by Coding Clinic.

Sepsis – Recent guidance directs coders that sepsis would be sequenced as principal when a patient has concurrent infections (i.e. pneumonia). That becomes problematic when a patient is admitted in acute respiratory failure with sepsis and staph or simple pneumonia. Advice directs that sepsis must be sequenced first even though the patient has multiple problems on admission. This advice does not allow the coder to sequence the most resource intensive diagnosis (staph or simple pneumonia or even respiratory failure) as the principal diagnosis. In addition, if the patient were put on a ventilator, the hospital would get no credit for the more appropriate payment of the ventilator DRG (475).

Acute Respiratory Failure – Under current Coding Clinic sequencing advice, acute respiratory failure is only recognized as a principal diagnosis when a patient has a respiratory condition. Recognition should be given to the fact that acute respiratory failure occurs with other conditions that include other body systems and we believe DRGs for acute respiratory failure for other MDCs (i.e. cardiovascular system) should be created.

The impact of Coding Clinic's sequencing guidelines can be seen when reviewing the movement over the past 5-10 years with the following DRGs:

DRG 87 – Respiratory Failure

DRG 89 – Simple Pneumonia

DRG 127 – Congestive Heart Failure

Attachment to #802

When comparing DRG 89 and DRG 127, the weight for DRG 127, generally a much less intensive DRG than pneumonia (expensive antibiotics are used that drives the weight of DRG 89 over the weight of DRG 127), has been slowly increasing over the past 5 years because patients with acute respiratory failure due to CHF are required to be sequenced with CHF as the principal diagnosis. No DRG has been provided to categorize patients with CHF and acute respiratory failure. Therefore, the CHF DRG has been slowly gaining ground and currently simple pneumonia and CHF reimburse approximately the same amount. We believe that there should be a DRG for acute respiratory failure for other conditions so these types of patients can be placed in appropriate paying DRGs as they are for respiratory conditions. This should also include a ventilator DRG to reimburse hospitals appropriately for other conditions that require use of a ventilator.

In addition, Coding Clinic advice on patients with pneumonia and acute respiratory failure on admission indicates that acute respiratory failure should be sequenced as principal diagnosis. This advice precludes a hospital from sequencing the most resource intensive pneumonia (i.e. staph pneumonia – DRG 79) as the principal diagnosis. Hospitals should be able to report the most resource intensive condition as the principal diagnosis rather than forcing acute respiratory failure as the principal diagnosis in all cases. We believe this guidance is having a profound impact over time on some DRG weights and rates.

We request CMS to consider revising the DRG assignments for patient's who are admitted with non-respiratory conditions such as sepsis, decubitus, and acute cardiac conditions who also require ventilation due to acute respiratory failure (either co-existing or following admission). Under the current coding guidelines hospitals receive no additional compensation for providing the mechanical ventilation to patients in these scenarios.

Further, We request that CMS and the American Hospital Association conduct DRG impact analyses prior to the implementation of revisions and additions to the coding guidelines that are published by the American Hospital Association in the Coding Clinic. This is to ensure the appropriateness of the DRG assignments that will result from the implementation of the revisions of and additions to the coding guidelines.

Examples from Coding Clinic

First Quarter, 2005

A patient who is admitted to the hospital with severe Staphylococcus aureus sepsis with acute respiratory failure.

Principal diagnosis:	038.11 Staphylococcus aureus septicemia
Secondary diagnosis:	995.92 Systemic inflammatory response syndrome due to infectious process with organ dysfunction 518.81 Acute respiratory failure

"In this example, sepsis is sequenced first because there is an instructional note under subcategory 995.92 indicating to code first the underlying systemic infection. In addition, code 995.92 has a "use additional code" note to specify organ dysfunction and lists acute respiratory failure (518.81). This instruction would mean that respiratory failure would be a secondary diagnosis" and precludes this visit from a DRG assignment that would recognize the resource consumption associated with the mechanical ventilation.

Attachment to #802

Second Quarter, 2003
Respiratory Failure
Question:
Coders continue to have questions regarding respiratory failure due to or associated with a respiratory condition. The advice previously published in *Coding Clinic*, Second Quarter 1991 and Second Quarter 2000,states "when the condition that occasions the admission to the hospital is respiratory failure due to an underlying condition, the respiratory failure is assigned as the principal diagnosis." If both pneumonia and respiratory failure are present at the time of admission and are treated equally during the hospital admission does the guideline regarding two or more interrelated conditions potentially meeting the definition of principal diagnosis, where either condition may be sequenced first, unless the circumstances of the admission, the therapy provided, the tabular list or the alphabetic index indicate otherwise apply?

Answer:
"If the reason for admission is respiratory failure and pneumonia, the respiratory failure should be sequenced first. These conditions are not co-equal. When respiratory failure is documented as being secondary to or associated with a respiratory condition, the respiratory failure should be sequenced as the principal diagnosis. This is consistent with previously published advice on respiratory failure. The guideline regarding two or more interrelated conditions meeting the definition of principal diagnosis does not apply to respiratory failure since this condition has been specifically addressed in separate *Coding Clinic* instructions. Clinically, the pneumonia led to the respiratory failure, which resulted in the patient being admitted. If respiratory failure develops after admission, the pneumonia would be sequenced first, and respiratory failure sequenced second."

First Quarter 2003
Question:
A patient is admitted in respiratory failure due to pneumocystis carinii, which is due to AIDS. Which set of guidelines should be used for the principal diagnosis in this case—the respiratory failure guidelines, or the HIV/AIDS guidelines?

Answer:
Assign code 042, Human Immunodeficiency Virus [HIV], as the principal diagnosis. Chapter specific guidelines such as the HIV coding guidelines take precedence over general coding guidelines. Assign codes 518.81, Acute respiratory failure, and 136.3, Pneumocystosis, as additional diagnoses.

It is our observation that the DRGs assigned to patients with non-respiratory conditions who require mechanical ventilation due to acute respiratory failure do not provide similar compensation for mechanical ventilation like DRG 475 with RW of 3.6166 or the DRGs assigned for burns with 96+ hours of ventilation, which have a higher RW of between 1.8727 and 13.0063.

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Hospital Inpatient PPS. If Sarasin Consulting can provide any further information, or if there are any questions or concerns with regard to this letter, please contact either Anita McAuley, RHIA (210) 590-8688 or Needacoder@aol.com.or myself Christi Sarasin, CCS at (410) 286-8678 or CDSarasin@aol.com, or
Sincerely,

Christi Sarasin, CCS
President and CEO Sarasin Consulting

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Submitter : Mr. Stephen Frayne **Date:** 06/24/2005

Organization : Connecticut Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1500-P-805-Attach-1.PDF

WI/BP
CBSAs
Hosp Redes.
MB/H
WI/GEN
WI/DC
Labor/S
Transfers
Q Data
IME
Pymt Rt/Outlier
IMPACT

Hefter
Hartstein
Miller
Kenly
Jones
Seifert
Knight
Treitel
WALZ
Hart
Bodden
Hammel
Lefkowitz
Ruiz
Truong
Kraemer

ATTACHMENT TO #805

CHA CONNECTICUT HOSPITAL ASSOCIATION

June 24, 2005

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

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

Dear Sir or Madam:

Please accept these comments from the Connecticut Hospital Association (CHA) on behalf of its thirty not-for-profit acute care hospital members, regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates [CMS-1500-P]. The CMS proposed rule sets forth numerous operational and policy changes to the hospital inpatient prospective payment system (IPPS). The comments provided herein explain the significant effect a number of the proposed operational and policy changes will have on Connecticut's hospitals.

A. Comment Summary

- CHA opposes: moving to the wage indices based on 100% of the new CBSAs and eliminating the 50% blend; reductions to the labor share; expansion of the transfer policy; and reductions to indirect Medical education.

- CHA supports: the consistent application of hold harmless provisions for hospitals redesignated and reclassified; the proposal to retroactively correct the wage index, with modification to recognize the circumstances that faced Connecticut hospitals in 2005.

- CHA requests: relief be fashioned to offset the consistent under-forecasting of the market basket that has occurred over the last several years; and development and application of a policy that assures every hospital a minimum increase.

110 Barnes Road • P.O. Box 90 • Wallingford, CT 06492-0090 • Phone: 203.265.7611 • Fax: 203.284.9318 • www.cthosp.org

B. Comment Detail

CBSAs

In FFY 2005, CMS implemented revised wage areas based on Core-Based Statistical Areas (CBSAs) defined using data from the 2000 Census. This change had a significant impact with many areas experiencing substantial increases or decreases in their wage adjustment. To mitigate the impact, CMS provided a much-needed transition for hospitals that were harmed by the redefinition of wage index areas. Hospitals that would have received a higher wage index under the prior geographic area definitions were provided a blended wage index combining 50% of the wage index based on the new definitions and 50% based on the old definitions.

CMS is proposing in this rule that hospitals receive 100% of their wage index based upon the new CBSA configurations beginning in FY 2006. CHA does not support this change and would request that last year's blend, i.e., 50% of the wage index based on the new definitions and 50% based on the old definitions, be made permanent. Given the magnitude of the decreases experienced last year, the affected Connecticut institutions just cannot afford to repeat the experience this year. Making last year's blended wage index permanent is a simple way to avoid that financial crisis.

Wage Data

During FFY 2004 and 2005, the Office of Inspector General (OIG) conducted reviews of the Medicare Cost Report, which focused on the data used to calculate the average hour wage with benefits that is used to calculate the wage index. The original instructions to complete Worksheet S-3, which is the primary data collection tool, required hospitals to use generally accepted accounting principles (GAAPs) in developing wage related costs. The OIG has found conflict between GAAP and Medicare's principles of cost findings and has recommended that GAAP be abandoned for this report.

We believe CMS' original approach, using GAAP, provides a consistent methodology for capturing these costs and causes them to be presented in a way that avoids wild swings from period to period.

Therefore, CHA requests the proposal be modified to use only GAAP principles.

Hospital Redesignations and Reclassifications

Under Section 1886(d)(8)(E) of the Act, an urban hospital can apply for redesignation as a rural hospital. Last year we commented that the approved redesignation of an urban hospital as rural under section 1886(d)(8)(E) of the Act resulted in the hospital's data having an adverse impact on the rural wage index. We noted that the "hold harmless" provisions that occur under section 1886(d)(8)(B) and section 1886(d)(10) when a hospital is granted reclassification were not being applied for redesignations. We asked that redesignations be provided the same "hold harmless" protection as reclassifications. The proposed rule incorporates that "hold harmless" protection and proposes to implement a new rule to effect the change. CHA thanks CMS for listening to our comments and supports the change as proposed by CMS.

Wage Index Data Corrections

CMS is proposing to correct the FY 2005 wage index retroactively on a one-time basis for a limited number of circumstances using the authority provided under section 903(a)(1) of Pub. L. 108-173. This provision authorizes the Secretary to make changes to items and services if failure to apply such changes would be contrary to the public interest. Outlined in the proposed rule are three criteria, all of which have to be met in order to be eligible for the adjustment. The criteria are: (1) the fiscal intermediary (FI) or CMS made an error; (2) the hospital informed the FI or CMS of the error; and (3) CMS agreed before October 1, 2004 that an error was made. CMS further states that only four hospitals in the country meet all three criteria and that under these circumstances a retroactive correction is appropriate and meets the criteria of section 903(a)(1) of Pub. L. 108-173.

CHA supports this change, but as drafted it precludes the same relief to Connecticut hospitals; it should be modified so that Connecticut hospitals can benefit from this provision.

Last year half of the hospitals in Connecticut had a huge decrease in their wage index resulting in a year-over-year payment cut from the Medicare program. We informed CMS in writing and in person that an error had occurred, consistent with the timeframes and method prescribed for commenting on proposed rules. CMS acknowledged that an error was made, but never to Connecticut hospitals. Instead, the error was acknowledged in the Home Health Agency rule published in the Federal Register Vol. 69, No. 204 / Friday, October 22, 2004 page 62130. In that rule it was noted that:

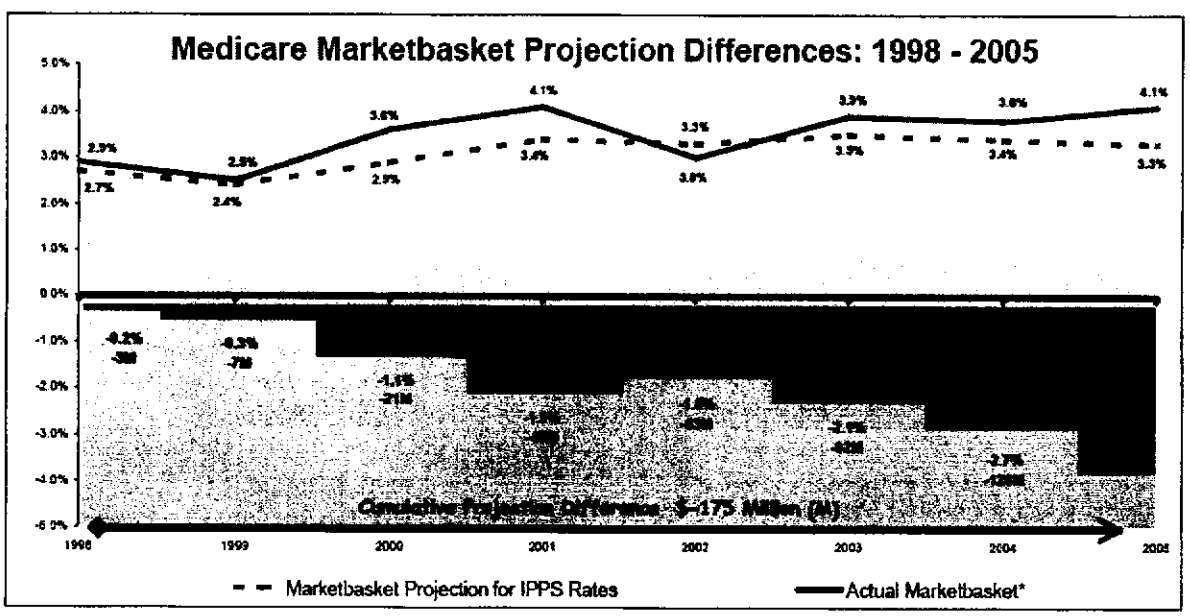
> Comment: ... commenters were specifically concerned that we unilaterally changed the designation of three hospitals in Litchfield County from their placement in the Hartford MSA to the rural region, thereby lowering both regions' wage indices. Commenters requested that this be reversed and those three hospitals be designated to the Hartford MSA as per previous longstanding CMS policy. One commenter also suggested that the redesignation of hospitals in Hartford was done as part of our proposal for revised MSA definitions. If so, then this is in conflict with our stated intent not to apply expanded MSA definitions for HHAs in CY 2005.
>
> Response: ... Upon thorough review of the commenter's concern, we have determined that only Sharon Hospital of Litchfield County, Connecticut was inadvertently designated to the rural Connecticut area in our July 30, 2004 correction notice (69 FR 45640). In this final rule, we are publishing an updated and corrected pre-floor and pre-reclassified hospital wage index that reflects Sharon Hospital's correct designation to the Hartford MSA (3283). In doing so, rural Connecticut's wage index value changes from 1.1586 in the proposed CY 2005 wage index published in the above correction notice, to 1.1917 in the final wage index published in this final rule. ... Conversely, the Hartford MSA wage index value changes from a value of 1.1068 to 1.1055. In addition, our review determined that there were technical errors in the hospital wage index calculation process for FY 2005 that had a slight overall impact to the wage index that we published in our correction notice (69 FR 45640). These technical errors have been corrected in the wage index published in this final rule.

Given the facts outlined above, failure to provide Connecticut hospitals the retroactive relief recommended would be contrary to the public interest. Therefore, we request that CMS modify the proposed criteria so that Connecticut is afforded the same equitable relief

Hospital Market Basket

We understand that the hospital update is based on a "market basket" factor that is intended to reflect the average change in the price of goods and services hospitals purchase in order to furnish inpatient care. In addition, we know that the price changes must be projected forward to estimate the increase for the subsequent year so that an appropriate market basket update can be determined in advance of payment. The projected market basket increase is not reconciled to the actual increases for the proxies that are used, ergo the prospective nature of the PPS methodology. CMS projects a hospital market basket increase of 3.2% for FFY 2006.

While it is expected that in some years the projection is higher than the actual and in others it is lower, over the life of the PPS, the differences should balance out. However, in recent years - seven out of the last eight - the projection has consistently been lower than the actual increase (see the graph below). The actual increase in FFY 2004 was 3.8% compared to a projected increase of 3.4%. In the proposed rule, CMS reports that, based on the most recent data, the FFY 2005 market basket increase is now estimated to be 4.1% compared to the estimated 3.3% increase that was projected for use in the update factor. We are very concerned that the methods being used to project the market basket increase are failing to provide reliable results. Given a 4.1% cost increase for FFY 2005, a projected FFY 2006 increase of 3.2% does not seem consistent with evidence that inflation is increasing in the general economy.



This consistent under-forecasting could not come at a worse time for Connecticut hospitals. Rates today are 3.8% below where they should be based on the actual inflation incurred; and, over time Connecticut hospitals have lost $175 million in funding due to this consistent under-forecasting. In addition, over the last two years Connecticut has seen virtually no increase in payments from the Medicare program. Therefore, we ask that a one-time increase of 3.8% be granted to correct for the

consistent under-forecasting. Granting such an increase, while not correcting for the past under funding, will offer great relief by bringing the current rates to their proper level.

Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary from time to time is to estimate the proportion of payments that are labor-related. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to update the inpatient PPS market basket at least once every five years. CMS proposes to update it every four years, beginning with rebasing and revising the market basket for FY 2006. For FY 2003, CMS rebased the market basket using 1997 data; however, CMS continued to calculate the labor-related share based on the 1992 data. The 1997 data would have raised the labor-related share to 72.5 percent from 71.1 percent, but there was concern at the time that the increase would hurt rural facilities that primarily have area wage indexes (AWIs) below 1.0. CMS cited the need to conduct additional analyses in deciding to leave the labor related share at the 1992-based 71.1 percent. Shortly after, Congress included in the MMA a provision that held hospitals with a wage index below 1.0 at a 62 percent labor-related share.

In this proposed rule, CMS is proposing to remove postage costs from the FY-2002 labor-related share because CMS no longer believes these costs are likely to vary by local labor market and to make several other changes. The combination of the proposed changes decreases the labor share from 71.1 to 69.7 percent.

These proposed changes, if adopted, would adversely affect hospitals with an AWI greater than 1.0. The labor share for hospitals with AWIs less than 1.0 will remain at 62 percent as specified in the MMA. In addition, this change would be applied in a budget neutral manner by increasing the standardized amount for all hospitals. As such, this provision will have a detrimental effect on high-wage area hospitals while diverting funds back to low-wage hospitals that have already been protected through the MMA. The CHA opposes this change and asks that CMS leave the labor-related share at 71.1 percent for FY 2006.

Post Acute Care Transfers

CMS' current policy subjects 30 DRGs to the post acute care transfer payment policy. The current policy requires that: 1) there must be at least 14,000 post acute care transfer cases; 2) at least 10% of the post acute care transfer cases occur before the geometric mean length of stay; 3) and the geometric mean length of stay is at least three days. The stated purpose of this 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."

CMS is proposing to modify the policy to: 1) there must be at least 2,000 post acute care transfer cases; 2) at least 20% of the cases in the DRG are discharged to post acute care; 3) at least 10% of the post acute care transfer cases occur before the geometric mean length of stay; 4) and the geometric mean length of stay is at least three days. The effect of this change is to dramatically increase the number of DRGs subject to the post acute care transfer payment policy from 30 to 231.

DRGs, by design, are clinically coherent groups of cases that, over time, have a consistent consumption (as measured by charges and length of stay) of hospital resources. Therefore, as

expected, not all cases will use the same amount of resources: some will use less than the average and some will use more.

In Connecticut, for the most recently completed year, there were 145,760 Medicare cases. The actual length of stay (LOS) for those cases was 5.66 days, while the expected geometric mean LOS for those cases was 4.42. In Connecticut, the reality is Medicare patients are staying 1.24 days longer than expected. The proposed policy names 231 DRGs; those 231 DRGS represent 66,701 of the 145,706 cases. The actual LOS for those 66,701 cases was 6.92 days, while the expected geometric mean LOS for those cases was 5.02. As with the total Medicare patient population, Connecticut Medicare patients assigned to these 231 DRGs are staying 1.9 days longer than expected.

These numbers speak volumes. It is obvious that day in and out, Connecticut hospitals set as their primary objective the appropriate recovery needs of Medicare patients, not the manipulation of a payment formula so as to collect the full DRG payment while minimizing costs.

Therefore, CHA opposes the transfer policy expansion proposed by CMS for the following reasons. First, the proposal undermines the very system it portends to support – if you remove all the short stay cases, then the average, without recomputation, is no longer the average. Second, the dollars being removed are not added back to the standardized rate to compensate for the now longer LOS of the remaining cases. Third, the facts make it clear that Connecticut hospitals are not manipulating the system and therefore no remedial action is necessary to remedy the situation. Connecticut hospitals are projected to lose $23.9 million in FFY 2006 as a result of this punitive and counterproductive proposed change.

Hospital Quality Data

To determine if a hospital qualifies for its full Medicare market basket update in FY 2006, CMS must determine if a hospital has submitted data on the 10 measures of heart attack, heart failure, and pneumonia care that were the "starter set" for the Hospital Quality Alliance. The proposed rule for FY 2006 includes several requirements for data to be considered "submitted" for purposes of receiving the full market basket update, including validation of the hospital's data.

While CHA supports using validated data for public reporting, CHA does not support linking validation results to the granting of the full update factor due to ongoing flaws in the validation process, which have resulted in numerous validation failures that are not related to the accuracy of the data submitted. In order for the validation process to work effectively, data must be successfully transmitted and received by CMS, accurately re-abstracted, and correctly calculated to determine the rate of agreement. Unfortunately, each step in this process has been problematic.

Problems with CMS' validation process have persisted over several quarters, and as some problems are resolved each quarter, new problems emerge. This has led to instability and considerable confusion. For example, the initial validation reports released in June for 3rd quarter 2004 (the quarter of data on which CMS has proposed that hospitals must pass validation in order to receive their full market basket update) failed many hospitals because CMS accidentally compared data from patients at different hospitals. Eventually CMS retracted those erroneous results, but they are indicative of the technical problems that have plagued the validation process.

In addition, CMS frequently changes the technical requirements for vendors submitting data on hospitals' behalf, but those detailed technical changes are not consistently communicated to data vendors and hospitals, impairing the process and resulting in inappropriate validation failures. For example, early in 2004, some hospitals failed validation because of a technical transmission error by the CMS-contracted quality improvement organization (QIO), which was beyond the hospitals' control. Although the hospitals appealed when they became aware of the error, and the QIO recommended that the appeals be approved, the appeals were ultimately denied. If that QIO error had occurred with the 3rd quarter 2004 data, instead of an earlier quarter, the result would have been dire.

To date, there is enough evidence of flaws in the validation process to suggest that passing validation should not be required in order for a hospital to receive the full Medicare market basket update. In order to resolve these flaws, the American Hospital Association has begun to collect national information about the problems with the validation process that have been identified by hospitals, and CHA and Connecticut hospitals will continue to work with AHA and CMS to modify the validation process to improve its accuracy and reliability. At this time, however, CHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update.

IME Adjustment

The IME adjustment is scheduled to decrease from an average adjustment of 5.8% to an average adjustment of 5.5%. This change will negatively affect two thirds of Connecticut's hospitals. CHA opposes this change.

Cost Outlier Threshold

The rule proposes to establish a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including IME, disproportionate share hospital DSH, and new technology payments, plus $26,675. While it appears that this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, CHA is concerned that the threshold is too high. In 2004, CMS paid out 3.4% in outlier payments while it reduced overall payments by 5.1% to fund the expenditure. In 2005, CMS paid out 4.4% in outliers while it reduced overall payments by 5.1% to fund that expenditure. Nationally, CMS under-spent the funds set aside for outliers by an estimated $610 million in FY 05 and $1.3 billion in FY 04. In Connecticut, over these two years this underpayment has resulted in a loss of funding in excess of $40 million dollars.

AHA has done a great deal of work to properly calculate the threshold to achieve a 5.1% expenditure. AHA estimates that the fixed-loss threshold to achieve 5.1 percent in FY 2005 should have been set at $21,640 as compared to the $25,800 actually utilized. If CMS leaves the threshold at $26,675, rather than dropping it to $24,050, AHA believes that CMS will under-spend by at least $510 million. CHA requests CMS work with AHA to develop a target so that expenditure matches the funding.

Minimum Rates of Increase

This year, and it seems likely again next year, the annual changes to Medicare will cause significant harm in Connecticut. Last year, 48 hospitals in the country were paid less in 2005 than 2004; 14 of the 48 were in Connecticut. If these proposed changes go into effect, nine hospitals in Connecticut will receive less in 2006 than they received in 2005 (see attached analysis). This situation should simply never happen.

When Health Plans were faced with such funding irregularities several years ago, they simply quit the program. Health Plans came back to the program when a guaranteed rate of increase (i.e. 2%) was developed and when funding was increased. It is time a similar guarantee is developed and implemented for hospitals.

We appreciate the opportunity to offer comments and thank you for your consideration.

Sincerely,

Stephen A. Frayne
Sr. Vice President, Health Policy

SAF:kas
By e-mail

CHA Analysis of Connecticut Impact of
CMS-1500-P Medciare Program; Proposed Changes to Hospital Inpatient Prospecticve Payment Systems and Fiscal Year 2006 Rates

1	2	3	4	5	6	7	8	9	10	11	12
Hospitals	Provider Number	Baseline FY 2005 Paymnets	Market Basket Update Factor	Elliminated Phase-in & Hold Harmless Provisions	IME Reduction	Labor Share Change 71.1% to 69.7%	FY 2006 Wage Index Factors	Expanded Transfer Policy	Projected FY 2006 Payments	Increase (Decrease) FY 2005 to FY 2006	Percent Change FY 2005 to FY 2006
The William W. Backus Hospital	070024	31,272,559	1,006,606	(63,774)	-	(72,491)	393,162	(481,621)	32,054,441	781,881	2.5%
Bradley Memorial Hospital	070009	10,518,783	339,438	-	-	(24,452)	140,776	(141,873)	10,832,673	313,890	3.0%
Bridgeport Hospital	070010	68,101,383	2,140,757	(540,250)	(352,490)	(250,711)	(496,769)	(867,465)	67,734,455	(366,928)	-0.5%
Bristol Hospital	070029	21,673,563	699,399	-	-	(50,382)	290,064	(359,625)	22,253,020	579,457	2.7%
Danbury Hospital	070033	57,587,649	1,813,666	(456,844)	(191,141)	(212,404)	(420,867)	(1,654,029)	56,466,029	(1,121,620)	-1.9%
Day Kimball Hospital	070003	14,249,842	459,838	-	-	(33,125)	190,710	(254,163)	14,613,102	363,260	2.5%
John Dempsey Hospital	070036	41,310,467	1,310,100	-	(383,200)	(143,291)	19,505	(1,041,244)	41,072,337	(238,130)	-0.6%
Greenwich Hospital	070018	28,850,256	916,896	-	(64,495)	(107,381)	(212,769)	(168,485)	29,214,023	363,767	1.3%
Griffin Hospital	070031	20,394,485	646,738	-	(72,839)	(67,583)	(177,851)	(431,931)	20,291,020	(103,465)	-0.5%
Hartford Hospital	070025	155,647,369	4,996,708	-	(805,249)	(359,940)	2,072,298	(2,836,624)	158,714,562	3,067,194	2.0%
The Charlotte Hungerford Hospital	070011	19,510,466	629,597	-	-	(45,353)	261,114	(505,748)	19,850,075	339,610	1.7%
Johnson Memorial Hospital	070008	10,938,481	352,981	-	-	(25,427)	146,393	(133,106)	11,279,323	340,841	3.1%
Lawrence Memorial Hospital	070007	38,602,988	1,242,453	(78,723)	(3,274)	(89,476)	485,279	(340,848)	39,818,399	1,215,411	3.1%
Manchester Memorial Hospital	070027	21,254,559	685,878	-	-	(49,408)	284,456	(317,577)	21,857,909	603,350	2.8%
Middlesex Hospital	070020	39,284,886	1,266,019	-	(81,927)	(94,406)	522,229	(841,907)	40,053,892	769,007	2.0%
MidState Medical Center	070017	26,918,037	856,669	-	-	(89,520)	(235,582)	(500,606)	26,948,998	30,961	0.1%
Milford Hospital	070019	14,478,782	460,789	-	-	(48,151)	(126,716)	(180,122)	14,584,581	105,799	0.7%
New Britain General Hospital	070035	48,441,854	1,559,274	-	(121,798)	(112,323)	646,682	(852,234)	49,561,455	1,119,601	2.3%
New Milford Hospital	070015	11,289,585	356,748	(89,561)	-	(41,780)	(82,784)	(177,686)	11,254,522	(35,063)	-0.3%
Norwalk Hospital	070034	44,952,279	1,427,904	-	(123,527)	(167,226)	(331,350)	(426,228)	45,331,852	379,573	0.8%
Rockville General Hospital	070012	12,266,695	395,843	-	-	(28,515)	164,169	(191,676)	12,606,516	339,821	2.8%
Saint Francis Hospital and Medical Center	070002	125,082,106	4,019,025	-	(537,245)	(289,512)	1,666,821	(3,308,071)	126,633,123	1,551,018	1.2%
Saint Mary's Hospital	070016	42,021,460	1,331,599	-	(180,288)	(139,149)	(366,186)	(755,375)	41,912,061	(109,399)	-0.3%
Hospital of Saint Raphael	070001	124,953,993	3,957,631	-	(595,284)	(413,564)	(1,088,338)	(2,056,212)	124,755,226	(198,767)	-0.2%
St. Vincent's Medical Center	070028	68,550,288	2,158,485	(543,811)	(241,272)	(252,787)	(500,883)	(898,153)	68,271,867	(278,420)	-0.4%
Sharon Hospital	070004	11,275,725	360,823	-	-	-	-	(217,553)	11,418,995	143,271	1.3%
The Stamford Hospital	070006	45,609,377	1,448,153	-	(144,897)	(169,598)	(336,049)	(387,035)	46,019,952	410,575	0.9%
Waterbury Hospital	070005	49,351,169	1,564,972	-	(177,000)	(163,536)	(430,363)	(683,606)	49,461,635	110,467	0.2%
Windham Community Memorial Hospital	070021	15,802,360	509,937	-	-	(36,734)	211,488	(183,358)	16,303,693	501,333	3.2%
Yale-New Haven Hospital	070022	166,278,725	5,251,390	-	(1,270,849)	(548,759)	(1,444,119)	(2,661,036)	165,605,353	(673,372)	-0.4%
Masonic Geriatric Healthcare Center	070039	2,595,244	82,594	-	-	(8,631)	(22,713)	(40,143)	2,606,351	11,107	0.4%
Total		1,389,065,416	44,247,911	(1,772,962)	(5,349,774)	(4,135,614)	1,221,806	(23,895,338)	1,399,381,444	10,316,029	0.7%
Percent Change			3.2%	-0.1%	-0.4%	-0.3%	0.1%	-1.7%		0.7%	

Leg Both

CMS-1500-P-807

CMS-1500-P804

508

Submitter : Mr. Thomas Donovan **Date:** 06/24/2005

Organization : SUNY Upstate Medical University

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-807-Attach-1.DOC

Transfers
IMPACT

Hefler
Hartstein
Walz
Hart
Kraemer

Attachment to #807

June 24, 2005

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

Attention: **CMS-1500P**

Dear Administrator McClellan:

University Hospital, SUNY Upstate Medical University, appreciates the 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).

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;
- 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. This becomes 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. This proposed change would reduce payments to University Hospital in excess of $1 million creating a serious financial hardship as we struggle to provide cost effective care to our Medicare beneficiaries in the most appropriate setting.

University Hospital agrees with comments made 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. The AHA analyses show that rural patients have essentially the same access. Consequently, the proposed rule would harm all hospitals and I urge the Agency to rescind this proposal.

Thank you for this opportunity to present the views of University Hospital. If you have any questions concerning these comments, please feel free to call me at (315) 464-6530.

Sincerely,

Thomas J. Donovan
Chief Financial Officer

Cc: Phillip S. Schaengold, J.D.

Submitter : Mr. Thomas Donovan **Date:** 06/24/2005

Organization : SUNY Upstate Medical University

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment dated 6/24/05

See CMS-1500-P-807 (# 508)

509

Submitter : Mr. V. Mark Perry
Organization : Adventist Medical Center
Category : Hospital
Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-810-Attach-1.PDF

Transfers
Labor/S
Q Data

Hafler
Hartstein
Walz
Hart
Seifert
Knight
Treitel
Bodden
Hammel

ATTACHMENT TO #810

Adventist Health

Adventist Medical Center

June 23, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Docket ID: CMS-1500-P
P. O. Box 8010
Baltimore MD 21244-1850

VIA www.cms.hhs.gov/regulations/ecomments/

Re: Proposed Changes to Hospital IPPS for FFY 2006

Adventist Medical Center is very concerned with the proposed IPPS changes to be effective on October 1, 2005.

Post-Acute Care Transfers (PACT) DRGs:

Adventist Medical Center opposes the expansion of the PACT DRGs from 30 to the proposed 223 on the following basis:

- The Social Security Act statutes that authorized implementation of per diem rates for PACT DRGs states in part that the Secretary could select DRGs "based upon high volume of discharges classified within such groups." As initially implemented, this threshold was defined as 14,000 discharges per year. CMS is now proposing an 85% reduction in the number of discharges within a DRG required to meet this definition. Given that there are far more than 2,000 hospitals in the United States, this new definition of "high volume" means that the average hospital would see less than one discharge per DRG for that DRG to qualify. It does not appear that this new definition meets the intent of Congress to apply PACT payments to "high volume" DRGs.

- The Social Security Act statutes state that in addition to being "high volume," DRGs must demonstrate a "disproportionate use of post discharge services." Given that CMS has identified the range of post acute care setting utilization for DRGs that presently qualify under the PACT to be from 15% to 76% with many of those percentages in well above the 20% threshold, the new 20% criteria appears arbitrary when considered in conjunction with the lowered definition of "high volume."

- The radical expansion of PACT DRGs violates the original premise of the inpatient prospective payment system. The basic concept of DRG PPS is that some cases will be more costly than the average (excluding outliers) and some cases will be less costly (inliers). By including the inlier cases in the calculation of DRG weights and than paying these cases on a per diem basis, CMS is underpaying other than inlier cases.

- The radical expansion of PACT DRGs will likely create an incentive for hospitals to extend the length of stay to at least one day short of the geometric mean length of stay. Since CMS has already implemented PPS payment systems for sub acute levels of care, it should not now adopt payment methods that would unduly influence a patient's level of care.

- The radical expansion of PACT DRGs is unfair to areas of the country that have shorter lengths of stay. Hospitals in these areas will now be penalized with lower reimbursement simply because they may have better practice patterns than areas of the country with longer lengths of stay. This also violates the original premise of DRG PPS which attempted to provide incentives for more appropriate utilization of resources.

- The radical expansion of PACT DRGs placed an undue burden on hospitals to keep track of what happens to a patient after a patient is discharged to another setting with no plan for further treatment.

Labor Related Share:

In support of its proposal to rebase the wage-index labor related share to FFY 2002, CMS compares the FFY 2002 with FFY 1992 but does not draw any conclusions regarding the related shifts by line items. Furthermore, CMS does not make comparisons to or draw conclusions about differences in the labor related share based on FFY 1997 which was initially analyzed for FFY 2002. The FFY 2002 proposal to rebase the labor related share to FFY 1997 would have resulted in an increase to the labor related share, but was ultimately withdrawn. This increase would have benefited those urban facilities with a wage index greater than 1.00.

Therefore, Adventist Medical Center opposes the proposal to rebase the wage-index labor related share to the FFY 2002 amount for the following reasons:

- The FFY 2002 proposal to rebase the labor related share to FFY 1997 would have resulted in an increase to the labor related share, but was ultimately withdrawn. This increase would have benefited those urban facilities with a wage index greater than 1.00. The proposal to now rebase the labor related share to FFY 2002 decreases the labor related share. Since those facilities with a wage index of less than 1.00 have already been assigned a labor related share of 62%, it appears that CMS is arbitrarily electing to rebase the labor related share only when CMS accrues the financial benefit.

- Had CMS compared the line item elements that make up the labor related share with FFY 1997 data, it would have seen greater variation among the line items than with FFY 1992 analysis. 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, and
    4. the consistency of CMS's methodology

  Before CMS updates the Labor Related Share to FFY 2002 data, it should address why it believes these fluctuations occurred and determine that it was not caused by changes in base data or methodologies.

- It appears that CMS has changed the labor related share without appropriately considering the budget neutrality adjustment for changes in the standardized amounts. Since those facilities with a wage index of less than 1.00 have already been assigned a labor related share of 62%, the reduction to the labor related share will result in a savings to the Medicare trust fund unless this savings is offset by an adjustment to the standardized rates.

Hospital Quality Data:

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

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

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

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

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

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

- Further, we believe that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL

measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data was submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

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

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

We appreciate the opportunity to comment on CMS proposed regulations for FY 2006, and hope that you will consider our comments to adjust the final regulations.

Sincerely,

Mark Perry
Adventist Medical Center
Vice President for Finance

Cc: Jim Aldrich, AH Director Budget & Reimbursement

510

Submitter : Ms. Jori Frahler

Date: 06/24/2005

Organization : Medical Device Manufacturers Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-835-Attach-1.DOC

CC List
NT
MedPAC
ICD-9-CM

Hefler
Hartstein
Walz
Hart
Brooks
Gruber
Fagan
Kelly
Hue
Treitel

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION

Attachment to #835

June 24, 2005

Via Electronic Submission

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

RE: [CMS-1500-P], Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year (FY) 2006 Rates

Dear Dr. McClellan:

I am filing these comments on behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market. MDMA represents over 200 medical device companies and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

We appreciate the opportunity to comment on the FY 2006 inpatient PPS proposed rule published on May 4, 2005. Specifically, we would like to express some concerns about CMS's interpretation of the criteria for new technology add-on payments, ICD-9-CM coding issues, maintaining the confidentiality of external data, the use of MedPAC recommendations and CMS's comprehensive review of the complications and co-morbidities (CC) list.

MDMA makes the following recommendations:

- Create a more transparent, open, and predictable process when evaluating new technologies for add-on payment status;
- Minimize the need for new technology add-on payments by expediting correct DRG assignment for technologies once they are approved;
- Expand the definition of "new" so that there is greater flexibility to acknowledge that FDA approval, ICD-9 coding and the manner and timing by which products are introduced are all considered;
- Reconsider the substantial clinical improvement requirement for new technology add-on payments;
- Increase the payment level of new technology add-ons to more accurately reflect the device cost and CMS payment levels within the IPPS;

- Maintain confidentiality of external data;
- Carefully analyze and conduct a public, comprehensive review of the MedPAC recommendations and the Complications and Co-morbidities list to minimize dramatic shifts in revenue for hospital providers that may adversely impact patients; and
- Expedite the introduction of ICD-10.

We discuss each of these recommendations in more detail below.

NEW TECHNOLOGY ADD-ON PAYMENTS

MDMA thanks CMS for its efforts in reviewing applications for new technology add-on payments, as such additional payment can help patients obtain access to the most effective care. MDMA hopes that CMS will consider implementing our recommendations to help improve patient access to the most effective medical technology and ensure continued medical device innovation.

Section 503 of the Medicare Modernization Act included a provision to expand the inpatient new technology add-on payment program to include a broader range of technologies. This legislation created a mechanism to help combat the problem of "payment lag," during which new and innovative technologies suffer inadequate payments for several years after they reach the market. Adequate payment is essential to hospital adoption of medical technologies and in turn the companies that develop and manufacture them. This is, particularly crucial for the smaller device companies that drive medical device innovation. Many device manufacturers, especially small entrepreneurs, lack the nationwide marketing, distribution, and reputation of larger companies in the industry.

In addition, the problem posed by the payment lag is compounded over time as patient access is limited when a technology does not receive adequate payment. Therefore, adequate payment for new and innovative medical technologies through consistent and fair application of new technology add-on payment rules is essential to the success of innovative and life-saving medical technologies. CMS's narrow interpretation of the statutory criteria for granting new technology add-on payments has created a situation whereby virtually no products can qualify and it is in direct conflict with Congressional intent to expedite access to new technologies. In fact the criteria are so steep and the process so opaque that many companies, especially small companies, cannot afford to undertake the process, at all based on its unpredictable nature.

Process Transparency and Predictability

MDMA requests that CMS infuse transparency and predictability into the process of determining which technologies are truly eligible for new technology add-on payment, as only three companies received new technology add-on payments in FY 2005 and only one technology has been deemed eligible for the added payment in FY 2006. For the add-on payments to be medically meaningful to patients and hospitals, which was the intent of the program, there must be a predictable path to approval and a consistent and reasonable set of requirements for manufacturers of novel technologies to meet.

Proactive Appropriate DRG Assignments for New Technologies

CMS should proactively assign new technologies to DRGs that are representative of resources required and costs incurred by these new technologies. This would require that CMS open the assignment process to stakeholders that can provide productive input on the intricacies of new technologies. Proactive DRG assignment will focus overall need for new technology add-on payment to technologies that are truly novel and not able to be represented in the DRG data set as was done with drug-eluting stents and other innovative cardiac devices.

Currently, ICD-9 coding (new codes or new technologies assigned to existing codes) does not include a discussion of resource utilization or device costs; rather, it focuses solely on the clinical aspects of the procedure. As a result, some technologies receive inaccurate DRG assignments which do not reflect the resources involved in performing the new procedure - ultimately serving as a barrier to the adoption of the new medical technology. A recent example of this issue is the CorCap Cardiac Support Device which was granted an ICD-9-CM procedure code prior to FDA approval. However, the subsequent DRG assignment was made without an adequate understanding of the procedure and so the device was assigned to a DRG that does not account for the resource utilization and subsequently for the cost of the procedure. Therefore, MDMA believes that collaboration between CMS and manufacturers is critical to avoid inappropriate DRG assignments and we encourage the agency to give thoughtful consideration to comments submitted in relation to the proposed grouping of new codes for implementation in FY 2006, taking care to ensure that initial DRG assignments accurately reflect clinical cohesiveness and resource utilization.

"Newness" Determination Period

Of particular concern is CMS's definition of a "new device." Although some devices achieve widespread market introduction quickly, many medical devices diffuse into the market slowly. In addition to the time it takes for a company to build production capabilities, negotiate with hospitals over contracts, and establish distribution facilities, many innovative devices require time-consuming and costly physician education programs. For small companies, this path requires careful planning to assure that monies raised through public and/or private investors will cover the cost of these necessary activities. Even so, many small companies choose to "roll out" a product slowly in order to reduce the financial impact of product launch and expand the capabilities of limited personnel. For this reason, a narrow interpretation of "new" does not take into consideration that many companies do not initiate a widespread launch.

MDMA believes there needs to be flexibility in CMS's standard for determining the payment period that a technology is considered "new" and therefore eligible for add-on payment status. This flexibility is essential to account for the multiple scenarios and diverse circumstances in which a new technology or service comes to market and therefore would be available for Medicare beneficiary care. For example, FDA approval of a new technology does not always pre-date ICD-9-CM code issuance, and vice versa. Also, as CMS correctly points out, even after a technology obtains FDA approval, for a variety of reasons, there can be delays in bringing the product to market. Further, existing, nonspecific procedure code linked to specific primary

diagnosis code(s) may serve as excellent proxies for identifying discharges in the Medicare claims data that utilized the new technology or service. MDMA therefore urges CMS to institute a flexible standard that considers a host of "newness" factors to ensure that both a maximum period of eligibility is achieved and the most appropriate period of time is dedicated to evaluating the new service within the Medicare data. This standard can be linked to several factors. MDMA suggests using whichever of the following represents the latter of the following date:

- Date of ICD-9 code assignment;
- Date of FDA approval plus six months; or
- The time/date at which 50% of the Fiscal Intermediaries are processing claims that include the technology in question.

MDMA also recommends that CMS consider extending the period for which devices may be considered new to four or even five years after which a technology is deemed "new". Given the numerous challenges associated with bringing a device from inception to market, MDMA believes that a device may be reasonably considered new for the purpose of add-on payments after more than three years. The price of a device may only be fully recognized in a DRG weight after several more years, especially if a hospital has to retrain its staff and invest heavily in capital equipment.

Marginal Cost Factor

MDMA further encourages CMS to consider increasing the payment rate for new technology add-on payments. Currently, new technology add-on payments are limited to 50 percent of the cost of the device over the DRG reimbursement.[1] Yet the Medicare Modernization Act's report language urged CMS to consider raising the add-on payment level from 50 percent to 80 percent of the difference between the standard DRG payment level and the cost of the procedure with the new technology. MDMA is disappointed that CMS did not address this issue in the FY 2006 proposed rule and we urge the agency to revisit this issue in the near future so that add-on payments conform to the marginal rate used for the inpatient outlier payment level.

Substantial Clinical Improvement

CMS should also work to clarify what standard they are using to determine what data are necessary to determine a "substantial clinical improvement." MDMA appreciates CMS's willingness to discuss this standard in open door meetings. However, it still seems that determinations of what may represent a substantial improvement are largely subjective and are made without stakeholder input. MDMA urges CMS to establish clearer standards on what constitutes a "substantial clinical improvement" and solicit more stakeholder opinion on this issue. Clear standards will help companies in the future as they plan clinical trials and apply for add-on payments.

[1] 42 C.F.R. § 412.88 (2005).

EXTERNAL DATA

MDMA applauds CMS for its continued willingness to consider non-MedPAR data in setting payment rates. We encourage the agency to increase its use of external data in the future. As we have commented in the past, we believe that if supplemental data exists in addition to or in the absence of CMS's own internal data, it should be considered in rate setting. MDMA further believes that CMS should be receptive in looking at external data especially for new technologies where there is no internal data. We do want to emphasize and remain concerned that the best data will not be available unless CMS agrees to hold it confidential. Manufacturers will be unwilling to release to CMS proprietary information that could be useful to competitors. Making a firm commitment to keep external data confidential would prevent that problem.

MEDPAC RECOMMENDATIONS

MDMA appreciates CMS responding to MedPAC recommendations in the Proposed Rule. Of particular interest to our membership are the recommendations regarding refinements to the hospital IPPS. While MDMA supports improving the accuracy of IPPS rates, we are concerned about the potential dramatic effects MedPAC's recommendations could have on Medicare inpatient payments to hospitals, not just specialty hospitals. We were encouraged by CMS's comments that the agency intends to thoroughly analyze and evaluate MedPAC proposals as well as other options prior to making any formal proposal. We ask that the agency conduct this process in a transparent manner that considers the input of a diverse group of stakeholders.

COMPREHENSIVE REVIEW OF THE COMPLICATIONS AND CO-MORBIDITIES (CC) LIST

MDMA understands the agency's concerns that changes in inpatient hospital care particularly decreases in length of stay may be marginalizing the effect the CC list is having on distinguishing hospital discharge resource use relative to years past. We therefore agree that it may be productive for the agency to conduct a substantive and comprehensive review of the CC list. As part of that review, we encourage CMS to evaluate the potential impact a secondary diagnosis may have on hospital charges and average length of stay.

Given that any revision of the CC list is likely to have a major impact on hospital revenue streams, we urge CMS to proceed carefully, systematically, and in a transparent manner. We support CMS's intent to examine several approaches, but believe that CMS should subject any proposed methodology, new standards and revised list to public comment that allows sufficient time for significant changes if needed before final implementation.

ICD-10-CM IMPLEMENTATION

MDMA would like to also highlight the industry's ongoing concerns about the ICD-9-CM coding system in general and the need to move to ICD-10. As we have commented in the past, we believe this expanded and improved coding system would provide CMS with more flexibility and accuracy in its nomenclature, especially in identifying the broad range of new medical

technologies constantly being introduced. With the formal recommendation of the National Committee on Vital and Health Statistics to move to ICD-10, CMS should initiate that process promptly.

* * * *

We thank CMS for the opportunity to comment on this proposed rule. As always, MDMA looks forward to working with the agency in the future to improve access to the best and latest technologies that our industry has to offer.

Sincerely,

Mark Leahey
Executive Director
Medical Device Manufacturers Association

511

Submitter : Mrs. Kathy Stumbo

Date: 06/24/2005

Organization : Our Lady of the Way Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-836-Attach-1.DOC

CMS-1500-P-836-Attach-2.DOC

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

ATTACHMENT 1 TO #836

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

Dear Dr. McClellan:

Our Lady of the Way Hospital (OLW) appreciates the opportunity to comment on Critical Access Hospital "Necessary Provider" Relocations. As CEO of a designated critical access hospital, I am very concerned of what may happen to OLW if the proposed rule is passed to prevent CAHs with necessary provider status from relocating.

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 <u>not required</u> 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.

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 obtained critical access status through state designation as a "necessary provider" in 2000. Continuation of this hospital is vital to the rural communities and individuals we serve.

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,

Kathy Stumbo
President and Chief Executive Officer

ATTACHMENT 2 TO #836

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

Dear Dr. McClellan:

Our Lady of the Way Hospital (OLW) appreciates the opportunity to comment on Critical Access Hospital "Necessary Provider" Relocations. As CEO of a designated critical access hospital, I am very concerned of what may happen to OLW if the proposed rule is passed to prevent CAHs with necessary provider status from relocating.

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 <u>not required</u> 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.

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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,

Kathy Stumbo
President and Chief Executive Officer

512

Submitter :

Date: 06/24/2005

Organization : **Office of Senator Sam Brownback**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-837-Attach-1.PDF

CAH Reloc

~~Hefter~~
~~Hartstein~~
Collins
Morey
Smith

SAM BROWNBACK
KANSAS

(202) 224-6521 Phone
(202) 228-1265 Fax

COMMITTEES:
APPROPRIATIONS
JOINT ECONOMIC
JUDICIARY
UNITED STATES
HELSINKI COMMISSION

United States Senate

WASHINGTON, DC 20510-1604

June 24, 2005

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

Dear Dr. McClellan:

I write you regarding CMS's proposed rule changes affecting Kansas Critical Access hospitals. There are eighty-two community hospitals that are designated and operating as CAHs in Kansas. Several of these CAHs were grandfathered into the CAH program from the earlier Essential Access Community Hospital/Rural Primary Care Hospital program. The remaining CAHs were designated based upon the necessary provider of health criteria. The Medicare Modernization Act of 2003 (P.L. 108-173) 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).

512 South Kansas Avenue
Topeka, KS 66603
(785) 233-2503 Phone
(785) 233-2616 Fax

100 N. North Broadway
Pittsburg, KS 66762
(620) 231-9040 Phone
620) 231-6047 Fax

811 North Main Street, Suite A
Garden City, KS 67846
(620) 275-1124 Phone
(620) 275-1807 Fax

245 North Waco, Suite 240
Wichita, KS 67202
(316) 264-8066 Phone
(316) 264-5076 Fax

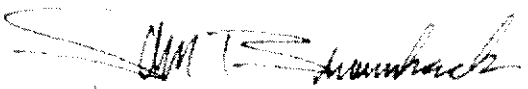
11111 West 95th, Suite 248
Overland Park, KS 66214
(913) 492-6578 Phone
(913) 492-7263 Fax

www.brownback.senate.gov

The arbitrary date proposed by CMS seems unrealistic. Further, it jeopardizes 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 forty to fifty 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 policy simply does not make any sense. Accordingly, I 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.

Thank you for considering my comments on the proposed rule changes. Please contact me or my staff person, Melanie Benning, at (202)224-3575, if you have any questions regarding these comments.

Sincerely,



Sam Brownback
United States Senator

513

Submitter : Mr. Lawrence Corbo III **Date:** 06/24/2005

Organization : Meridian Health

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-838-Attach-1.DOC

Pymt/Outliers
TRANSfers
MB/H

Hefter
Hartstein
Treitel
Walz
Hart
Seifert
Knight

Attachment to #838

June 24, 2005

Mark McClellan, M.D., Ph.D
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Roon 314-G
Washington, DC 20201

RE: Proposed Changes to the Hospital Prospective Payment System and Fiscal Year 2006 Rates; CMS-1428-P

Dear Dr. McCellan

Meridian Health System respectfully submits the following general comments as they pertain to the proposed changes to the Hospital Prospective Payment System ("PPS") related to the proposed changes as published in the May 4, 2005 Federal Register. Meridian Health System is a three hospital System located in Monmouth/Ocean Counties in New Jersey. The three hospitals that comprise Meridian are Jersey Shore University Medical Center (Provider # 310073); Ocean Medical Center (Provider # 310052) and Riverview Medical Center (Provider # 310034).

Outliers

Meridian Health System is not in support of increasing the outlier threshold. Medicare provides extra payments for unusually high cost cases in order to limit hospitals financial risk from extraordinary costs, and diminish any financial incentive to avoid Medicare patients with serious illness. CMS is proposing an increase in the outlier threshold to $26,675 for FY 2006, an unjustified increase over the FY 2005 threshold of $25,800. This increase will make it more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating high-cost cases.

In fact, CMS estimates that actual outlier payments for FY 2005 will be 4.4 percent of actual total inpatient payments, which is .07 percentage points less that the 5.1 percent withheld from hospitals to fund outlier payments. Here at Meridian Health, our two community hospitals, Ocean Medical Center and Riverview Medical Center, are trending at about .27 and 1.71 percent of actual total inpatient payments, respectively. Our major teaching tertiary hospital, Jersey Shore University Medical Center, is trending at about 1.4 percent of actual total inpatient payments. Further increases to the outlier threshold would all but eliminate reimbursement on these critically ill patients.

CMS needs to revisit the methodology used to increase the threshold and reconsider using one of the following methods:

- Using data projections such as the hospital market basket (rather than actual2003-2004 data) to update charges for the purposes of determining outlier threshold, or

- Returning to its previous methodology that measured the percent change in costs using the two most recently available hospital cost reports.

The outlier threshold must be lowered to reflect the modifications made to the outlier payment policy. It is absolutely necessary to ensure hospitals receive the full 5.1% of payments that will be withheld from base inpatient payment in 2006, and ensure that hospitals have access to these special payments to cover extremely high-cost patients.

Post Acute Care Transfers

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

Last year, after "an extensive analysis to identify the best method by which to expand the transfer policy," CMS adopted four specific criteria that a DRG must meet, for both of the two most recent years for which data is available, in order to be added to the post-acute care transfer policy. Now, a year later, CMS is proposing to adopt an additional set of "alternative criteria" that would be applied to a DRG that failed to meet the FY 2005 criteria.

Meridian objects to CMS changing its rules and criteria year to year in order to ensure certain DRGs are included in the transfer policy and requests that this provision be withdrawn in its final rule.

Hospital Market Basket

The sum of the labor-related hospital market basket cost category weights represents the portion of the standardized amount that is wage-adjusted. The current labor share is 71.1% and it is based on FY 1992 data. CMS would have updated the weights in FY 2003 based on FY 1997 data, but declined to do so because the update would have increased the labor share to 72.5%, which would have hurt rural and other low-wage hospitals. Now CMS is proposing to update the weights based on FY 2002 data, which would reduce the labor share to 69.7% and hurt high-wage urban hospitals. This change would not materially help rural and other low-wage hospitals because their labor share was fixed at 62% in the Medicare Modernization Act of 2003.

We can make a good case on behalf of relatively high-wage hospitals that CMS should not update the cost component weights in FY 2006 to make up for not updating the weights in FY 2003. However, we would support CMS updating the weights in FY 2006 *if* the Agency also designated professional liability insurance as a labor-related cost. These costs are clearly wage-related—indeed, they are reported in the wage index—and are clearly locally determined. We believe that the failure to include professional liability insurance in the wage-adjusted portion of the standardized amount in the past was a grave oversight. Including this important cost component in the labor share would bring it up to 71.3%, which is virtually the same as the current labor share of 71.1%.

Sincerely

Lawrence J Corbo III
Manager, Corporate Reimbursement
Meridian Health

CMS-1500-P-842

& cms-1500p839

514

Submitter : Ms. Yvette Hayes **Date:** 06/24/2005

Organization : Mountain States Health Alliance

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-842-Attach-1.DOC

MB|EX Hos
CBSA
TRANSfers

Hefler
Wartstein
Seifert
Knight
Treitel
Ellington
Kenly
Miller
Walz
Hart

Attachment to #842

June 24, 2005

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

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

Dear Mr. Administrator:

Mountain States Health Alliance is a locally owned and managed healthcare system in the state of Tennessee. The system is comprised of 10 hospitals that provide a full range of inpatient services to include acute care, psychiatric, rehabilitation, and skilled nursing services.

This letter is to comment on the proposed changes to the regulations for Hospital Inpatient services paid on behalf of Medicare beneficiaries:

I. Excluded Hospital Market Basket
   a. We agree that a separate market basket for hospitals and hospital units excluded from the Inpatient PPS should be established to accurately account for the cost structure of these hospitals/units.

II. Core-Based Statistical Areas
   a. In FY2005 IPPS Final rule, hospitals that experienced a significant payment decrease in their wage index due to solely to the adoption of the new labor market area changes were allowed a blend based on 50% of the CBSA labor market area definitions and 50% of the "Old" MSAs.

   b. We continue to disagree with the full implementation of these new definition of statistical areas, which is proposed beginning in FY2006.

      i. Our hospitals are still adjusting to the millions of dollars in revenues lost on our Medicare patients (40% utilization) as the result of the massive changes that were implemented to wage index.

Attachment to #842

II. Core-Based Statistical Areas

ii. If the new CBSA definitions are fully implemented this year, it will mean an additional $1.75M decrease in reimbursement for our hospitals from FY05

1. Johnson City * (27440) 0.8195 to 0.7969
2. Johnson City (27740) 0.8184 to 0.7958
3. Kingsport (28700) 0.8235 to 0.8095

* Hospitals located with Washington County received a commuter adjustment of 0.0011.

c. We ask CMS to continue to defer 100% adoption of the new CBSA definitions to allow hospital's one more year to adjust to the significant reimbursement impact. We propose using a 75% CBSA/25% MSA Blend to ease the financial burden of taking care of the same number of Medicare beneficiaries with fewer dollars.

III. Post acute Care Transfers

a. As indicated in the regulations, the purpose of the post acute care transfer payment policy was to avoid or take away any incentive for hospitals to transfer patients to post acute care setting early in a patients stay.
b. Historically, one of the main criteria used to determine if a DRG may be suspect was at that the DRG have at least 14,000 transfer cases for the last two (2) years. This criterion was reasonable if you were looking for hospitals abuse or fraudulent patterns verses just a means to limit or reduce reimbursement to providers.
c. However, the extensive analysis of the FY 2003 and FY 2004 MedPAR data of post acute care transfers did not disclose any additional DRGs that met the existing criteria. This analysis showed that about 50% (223 DRGs) had some similar characteristics, not because the volumes where considered high or disproportionate, and that these characteristics justify changing the criteria used to include a DRG in the post acute care transfer policy.
d. We disagree strongly with the proposed revisions to the criteria on this basis and believe that this change is not intended to look for excessive transfers patterns which would indicate abuse or gaming the Medicare program but just a means to reduce reimbursement to hospital that are only concerned with providing the best care and treatment to patients in the proper and least expensive setting. We ask you not to implement this expansion to the additional 223 DRGs proposed.
e. If this provision is adopted as is, it would mean a loss of $1.1M alone to our flagship hospital (+500 Bed), which is the main provider of services in the Washington County, Johnson City, TN area. We estimate that we could experience a loss system wide up to $2M.

If you have any questions concerning these comments, you can contact Yvette C. Hayes, Corporate Director, Reimbursement, Mountain States Health Alliance at (423) 431-1941

Submitter : Ms. Yvette Hayes **Date:** 06/24/2005

Organization : Mountain States Health Alliance

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

See CMS-1500-P-842 (#514)

515

Submitter : Mr. John Shaw **Date:** 06/24/2005

Organization : Next Wave

Category : Health Care Professional or Association

DRG/GEN (Refinement) CC List

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

Refinement of DRGs ? MEDPAC, Severity, CCs, Criteria

See attachment for details.

Issues

DRG Reclassifications

See attachment for details.

CC List

See attachment for details.

CMS-1500-P-843-Attach-1.DOC

NEXT WAVE

"We Understand Health Care"

Attachment to #843

June 24, 2005

Mr. Marc Harstein
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850 http://www.cms.hhs.gov/regulations/ecomments

Re: File Code CMS-1500-P - Refinement of DRGs – MEDPAC, Severity, CCs, Criteria

Dear Mr. Harstein:

We are a health services research and consulting firm which specializes in using data to classify patients into categories for policy, management, financing, and quality improvement. Our staff have worked on the design, refinement, and implementation of Diagnosis Related Group (DRG) payment systems at the national and state level since the 1970's. Projects for HCFA, various State regulators and Legislatures, Provider associations, and individual institutions, include:

- Incorporating DRGs into existing State payment systems
- Design and implementation of new State DRG payment systems
- Refinement of DRGs for different populations (non-Medicare, Children)
- Refinement of DRGs for referral patient populations (high risk cardiac, orthopedics, etc.)
- Severity adjustment to DRGs beyond simple cc splits
- Evaluation and refinement of source data and ICD-9-CM codes to support DRGs
- Similar projects for nursing homes (Resource Utilization Groups – RUGS)

We are writing to offer suggestions for DRG refinement based on almost 30 years experience in these areas at both the policy and pragmatic level.

Background and Context - Policy Drivers

The most basic driver is the ongoing growth of health care expenditures, particularly since a large portion is financed through Federal and State Medicare and Medicaid payments. Service needs are expanding with the aging of the population, while at the same time Federal and State tax revenues are increasingly constrained. DRGs are the major control point for Hospital payments. Payments that are too high waste taxpayer resources and/or provide perverse incentives for providers to seek out more profitable patients. At the same time, payments that are too low constrain beneficiary access to necessary services, impair the quality and safety of these services, and/or place the continued existence of providers that care for "unprofitable" patients at risk.

The need for a closer alignment of payments and costs is highlighted in recent months with the attention of MEDPAC, Congress, the AHA and other interest groups indicating that the current categories are unbalanced, particularly in the context of physician-owned cardiac, orthopedic, and

surgical hospitals. Both MEDPAC and Congress have recently called for severity refinement of the DRGS, and Administrator McClellan has committed CMS to do so.
There were specific requests for comment on the need for overall guidelines for DRG reclassifications, input on a comprehensive review of complications and co-morbidities, responses to MEDPAC recommendations, issues relating to Specialty Hospitals, more meaningful indicators of clinical severity, implications for resource use, and a desire to maintain the integrity of the existing DRG framework. Since most of these areas overlap, we have structured our comments from an overall systems perspective. Major focus areas may therefore address several of the requests for comment at the same time.

Guidelines for Making DRG Refinement Decisions

We believe that there is a critical need for general payment equity and refinement guidelines. The overall healthcare delivery system is so complex that without such guidelines, significant policy inconsistencies are inevitable. This in turn will continue to focus attention and efforts of all involved on these inconsistencies or misalignments rather than on how to provide safe, effective, and efficient care to Medicare beneficiaries. Recommended guidelines should address:

- Payment Equity – should not over-reimburse or under-reimburse any group
- Coherent reimbursement structure - that makes sense both clinically and financially
- Consistent and predictable decision rules across clinical specialties
- Responsive incrementally to changes in medical practice to avoid disruptive realignment

Payment Equity

Over-reimbursement windfalls produce an incentive to change admission patterns to admit more "profitable" patients. Avoiding these windfalls provides additional funding to provide access and equitable payment to any class of patient, clinical specialty, provider, locality, that may not currently be profitable. Regulatory, Legislative, and Provider attention over the past 5 years on emotionally charged "equity" issues such as Cost Outliers, the 75% rule, timely access to new technology, and MD owned Specialty Hospital growth contributed in large part to the healthcare industry NOT responding effectively to system-wide patient safety concerns raised by the Institute of Medicine (IOM) in their report "To Err is Human."

- One strong recommendation is to evaluate the "materiality" of the need for refinement from the perspective of the likelihood of initiating behavioral change. If a potential cost versus payment gap of approximately $ 100,000 total per facility (or about $2,000-4,000 per case) exists, selective admission shifts or coding/costing practice shifts are likely.
- Consistent evidence that all parties accept typically reduces controversy by 65%. If, however, each party has their own set of evidence that cannot be validated by other parties, the type of controversy outlined above will continue.

Coherent Reimbursement Structure

Results should show statistical evidence of difference, and also be clinically coherent – especially relative to differences in referral patterns. High risk patients should be referred to regional centers of excellence with the expertise to care for them – and payments should reflect any higher costs. Forced referral of "low margin" patients to facilities if last resort should be avoided.

Consistent and Predictable Decision Rules

Payment recognition for DRG refinement is not currently consistent across clinical specialties or across patient types within a specialty, likely due to different evaluation teams addressing recommended changes without overall guidelines. These guidelines should address:

- How much difference represents a "clear differentiation" supporting refinement?
  - Is there an absolute dollar difference?
  - Is there a percentage difference?
- Is there a threshold for "substantial" number of cases?
- If disproportionate impact across hospitals (e.g. high risk patients go to regional centers of excellence), how much is enough to justify a refinement?

Specific Recommendations

Following are specific comments on technical issues:

- For examination of Complications and Co-morbidities (CCs), there is a need for BOTH a General/Standard list of CCs that address patient condition across body systems AND a need for clinical specialty (or sometimes even by major procedure) to address unique severity conditions for that specific population. Structurally, we recommend:
  - Create a general list of complications across major categories (perhaps after removing pre-MDC cases) similar to the current
  - Run the same analysis for each MDC or DRG clinical pair and examine differences, including both statistical and clinical expert review
    - Use cc exclusion lists by MDC to remove diagnosis that do not impact
    - Add-in a new MDC (or procedure) specific list of "Selective" diagnosis for this specific patient population
- For evaluating both CCs and DRG refinement, we recommend abandoning Length of Stay, since in today's clinical environment, it is determined more by post-acute-care referral dynamics than by patient need. Standardized Costs (i.e. Operating Cost to Charge ratio adjusted Standardized Charges) should be used instead. At a State level, average charge mark-ups over cost vary from 30% in Maryland to 400%+ in New Jersey and California. This order of magnitude skewing of charges significantly outweighs any minor cost to charge inaccuracies within hospitals. There are not enough cases to do facility specific relative weighting due to wide variation on hospital specialization today.
- In defining CCs, consider differentiating co-morbidities from complications. The former are predictable, and can be used to easily affect admission selection .

We look forward to providing further input over the next year.

John D. Shaw
President

516

Submitter : Dr. Peter Angood

Date: 06/24/2005

Organization : Society of Critical Care Medicine

Category : Health Care Professional or Association

Issue Areas/Comments

Issues

DRG Reclassifications

Need new Sepsis DRGs, Section II.B.7. See attachment.

CMS-1500-P-844-Attach-1.PDF

CMS-1500-P-844-Attach-2.DOC

DRG/GEN

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

ATTACHMENT 1 TO # 844

Epidemiology of severe sepsis in the United States: Analysis of incidence, outcome, and associated costs of care

Derek C. Angus, MD, MPH, FCCM; Walter T. Linde-Zwirble; Jeffrey Lidicker, MA; Gilles Clermont, MD; Joseph Carcillo, MD; Michael R. Pinsky, MD, FCCM

Objective: To determine the incidence, cost, and outcome of severe sepsis in the United States.

Design: Observational cohort study.

Setting: All nonfederal hospitals (n = 847) in seven U.S. states.

Patients: All patients (n = 192,980) meeting criteria for severe sepsis based on the International Classification of Diseases, Ninth Revision, Clinical Modification.

Interventions: None.

Measurements and Main Results: We linked all 1995 state hospital discharge records (n = 6,621,559) from seven large states with population and hospital data from the U.S. Census, the Centers for Disease Control, the Health Care Financing Administration, and the American Hospital Association. We defined severe sepsis as documented infection and acute organ dysfunction using criteria based on the International Classification of Diseases, Ninth Revision, Clinical Modification. We validated these criteria against prospective clinical and physiologic criteria in a subset of five hospitals. We generated national age- and gender-adjusted estimates of incidence, cost, and outcome. We identified 192,980 cases, yielding national estimates of 751,000 cases (3.0 cases per 1,000 population and 2.26 cases per 100 hospital discharges), of whom 383,000 (51.1%) received intensive care and an additional 130,000 (17.3%) were ventilated in an intermediate care unit or cared for in a coronary care unit. Incidence increased >100-fold with age (0.2/1,000 in children to 26.2/1,000 in those >85 yrs old). Mortality was 28.6%, or 215,000 deaths nationally, and also increased with age, from 10% in children to 38.4% in those >85 yrs old. Women had lower age-specific incidence and mortality, but the difference in mortality was explained by differences in underlying disease and the site of infection. The average costs per case were $22,100, with annual total costs of $16.7 billion nationally. Costs were higher in infants, nonsurvivors, intensive care unit patients, surgical patients, and patients with more organ failure. The incidence was projected to increase by 1.5% per annum.

Conclusions: Severe sepsis is a common, expensive, and frequently fatal condition, with as many deaths annually as those from acute myocardial infarction. It is especially common in the elderly and is likely to increase substantially as the U.S. population ages. (Crit Care Med 2001; 29:1303–1310)

KEY WORDS: sepsis; severe sepsis; sepsis syndrome; organ failure; intensive care; outcome; resource use; mortality; elderly; epidemiology

Sepsis is a major challenge in medicine. Massive resources have been invested in developing and evaluating potential therapies, and considerable effort has been undertaken to understand the systemic inflammation and multiple-system organ failure characteristics of severe sepsis (1, 2). Yet, information on the incidence, cost, and outcome of sepsis remains scarce and incomplete. In 1990, the Centers for Disease Control (CDC) estimated that there were 450,000 cases of sepsis per year in the United States, with >100,000 deaths (3). The CDC warned that the incidence was increasing, citing the aging of the U.S. population and the increased prevalence of human immunodeficiency virus (HIV) infection as contributing factors. However, the CDC study counted cases of septicemia, not severe sepsis, which often occurs in patients without positive blood cultures (4–6). Furthermore, this study was based on data from the National Hospital Discharge Survey that are >10 yrs old, provide no information on patient management, and represent only 1% of all hospital discharges.

In 1992, the American College of Chest Physicians/Society of Critical Care Medicine (ACCP/SCCM) Consensus Conference arrived at the current definition of sepsis as a systemic inflammatory syndrome in response to infection which, when associated with acute organ dysfunction such as acute renal failure, is said to be severe (7). These criteria have been adopted widely both in clinical practice and in research. However, there have only been two epidemiologic studies in the United States that used these criteria. One was a single-center study (8), and the other included only eight academic medical centers (9). Neither study included children or provided information on population incidence or costs of care. Therefore, we conducted a study of a large, nationally representative sample to determine estimates of the incidence, associated costs, and outcome of severe sepsis in the United States.

METHODS

Data Sources. We constructed a patient database for calendar year 1995 from seven state hospital discharge databases—Florida (10), Maryland (11), Massachusetts (12), New Jersey (13), New York (14), Virginia (15), and Washington (16). We selected these states

From the Critical Care Medicine Division, Department of Anesthesiology and Critical Care Medicine, and the Center for Research on Health Care (DCA, GC, JC, MRP), University of Pittsburgh, Pittsburgh, PA; and Health Process Management (WTL-Z, JL), Inc., Doylestown, PA.

Address requests for reprints to: Derek C. Angus, MD, MPH, FCCM, Room 604 Scaife Hall, Critical Care Medicine, University of Pittsburgh, 200 Lothrop Street, Pittsburgh, PA 15213. Email: angusdc@anes.upmc.edu

based on their geographic representation, data quality and availability, and inclusion of centers in which we could assess the validity of our selection criteria for severe sepsis. For each case, we extracted the following: demographic characteristics; International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes for principal discharge diagnosis, ≤14 secondary discharge diagnoses and 15 procedures; hospital discharge status; and selected charge items, listed by both units consumed and dollars charged using the major Health Care Financing Administration (HCFA) UB-92 code categories.

We obtained national and state population data from the U.S. Census (17). The seven-state population in 1995 was 63,497,167, or 25% of the U.S. population. Because the U.S. Census does not report separately the number of infants <1 yr of age, we also obtained the National Center for Health Statistics 1995 natality report (18). We determined hospital characteristics from the 1995 HCFA Provider Specific File (19) and the American Hospital Association (AHA) Guide to the Health Care Field (20).

Case Selection and Definitions. To identify cases with severe sepsis, we selected all acute care hospitalizations with ICD-9-CM codes for both a bacterial or fungal infectious process (Appendix 1) and a diagnosis of acute organ dysfunction (Appendix 2). Classifying acute organ dysfunction is controversial with debate over the choice of measurements and the number of systems to measure. We constructed our system by selecting ICD-9-CM codes suggestive of new onset dysfunction within the six organ systems proposed by Marshall et al. (21) and used by Sands et al (9). We excluded gastrointestinal failure (other than hepatic failure) because it is difficult to define (21, 22).

We organized patient data under the following categories: demographic; infectious etiology; presence of underlying comorbidity, as determined by a Charlson-Deyo score >0 (23); resource use, which included intensive care unit (ICU) use and length of stay (LOS), hospital LOS, and total hospital costs; and hospital mortality. We estimated costs by multiplying reported charges by the hospital-specific cost-to-charge ratios derived from the HCFA Provider Specific File (19). We defined cases as surgical if they had a major surgical procedure other than tracheostomy.

Comparison of ICD-9-CM Selection Criteria to Standard Clinical and Physiologic Criteria for the Definition of Severe Sepsis. Sands et al. (9) prospectively identified a stratified random sample of patients with severe sepsis at eight academic medical centers during 1993 and 1994 using the ACCP/SCCM Consensus clinical and physiologic criteria (7). Our study included 1995 data from five of the eight hospitals. Although Sands et al. (9) did not report individual hospital data by hospital name, we were able to compare aggregate data regarding hospital incidence rates and several patient characteristics to determine the extent to which our ICD-9-CM-based selection criteria identified a similar cohort.

Statistical Analyses. We compared continuous data by the Mann-Whitney U test and categorical data by chi-square or Fisher's exact test as appropriate. We assessed risk factors for hospital mortality by multivariate logistic regression with sequential sum of squares. We generated national estimates using the cohort age- and gender-specific rates. We constructed the databases in Foxpro (Microsoft Corp, Redmond, WA) and conducted analyses in Data Desk (Data Description, Ithaca, NY) and SAS (SAS Institute, Cary, NC).

RESULTS

Comparison of Study Selection Criteria With Prospective Clinical and Physiologic Criteria. Table 1 provides comparative data on the cohort of patients selected by ICD-9-CM criteria with those identified previously by Sands et al (9). Although the ICD-9-CM criteria generated higher occurrence rates, the Sands et al. cohort did not include any floor patients without blood cultures. Baseline and process of care characteristics were very similar between the two groups. In particular, there were no statistical differences in age, gender, ICU occurrence, and ICU admission rates between the cohorts. The distribution of site of infection was statistically different but clinically very similar.

Incidence. Of the 6,621,559 hospitalizations recorded in the seven states, we identified 192,980 cases of severe sepsis. The mean age was 63.8 yrs, and 49.6%

Table 1. Comparison of validation and reference cohorts

Characteristic	Validation Cohort (n = 3,895)	Reference Cohort (n = 1,342)[a]	*p* Value
Study period	Jan 1995–Dec 1995	Jan 1993–Apr 1994	
Sampling frame	All patients identified at five of eight hospitals using ICD-9-CM criteria	Stratified sample of ICU patients and floor patients in whom blood cultures were drawn at eight hospitals using prospective clinical and physiologic criteria (9)	
Hospital occurrence rates per 100 discharges	2.1–4.3	1.1–3.3[b]	
ICU occurrence rate, %	11.2	10.4	.06
Male, %	53	56	.06
Age, mean, median yrs[c]	59, 62	59, 61	
Site of infection, %			
Respiratory	38.4	42.4	.01
Primary bacteremia	14.6	11.6	.01
Genitourinary	8.7	11.0	.01
Abdominal	9.3	9.9	.51
Device-related	4.9	6.1	.09
Wound/soft tissue	8.9	5.1	<.001
Central nervous system	1.1	2.4	<.001
Endocarditis	1.5	1.2	.43
Other/undetermined	12.6	10.3	.02
ICU admission rate, %	58	59	.52
ICU LOS, mean, median days[c]	15.7,7	17.7,8	

ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; ICU, intensive care unit; LOS, length of stay.

[a]Sands et al. (9) described their cohort as having "confirmed sepsis syndrome." However, their criteria are the American College of Chest Physicians/Society of Critical Care Medicine criteria for severe sepsis (7) and consist of signs of infection plus organ failure; [b]The 95% confidence interval across sites ranged from 1.0 to 4.1; [c]We could not test for differences in age or ICU LOS because we only had the measures of central tendency and not the actual distributions of these variables for the Sands et al. cohort.

Table 2. Characteristics of study cohort (n = 192,980)

Characteristic	Occurrence, %	Mortality, %
Underlying comorbidity		
Chronic obstructive pulmonary disease	12.3	32.1
Neoplasm (nonmetastatic)	11.6	36.9
HIV disease	6.3	34.0
Chronic liver disease	4.5	37.1
Chronic renal disease	5.4	36.7
Neoplasm (metastatic)	5.3	43.4
Complicated diabetes	3.2	24.0
Peripheral vascular disease	3.1	30.9
Autoimmune disease	1.5	23.5
Any underlying comorbidity	55.5	31.8
Acute organ dysfunction		
Number of systems		
1	73.6	21.2
2	20.7	44.3
3	4.7	64.5
≥4	1.0	76.2
Organ system		
Respiratory	45.8	40.1
Cardiovascular	24.4	32.4
Renal	22.0	38.2
Hematologic	20.6	22.8
Central nervous system	9.3	24.4
Hepatic	1.3	54.3
Site of infection		
Respiratory	44.0	32.9
Bacteremia, site unspecified	17.3	41.2
Genitourinary	9.1	16.1
Abdominal	8.6	19.5
Wound/soft tissue	6.6	20.6
Device-related	2.2	18.1
Central nervous system	0.8	29.5
Endocarditis	0.6	33.1
Other/unspecified	10.8	15.4
ICU admission	51.1	34.1
Medical condition	71.4	29.2
Surgical condition	28.6	26.2

HIV, human immunodeficiency virus; ICU, intensive care unit.

were male. Descriptive characteristics are provided in Table 2. After we adjusted for age and gender, the national incidence rate was 3.0 cases per 1,000 population (2.26 cases per 100 hospital discharges). This produced a national estimate of 751,000 cases per annum, of which 416,700 (55.5%) had underlying comorbidity and 160,700 (21.4%) were surgical. Overall, 383,000 (51.1%) received ICU care. An additional 84,000 (11.1%) received care in a coronary care unit, and 46,000 (6.2%) were ventilated in an intermediate care unit but never received ICU care.

The number of cases and incidence rates by age are shown in Figure 1. The incidence was high in infants (5.3/1,000 aged <1 yr), decreased quickly in older children (0.2/1,000 aged 5–14 yrs), increased slowly through most of adulthood (5.3/1,000 aged 60–64 yrs), and increased sharply in the elderly (26.2/1,000 aged ≥85 yrs). The number of cases also increased with age, although the peak was earlier, such that more than half of patients were ≥65 yrs (437,400, 58.3%) and more than one third were ≥5 yrs (274,000, 36.6%). There was also a "bump" in the number of young adults attributable to patients with HIV-related conditions (n = 47,200, average age 38.5 yrs).

Excluding patients with HIV disease, the overall incidence rate for women was similar to that of men (2.87 vs. 2.83 cases per 1,000 population). However, the age-specific incidence rate was lower in women than in men such that, from age 30 onward, women had a rate similar to that of men 5 yrs younger (Fig. 2). Women were more likely to have genitourinary infections (11.8 vs. 6.3%, $p <$ .0001) and less likely to have respiratory infections (39.9 vs. 48.1%, $p <$ .0001) but otherwise had a similar distribution of sites of infection.

Mortality. The overall hospital mortality rate was 28.6%, which represents 215,000 deaths nationally. Mortality rates were higher for patients with preexisting disease, medical conditions, ICU care, and more organ failure (Table 2). Mortality increased with age from 10% in children to 38.4% in those ≥85 yrs (Fig. 3). This trend was most obvious in those without underlying comorbidity. For patients with underlying comorbidity, mortality was much higher and changed little throughout most of adulthood.

There was no gender difference in mortality in children, but the mortality rate for men was slightly higher than for women (29.3 vs. 27.9%, $p <$ .0001). The widest difference (20.9 vs. 13.9%, $p <$ .0001) occurred in those 25–30 yrs of age, but the effect was observed throughout adulthood. Excluding HIV cases, mortality rates for women aged ≥30 yrs, like the incidence rates, were similar to that of men 5 yrs younger (Fig. 2). In multivariate regression, these differences were explained by differences in age, underlying comorbidity, and site of infection. In other words, although the chances of developing sepsis differed for men and women by age, the likelihood of dying from sepsis was the same for men and women after adjusting for age, underlying comorbidity, and site of infection.

Hospital Resource Use and Costs. The average LOS and cost per case were 19.6 days and $22,100. Nonsurvivors had a similar LOS (19.9 vs. 19.4 days, $p <$ .005) but cost considerably more ($25,900 vs. $20,600, $p <$ .0001) than survivors. ICU patients stayed longer (23.3 vs. 15.6 days, $p <$ .0001) and cost more ($29,900 vs. $13,900, $p <$ .0001) than non-ICU patients, and surgical patients stayed longer (24.0 vs. 18.3 days, $p <$ .0001) and cost more ($30,800 vs. $19,700, $p <$ .0001) than medical patients. Males stayed slightly longer (19.6 vs. 19.5 days, $p <$ .0001) and cost more ($23,000 vs. $21,200, $p <$ .0001) than females. LOS varied little with the number of organ systems in which acute dysfunction developed (range, 18.5–22.8 days), but average costs increased from $19,500 for those with acute dysfunction in one system to $32,800 for those with dysfunction in four or more systems.

Average and total costs by age are shown in Figure 4. Adult costs were generally stable around $21,000–25,000, except in the oldest patients ($14,600 for those aged ≥85 yrs). Infants were the most expensive, with an average cost of $54,300, whereas the average cost for patients aged 1–19 yrs was $28,000. ICU admission rates were generally high

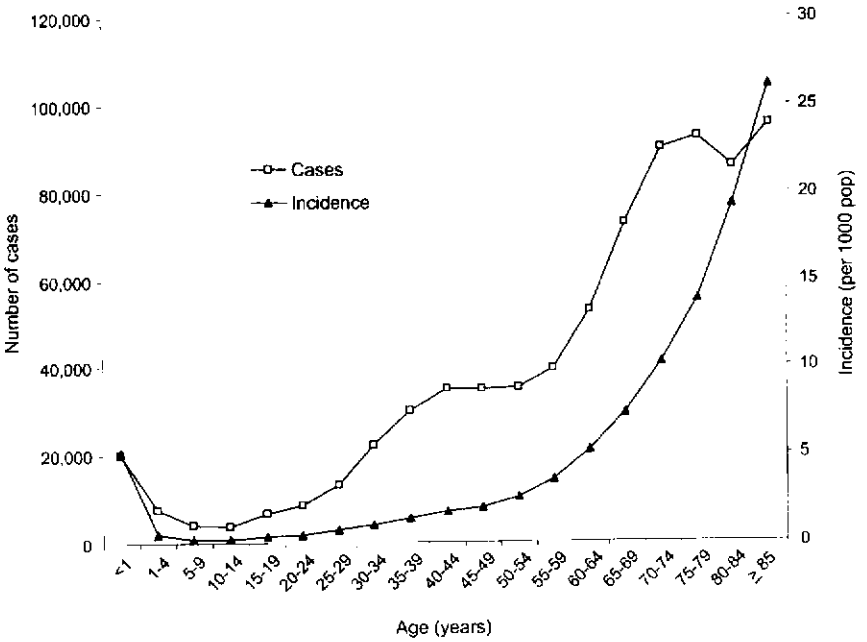


Figure 1. National age-specific number and incidence of cases of severe sepsis. National estimates are generated from the seven-state cohort using state and national age- and gender-specific population estimates from the National Center for Health Statistics and the U.S. Census. *pop*, population.

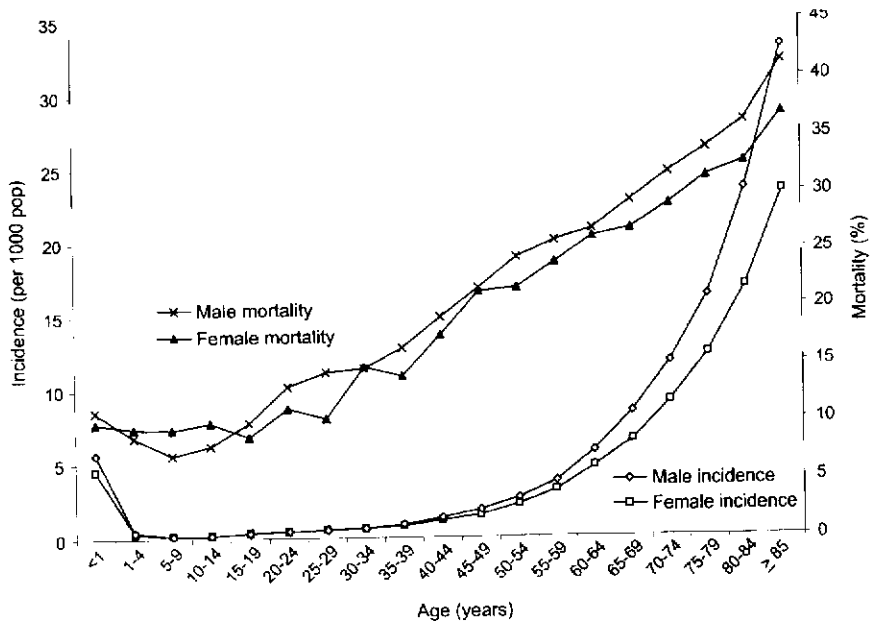


Figure 2. National age-specific incidence and mortality rates for all cases of severe sepsis by gender, excluding those with HIV disease. National estimates are generated from the seven-state cohort using state and national age-specific population estimates from the National Center for Health Statistics and the U.S. Census. The incidence among women was equivalent to that of men 5 yrs younger. A similar age-based difference was seen in mortality but, in multivariate regression, this difference was explained by underlying comorbidity and site of infection. *pop*, population.

across all ages but were highest in infants (58.2%) and lowest in adults aged 30–39 yrs (41.1%) and those aged ≥85 yrs (40%). Of note, patients with HIV disease had a much lower ICU admission rate (26.0%), partially explaining the lower ICU admission rates in those aged 30–39 yrs.

The total national hospital cost associated with the care of patients who incurred severe sepsis was $16.7 billion. The costs of care for patients aged <1 yr and 1–19 yrs were $1.1 billion and $622 million, representing 6.6% and 3.7% of the total costs. The costs of care for patients aged ≥65 and ≥75 yrs were $8.7 billion and $5.1 billion, representing 52.3% and 30.8% of the total costs.

Comparison of Teaching to Nonteaching Hospitals. There were 847 hospitals in our data set, of which 84 (9.9%) were teaching institutions. About one fourth of all cases were managed at these teaching hospitals (Table 3). Patients at teaching hospitals were younger, more likely to have HIV disease, and less likely to have chronic obstructive pulmonary disease but otherwise had similar comorbidity, ICU use, and mortality. Both costs and LOS were considerably higher at teaching hospitals. Higher costs and longer LOS also were incurred in larger hospitals when we stratified hospitals by the number of beds (data not shown).

Population-Based Projections of the Future National Occurrence of Sepsis. Assuming only the U.S. Census-projected changes in the population, we estimated the number of cases to increase steadily at 1.5% per annum, yielding 934,000 and 1,110,000 cases by the years 2010 and 2020. This increase is faster than the anticipated population growth and is attributable to the high incidence of sepsis in older patients and the disproportionate growth of the elderly in the U.S. population.

DISCUSSION

We found that severe sepsis is very common, consumes considerable healthcare resources, and is associated with a high mortality rate. The 215,000 deaths we estimated were 9.3% of all deaths in the United States in 1995 and equaled the number of deaths after acute myocardial infarction (24). Although many of the deaths after sepsis may not be caused by sepsis, the magnitude of our national estimates underscores the importance of sepsis as a major health problem.

Our overall hospital mortality rate of almost 30% was typical of most prior sepsis studies, but the rate was much lower in children and previously healthy adults. Pediatric and adult sepsis populations have not been studied together before, but a recent study of pneumococcal bacteremia also demonstrated wide variation in mortality from 3.2% in children to 43% in the elderly (25). Such variation raises the possibilities that the attribut-

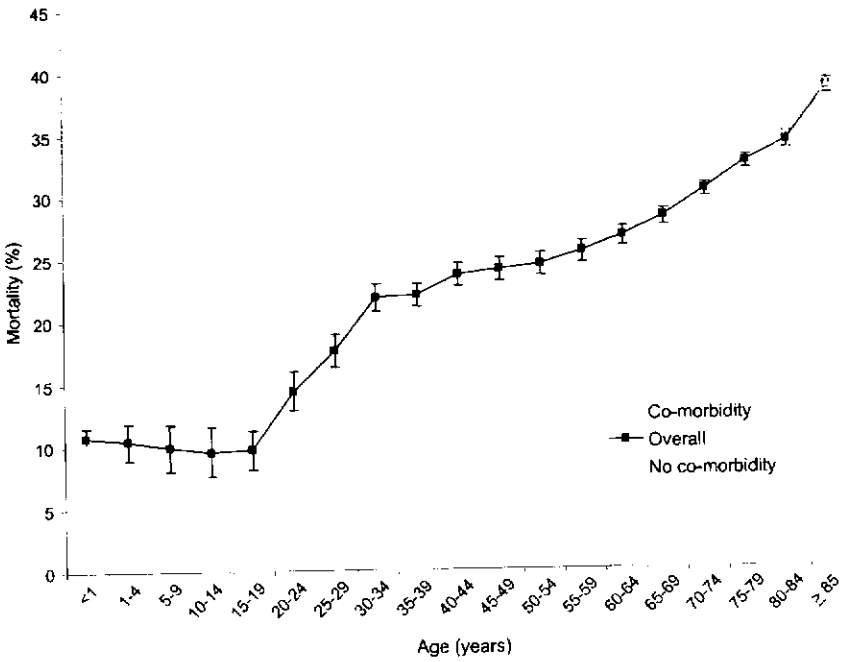


Figure 3. National age-specific mortality rates for all cases of severe sepsis and for those with and without underlying comorbidity. Comorbidity is defined as a Charlson-Deyo score (23) >0. National estimates are generated from the seven-state cohort using state and national age- and gender-specific population estimates from the National Center for Health Statistics and the U.S. Census. Error bars represent 95% confidence intervals.

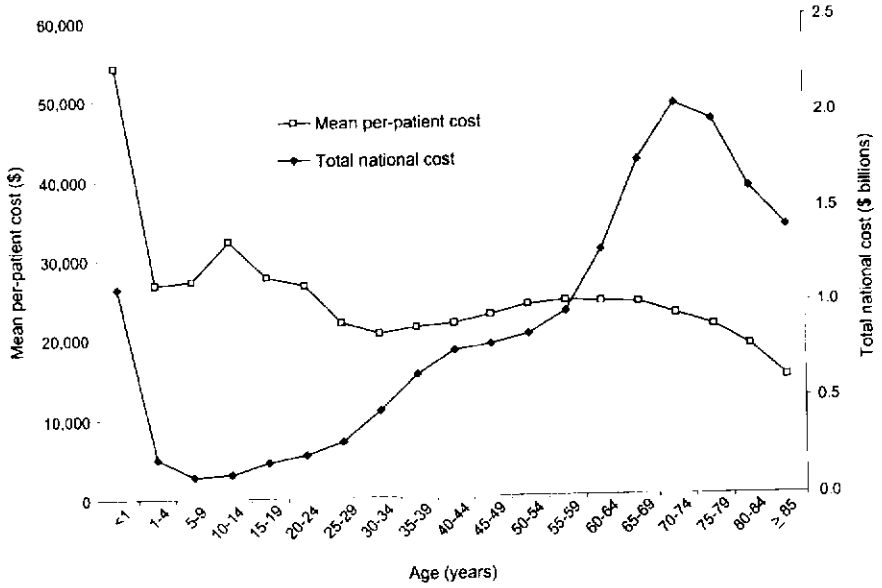


Figure 4. National age-specific average and total hospital costs for severe sepsis. Costs are calculated by multiplying total hospital charges by the hospital-specific cost-to-charge ratio derived from the Health Care Financing Administration Provider Specific File (19). All costs are expressed as 1995 U.S. dollars. National estimates are generated from the seven-state cohort using state and national age- and gender-specific population estimates from the National Center for Health Statistics and the U.S. Census.

able mortality of sepsis may be much less than the commonly observed 30% and that the mechanism by which sepsis causes death is highly dependent on individual patient factors, many of which may not be reversible by single antisepsis agents. This potential for an attributable mortality much lower than 30% supports the argument that many recent trials of antisepsis agents were underpowered, designed only to find unrealistically large effect sizes (26).

Clinical trials of antisepsis agents often exclude the very elderly, patients with HIV disease, and patients with malignancy. This is because these patients are believed to be at higher risk of death, as confirmed by our data, and less likely to respond to treatment. The conventional wisdom also may have been that such patients are rare. However, we found that these patients are a large proportion of the sepsis population, and their exclusion will compromise the external validity, or representativeness, of these trials. Because new antisepsis therapies may well be expensive to use (27), a full understanding of their effectiveness and cost-effectiveness in different patient populations is essential.

Beyond the implications for clinical trials, our observation that sepsis is a disease of the elderly also mandates consideration of the appropriateness of care, including determination of patient preferences. Our data suggest that there are already differences in the aggressiveness of treatment in this group, with lower length of stay, ICU use, and hospital costs in those aged >85 yrs. Yet, aggressive care is not futile in the elderly, and the majority survive to hospital discharge. Unfortunately, there are limited data on the subsequent survival (28) or quality of life (29) after sepsis, especially in the elderly. Such information will be crucial in determining optimal healthcare policy as the U.S. population ages and the number of cases of sepsis increases. There also may be other important trends over time. The large proportion of cases related to HIV may change over time. There is hope that the incidence of HIV infection will continue to decrease, but, with new therapies prolonging survival, prevalence will likely increase. Forecasting the consequences for severe sepsis will be difficult, and we recommend continued follow-up.

Several recent studies have suggested that gender, perhaps through differences in sex hormones (30–32), may be an important risk factor for adverse outcome in infection and sepsis. However, some studies found that women fared better (30, 31) whereas others found the opposite (32). We found that women did have lower age-adjusted severe sepsis rates, mainly attributable to fewer episodes of respiratory origin. We do not know, however, whether this represents a difference in the distribution of risk factors, such as chronic obstructive pulmonary disease, or a difference in access to care. We also found that mortality was lower in women

Table 3. Comparison of teaching[a] to nonteaching hospitals

Characteristic	Teaching[b]	Nonteaching
n (% of total)	53,089 (27.5)	139,891 (72.5)
Age, mean, median yrs	57.0, 63	66.5, 72
Gender, % male	51.9	48.8
Average number of organ systems with acute dysfunction	1.35	1.33
Comorbidity		
Charlson-Deyo index >0, %	55.0	55.7
Chronic obstructive pulmonary disease, %	7.8	13.9
HIV disease, %	10.1	4.9
Resource use		
Hospital LOS, mean ± SD, median	24.1 ± 33.4, 15	17.6 ± 32.4, 11
Hospital cost, mean ± SD, median U.S. $1,000	30.6 ± 40.7, 17.3	18.4 ± 27.7, 10.4
ICU admission rate, %	51.8	50.8
ICU LOS, mean ± SD, median	13.8 ± 20.0, 7	10.0 ± 13.8, 6
Hospital LOS for ICU patients, mean ± SD, median	28 ± 36.9, 19	20.8 ± 34.4, 14
Hospital cost for ICU patients, mean ± SD, median U.S. $1,000	42.1 ± 47.1, 27.6	24.6 ± 31.3, 15.7
Hospital mortality, %	29.7	28.1

HIV, human immunodeficiency virus; LOS, length of stay; ICU, intensive care unit.

[a]Teaching defined as member of the Council of Teaching Hospitals, derived from the American Hospital Association 1995 Guide to the Health Care Field (20); [b]All variables were statistically significantly different between teaching and nonteaching hospitals ($p < .0001$) with the exception of the Charlson-Deyo index >0.

We believe that this study highlights a variety of epidemiologic and health services research issues that remain poorly understood, including optimal delivery of care for vulnerable and elderly populations.

but that this was explained by differences in age, comorbidity, and site of infection. The gender differences we observed were consistent throughout adulthood, with no obvious link to menopause, suggesting that the differences are not solely mediated through sex hormones. Thus, we recommend that future research on gender differences in sepsis focus on understanding the processes that lead to the site and type of infection and on understanding whether there are systematic differences in healthcare access and delivery.

There is limited information on the hospital costs and resource use associated with the care of septic patients. Chalfin et al. (33) analyzed 1,405 patients at a teaching hospital and estimated mean total charges of $38,304 in survivors and $49,182 in nonsurvivors. When we adjust for inflation and use an average cost-to-charge ratio, these estimates are consistent with our findings for costs at teaching hospitals. Costs of care appear lower at nonteaching hospitals, attributable presumably to differences in case-mix, differences in care, such as the costs of teaching, or both. Perhaps contrary to clinical intuition, we found that many patients with sepsis did not receive ICU care. This observation was also made by others (8, 9). Whether such patients would have benefited from ICU care is unclear, and it is possible that the ACCP/SCCM definition for severe sepsis, intended for ICU patients, selects different types of patients on the hospital floor.

The major limitations of our study relate to the use of administrative data to define sepsis. We selected states from the West, Northeast, Midatlantic, and Southeast regions. Although these regions represent the most heavily populated areas of the United States, we did not have representation from the Midwest or Southwest. Unfortunately, there are no statewide hospital databases from these regions with the appropriate level of detail and quality for this study. However, when generating national estimates, we adjusted for differences in population distribution between the seven-state cohort and the entire country, and we do not anticipate that additional data from the Midwest or Southwest would have altered any of our national estimates substantially. We used data from 1995, the last full year for which data were available from all seven states when we began the study. There have been no significant changes in the management of sepsis since that time, and therefore, other than the 1.5% annual increase in incidence with the aging of the population, we believe our estimates reflect current practice.

We could only identify sepsis by using ICD-9-CM codes, rather than clinical and physiologic measurements. The data set was not designed primarily for research and consequently did not necessarily have the same level of data auditing and quality that might be expected in a prospective study. Although our definition combined infection with organ dysfunction within the same admission, the time overlap was not as tight as in clinical trials, which usually specify an overlap of infection and organ failure within a time window of 12–72 hrs, depending on the study. Our definition of severe sepsis also could be considered more inclusive than others (e.g., a patient with bacterial pneumonia would be considered to have severe sepsis if mechanical ventilation was required). Finally, both the hospital costs and mortality rates are all-cause estimates and not the attributable costs or mortality rates of sepsis. Thus, preventing sepsis altogether would only diminish, and not extinguish, these costs and deaths. At the same time, our estimates do not include costs or mortality rates after hospital discharge. There is evidence that hospital survivors of severe sepsis remain at considerably increased risk of death compared with nonseptic controls (28).

Despite these limitations, our approach captured patients similar to those identified using more rigorous prospective screening criteria. In addition to the close comparison with Sands et al. (9), our findings with regard to site of infection, ICU use, and hospital mortality are also very similar to the other U.S. study, by Rangel-Frausto et al. (8) We believe the comparison of our ICD-9-CM coding scheme to the prospective criteria was a strength of this study. However, the validity of our approach could have been verified further if the comparison cohort

included children and if detailed chart review had been possible.

In conclusion, we found that severe sepsis is a common, frequently fatal, and expensive condition. It is especially common in the elderly and is likely to increase substantially in the coming years as the U.S. population ages. Although we applaud the continued search for effective antisepsis drugs, we also encourage attention to other aspects of care. In particular, we believe that this study highlights a variety of epidemiologic and health services research issues that remain poorly understood, including optimal delivery of care for vulnerable and elderly populations.

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APPENDIX 1

ICD-9-CM Codes Used to Identify a Bacterial or Fungal Infection

001, Cholera; 002, Typhoid/paratyphoid fever; 003, Other salmonella infection; 004, Shigellosis; 005, Other food poisoning; 008, Intestinal infection not otherwise classified; 009, Ill-defined intestinal infection; 010, Primary tuberculosis infection; 011, Pulmonary tuberculosis; 012, Other respiratory tuberculosis; 013, Central nervous system tuberculosis; 014, Intestinal tuberculosis; 015, Tuberculosis of bone and joint; 016, Genitourinary tuberculosis; 017, Tuberculosis not otherwise classified; 018, Miliary tuberculosis; 020, Plague; 021, Tularemia; 022, Anthrax; 023, Brucellosis; 024, Glanders; 025, Melioidosis; 026, Rat-bite fever; 027, Other bacterial zoonoses; 030, Leprosy; 031, Other mycobacterial disease; 032, Diphtheria; 033, Whooping cough; 034, Streptococcal throat/scarlet fever;

035, Erysipelas; 036, Meningococcal infection; 037, Tetanus; 038, Septicemia; 039, Actinomycotic infections; 040, Other bacterial diseases; 041, Bacterial infection in other diseases not otherwise specified; 090, Congenital syphilis; 091, Early symptomatic syphilis; 092, Early syphilis latent; 093, Cardiovascular syphilis; 094, Neurosyphilis; 095, Other late symptomatic syphilis; 096, Late syphilis latent; 097, Other and unspecified syphilis; 098, Gonococcal infections; 100, Leptospirosis; 101, Vincent's angina; 102, Yaws; 103, Pinta; 104, Other spirochetal infection; 110, Dermatophytosis; 111, Dermatomycosis not otherwise classified or specified; 112, Candidiasis; 114, Coccidioidomycosis; 115, Histoplasmosis; 116, Blastomycotic infection; 117, Other mycoses; 118, Opportunistic mycoses; 320, Bacterial meningitis; 322, Meningitis, unspecified; 324, Central nervous system abscess; 325, Phlebitis of intracranial sinus; 420, Acute pericarditis; 421, Acute or subacute endocarditis; 451, Thrombophlebitis; 461, Acute sinusitis; 462, Acute pharyngitis; 463, Acute tonsillitis; 464, Acute laryngitis/tracheitis; 465, Acute upper respiratory infection of multiple sites/not otherwise specified; 481, Pneumococcal pneumonia; 482, Other bacterial pneumonia; 485, Bronchopneumonia with organism not otherwise specified; 486, Pneumonia, organism not otherwise specified; 491.21, Acute exacerbation of obstructive chronic bronchitis; 494, Bronchiectasis; 510, Empyema; 513, Lung/mediastinum abscess; 540, Acute appendicitis; 541, Appendicitis not otherwise specified; 542, Other appendicitis; 562.01, Diverticulitis of small intestine without hemorrhage; 562.03, Diverticulitis of small intestine with hemorrhage; 562.11, Diverticulitis of colon without hemorrhage; 562.13, Diverticulitis of colon with hemorrhage; 566, Anal and rectal abscess; 567, Peritonitis; 569.5, Intestinal abscess; 569.83, Perforation of intestine; 572.0, Abscess of liver; 572.1, Portal pyemia; 575.0, Acute cholecystitis; 590, Kidney infection; 597, Urethritis/urethral syndrome; 599.0, Urinary tract infection not otherwise specified; 601, Prostatic inflammation; 614, Female pelvic inflammation disease; 615, Uterine inflammatory disease; 616, Other female genital inflammation; 681, Cellulitis, finger/toe; 682, Other cellulitis or abscess; 683, Acute lymphadenitis; 686, Other local skin infection; 711.0, Pyogenic arthritis; 730, Osteomyelitis; 790.7, Bacteremia; 996.6, Infection or inflammation of device/graft; 998.5, Postoperative infection; 999.3, Infectious complication of medical care not otherwise classified.

Where 3- or 4-digit codes are listed, all associated subcodes were included. There were 1,286 distinct infection codes in our schema. Of these, only 642 codes were detected in the sample. Among the 642 codes, 225 codes accounted for 99% of the sample and 68 codes accounted for 90%.

Appendix 2. ICD-9-CM-based classification of acute organ dysfunction

Organ System	ICD-9-CM Code Description	ICD-9-CM Code[a]
Cardiovascular	Shock without trauma	785.5
	Hypotension	458
Respiratory	Mechanical ventilation[a]	96.7
Neurologic	Encephalopathy	348.3
	Transient organic psychosis	293
	Anoxic brain damage	348.1
Hematologic	Secondary thrombocytopenia	287.4
	Thrombocytopenia, unspecified	287.5
	Other/unspecified coagulation defect	286.9
	Defibrination syndrome	286.6
Hepatic	Acute and subacute necrosis of liver	570
	Hepatic infarction	573.4
Renal	Acute renal failure	584

ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.
[a]Where 3- or 4-digit codes are listed, all associated subcodes were included.

Attachment 2 to #844

701 Lee Street
Suite 200
Des Plaines, IL 60016

Society of
Critical Care Medicine
The Intensive Care Professionals

Telephone (Main Switchboard): (847) 827-6869
Fax: (847) 827-6886
www.sccm.org

June 24, 2005

BY ELECTRONIC SUBMISSION

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 443-G
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; CMS-1500-P; Section II.B.7 MDC 18 (Infectious and Parasitic Diseases (Systemic or Unspecified Sites)): Severe Sepsis

Dear Administrator McClellan:

The Society of Critical Care Medicine (SCCM) appreciates this opportunity to submit comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule concerning changes to the hospital inpatient prospective payment system for fiscal year 2006, as published in the May 14, 2005 *Federal Register* (70 *Fed. Reg.* 23305). Specifically, SCCM is commenting only on CMS' failure to create new DRGs for severe sepsis, Section II.B.7 of the proposed rule.

SCCM is the only professional society devoted exclusively to the advancement of multidisciplinary, multi-professional, intensive care through promoting excellence in patient care, education, research, and advocacy. Our 12,000 members include a diverse group of highly trained professionals who provide care in specialized care units and work toward the best outcome possible for seriously ill patients.

Members of SCCM are keenly aware of the significant challenge that severe sepsis presents to the US health care system. The mortality rate for patients with severe sepsis remains between 25-30%, and the cost per patient is substantial.

CMS in the proposed rule appears to agree, as it stated "we recognize that Medicare beneficiaries with severe sepsis are quite ill and require extensive hospital resources." See p. 23330. CMS recognizes this fact but then does not address the issue. CMS claims incorrectly that there is not a current definition of severe sepsis that is specific enough to identify a meaningful cohort of patients in terms of clinical coherence and resource utilization to warrant a separate DRG.

However, there is a well accepted published definition of severe sepsis created through consensus, and we urge the agency to carefully examine the data we present using this definition. We believe that these data show very clearly that there in fact should be two new DRGs created for severe sepsis, and there is a mechanism to identify the

cases that belong in these two new DRGs. Further, these DRGs would be very coherent in terms of clinical condition and resource utilization.

As reported in the Critical Care Medicine article 1/ attached, there is a consensus definition of severe sepsis. In 1992, the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference arrived at the definition that is still used today. Severe sepsis is a systemic inflammatory syndrome in response to infection which is associated with acute organ dysfunction. From a DRG coding perspective, one approach that CMS should consider would be to combine the diagnosis codes for infection plus organ dysfunction, with an ICD-9 procedure code for organ support, such as ventilation management (96.7x), acute renal replacement (39.95, 54.98), or vasopressor support (00.17) 2/

Through a consultant, we have reviewed the FY 2003 inpatient prospective payment system (IPPS) data using this definition of severe sepsis. In sum, we found 250,162 cases of severe sepsis with organ support (SSOS) out of a total 10,965,953 cases or 2.3%. Deaths totaled 92,814 with SSOS out of a total 482,964 or almost one in five of the Medicare patients who died in the hospital in FY 2003 had severe sepsis with organ support. The cost to care for these patients with SSOS was $10 billion out of a total cost of $112.5 billion or 8.9%. Of the total outlier cost of $4.51 billion, SSOS patients accounted for $1.6 billion or 35.5%.

In examining the data, it appears that the SSOS cases fall into two distinct categories – SSOS medical cases and SSOS surgical, with the SSOS surgical cases costing almost twice as much as the SSOS medical cases. There is, however, coherence within these two groups both clinically and with respect to resource utilization. Therefore, SCCM is recommending that two new DRGs be created for severe sepsis – one for medical severe sepsis with organ support and another for surgical severe sepsis with organ support.

CMS is correct that utilizing the above definition for severe sepsis requiring organ support would draw cases that currently fall into hundreds of DRGs. However, the vast majority of the medical SSOS cases (82.5%) fall into just 10 different DRGs and most of the surgical SSOS cases (70.8%) fall into another 10 DRGs. Moreover, 43% of the SSOS patients from FY 2003 fall into just two DRGs – 475, respiratory diagnosis with ventilator management, and 483, tracheostomy 3/. Just as the current grouper logic considers the extreme cost of prolonged mechanical ventilation with a tracheotomy independent of whether this need was present at admission in assigning cases to DRGs 541 and 542 (the new replacements for DRG 483), the costs and complexity of managing SSOS cases are likewise so great and independent of severe sepsis being present ad admission, that the new DRGs should also be pre-MDC and not require a principal diagnosis of severe sepsis.

The mean cost of the SSOS cases in these two DRGs is similar to the mean cost for those DRGs overall. While DRGs 541 and 542 (the new DRGs for former DRG 483) are higher in the grouper logic than the proposed SSOS DRGs, thereby keeping many of the most expensive cases there, the need to look at both primary and secondary diagnoses for severe sepsis necessitates that the SSOS DRGs be pre-MDC. This would remove many cases from DRG 475, even though they are currently adequately paid there.

1/ D.C. Angus et al., Epidemiology of Severe Sepsis in the United States: Analysis of Incidence, Outcome, and Associated Costs of Care, 29 Critical Care Medicine 1303-10 (2001)

2/ The ICD-9 code for vasopressor support was effective only on October 1, 2004. Therefore, in reviewing the 2003 MedPar data that is discussed later in these comments, we used the ICD-9 code for shock and an ICU length of stay of one or more days as a proxy for vasopressor support.

3/ We note that since FY 2003, DRG 483 has been split into two new DRGs, 541 and 542. We recommend that cases of SSOS that also track into DRGs 541 remain in that DRG.

Top 10 Medical SSOS DRGs FY 2003

DRG	Description	Cases	Mean Cost	SSOS Cases	SSOS Mean Cost
475	Respiratory Diag with Vent	102,208	$24,931	80,541	$26,759
416	Septicemia Age >17	194,869	$10,979	22,724	$21,303
127	Heart Failure & Shock	646,417	$7,709	8,402	$25,992
316	Renal Failure	139,345	$9,033	6,990	$24,084
121	Circ Dis w Ami & Maj Comp, Alive	150,474	$10,777	5,031	$26,387
123	Circ Dis w Ami & Maj Comp, Expir	34,326	$10,732	4,001	$22,695
014	Specific CV Disor Except Tia	225,174	$8,719	3,336	$27,717
144	Other Circ System Diag w CC	87,932	$8,821	2,556	$25,226
174	G.I. Hemorrhage w CC	242,657	$7,060	1,953	$26,260
320	Kidney & UT Infect Age > 17 w CC	197,418	$5,996	1,679	$18,859

Top 10 DRGs account for 82.5% of medical severe sepsis organ support cases.

Top 10 Surgical SSOS DRGs FY 2003

DRG	Description	Cases	Mean Cost	SSOS Cases	SSOS Mean Cost
483	Tracheostomy for w/mech. vent.	41,171	$109,603	26,404	$110,942
148	Maj Small & Lg Bowel Procs CC	126,952	$23,642	9,134	$45,595
468	Extensive or Proc Unrel Prin	49,559	$25,542	4,145	$50,203
415	OR Proc for Infect & Parasit	42,246	$25,653	5,749	$48,679
110	Maj Cardo Procedures w CC	51,066	$28,127	2,703	$53,879
076	Oth Resp System or Procs	42,810	$19,356	2,962	$48,200

DRG	Description	Cases	Mean Cost	SSOS Cases	SSOS Mean Cost
154	Stom, Esoph & Duod Procs	26,523	$28,863	2,485	$50,921
075	Major Chest Procedures	40,123	$21,587	2,057	$51,683
001	Crani Age >17 Except Trauma	29,957	$26,771	2,103	$51,165
478	Oth Vascular Procs w CC	101,627	$16,995	1,480	$47,429

Top 10 DRGs account for 70.8% of surgical severe sepsis organ support cases.

However, as the charts above show, the SSOS cases that fall into DRGs other than 475 and 483 are not at all similar in costs to the median cost of those DRGs. For example, for these medical SSOS cases, the median costs are more than twice as much as the median for the DRGs. A new DRG should be created for these medical SSOS cases, which reflects these much higher costs. This new DRG would be clinically coherent as including the medical SSOS cases and would be weighted to more accurately capture the increased resources required to treat these patients.

Similarly, for the surgical SSOS cases, the median costs are twice as much as the median for the DRGs. CMS should create a new DRG for these surgical SSOS cases. Again, this new DRG would be clinically coherent and would be weighted more appropriately to accurately capture the resources utilized.

Conclusion

In conclusion, contrary to the CMS position, SCCM believes that the agency can, indeed, identify cases of severe sepsis with organ support. The agency would have to look for a combination of ICD-9 codes and then place these cases into newly created DRGs. This process would be budget neutral, as the DRGs from which these cases are removed would have to be reweighted. This process would leave these current DRGs more clinically coherent, while also creating clinically coherent new DRGs.

Creation of these new DRGs would also facilitate better data collection and sharing regarding these cases. Effective care of the severely septic patient often spans multiple venues, including the ER, ICU, and stepdown units. Common approaches to care and information-dense handoffs are critical to obtaining a successful outcome. Best practices do exist and are continually being updated. Severe sepsis DRGs that accurately reflect these cases will lead to more streamlined care and the integration of multiple care processes, resulting in better care. Further, establishing severe sepsis DRGs will encourage institutions to carefully examine the costs and inefficiencies in current practice and will stimulate the types of trans-unit consensus approaches to management that appear to globally improve outcomes. This would seem to be well in-line with CMS' Pay4Performance objectives.

SCCM looks forward to working with CMS staff to implement a methodology that will track the severe sepsis cases and place them into more appropriate, new DRGs.

Respectfully submitted by,

Peter B. Angood, MD, FCCM
President
Society of Critical Care Medicine

Attachment (Critical Care Medicine article)

517

DRG/GEN

Submitter : Dr. Arthur Crumbley **Date:** 06/24/2005

Organization : Medical University of South Carolina

Category : Physician

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

With the introduction of the ABIOMED AB5000 ventricular assist system, patients presenting in cardiogenic shock have a much better outlook than previously. Many hospitals have the simpler BVS system and place patients with acute MIs, or failure to wean from cardiopulmonary bypass on this device. However successful support beyon 10-14 days is rare with the BVS. IN contrast, with the AB ventricles patients can become ambulatory and enjoy the benefits of physical and nutritional support as well as resolution of the multiple organ failure they often have as a result of their profound cardiac failure. We have supporte 8 patients with the AB ventricles with 5 long term survivors, three went on to be transplanted and two fully recovered cardiac function. Several of the patients were supported for more than 2 months. As you can see, the support of these patients requires a major financial committment on the part of the hospitals who choose to treat this very challenging group of patients. An expansion of the DRG value to a reasonable reimbursement of the cost of the device (often 2 are used in the BIVAD mode) and the prolonged ICU that leads to recovery would free the hospitals from the financial burden of severe losses when taking on these patients.
We have been very satisfied with the AB ventricles and believe that they will soon be approved as bridge to transplantation as well as the current role as bridge to recovery.
The providers of health care for these patients (primarily tertiary care and heart transplant centers) await your wise decision.

CMS-1500-P-847-Attach-1.DOC

Attachment to #847

Initial Experience with the ABIOMED AB5000 Ventricular Assist Device: A Single Center Report

Arthur J. Crumbley*, John S. Ikonomidis*, Adrian VanBakel, Naveen Pereira, Joseph Sistino

Background: The ABIOMED AB5000 is a pneumatic, pulsatile, paracorporeal ventricular assist device (VAD), introduced in 2003 as a bridge to recovery. Results of support with this system have not been reported to date.
Methods: Eight patients received biventricular support for 11 to 81 days between 12/03 and 4/05. Site of systemic inflow cannulation was atrial in 6 and apical in 2 patients. Indications for implantation were bridge to recovery (n=4) and bridge to transplant (n=4). Pre-device implantation diagnosis included post-cardiotomy shock (n=3), acute fulminant myocarditis (n=1) and end-stage idiopathic dilated cardiomyopathy (n=4). One patient was converted from a BVS5000 placed elsewhere. The anticoagulation regimen used was heparin/aspirin (n=7) and argatroban/aspirin (n=1). Two were subsequently converted to coumadin/aspirin.
Results: A total of six patients survived, four successfully transplanted and two recovered. The two deaths were from air embolism and intractable gastrointestinal bleeding. Complications included hemorrhage (n=5), and self-limited hemolysis (n=3). Two patients were managed off anticoagulation for 7 and 13 days without thrombotic complications. Two patients required venovenous extracorporeal membrane oxygenator for pre-existing acute respiratory distress syndrome. The left atrial inflow cannula required repositioning in 2 patients for intermittent obstruction. There were no pump failures over a mean follow-up period of 31+/-26 days. Four patients were ambulatory on support.
Conclusion: The AB5000 is a reliable intermediate term VAD. Advantages include biventricular support, ability to briefly interrupt anticoagulation, nonoperative transition from BVS5000 support and possible full ambulation with physical rehabilitation.

518

Submitter : Denise Love **Date:** 06/24/2005

Organization : National Association of Health Data Organizations

Category : Other Association

Q Data

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Hefter
Wartstein
Bodden
Hammel

CMS-1500-P-854-Attach-1.DOC

CMS-1500-P-854-Attach-2.DOC

ATTACHMENT 1 TO # 854

NAHDO

NATIONAL ASSOCIATION OF HEALTH DATA ORGANIZATIONS

Improving Health Care Data Collection and Use Since 1986

June 24, 2005

Re: Hospital Quality Data

Comments from the National Association of Health Data Organizations (NAHDO) on the Reporting of Hospital Quality Data for Annual Hospital Payment Update (§412.64(d)(2))

Please accept the following comments on behalf of the National Quality Workgroup of the National Association of Health Data Organizations (NAHDO). We commend the hospital quality reporting of hospital-level process measures to the Centers for Medicare and Medicaid Services (CMS), and see this as a starting point to full hospital transparency and accountability.

Some states are evaluating the correlation (or lack thereof) between "process" measures and outcomes measures and believe further evaluation is warranted. We believe that the addition of outcomes measures to this initiative will align with efforts by private purchasers to financially-reward high quality providers for improving the outcomes of care as the next step, thus establishing CMS as a leader in improving hospital quality.

We, as state leaders in statewide quality reporting initiatives, have years of experience in collecting and disseminating hospital outcomes information and we are willing to share lessons learned to advance the Hospital Quality Data for Annual Hospital Payment initiative. The charter of the NAHDO Quality Reporting Workgroup is to:

- Represent states and unique state-specific issues in the national quality agenda
- Address technical and political issues specific to public reporting of statewide hospital data
- Transfer knowledge and lessons learned across states
-

About NAHDO

NAHDO is a national non-profit membership and educational association representing statewide health care data systems maintained by state and private health data agencies. NAHDO has been working since 1986 to promote the uniformity and public availability of hospital and health care data.

Thank you for this opportunity to provide comment on the CMS Hospital Quality Data policies.

Sincerely,

Denise Love

Denise Love
Executive Director

375 Chipeta Way, Suite A • Salt Lake City, Utah 84108
Telephone: 801-587-9104 • Fax: 801-587-9125 • E-mail: nahdoinfo@nahdo.org • Web: www.nahdo.org

ATTACHMENT 2 TO #854

NAHDO

NATIONAL ASSOCIATION OF HEALTH DATA ORGANIZATIONS

Improving Health Care Data Collection and Use Since 1986

June 24, 2005

Re: Hospital Quality Data

Comments from the National Association of Health Data Organizations (NAHDO) on the Reporting of Hospital Quality Data for Annual Hospital Payment Update (§412.64(d)(2))

Please accept the following comments on behalf of the National Quality Workgroup of the National Association of Health Data Organizations (NAHDO). We commend the hospital quality reporting of hospital-level process measures to the Centers for Medicare and Medicaid Services (CMS), and see this as a starting point to full hospital transparency and accountability.

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Thank you for this opportunity to provide comment on the CMS Hospital Quality Data policies.

Sincerely,

Denise Love

Denise Love
Executive Director

375 Chipeta Way, Suite A • Salt Lake City, Utah 84108
Telephone: 801-587-9104 • Fax: 801-587-9125 • E-mail: nahdoinfo@nahdo.org • Web: www.nahdo.org

519 WALZ HART HEFTER HARTSTEIN

Submitter :

Date: 06/24/2005

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-832-Attach-1.DOC

TRANSFERS

Attachment to #832

Anita McAuley
7010 Elusive Pass
San Antonio, TX 78233

June 23, 2005

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

Re: File Code CMS-1500-P – Post Acute Care Transfers

Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (Federal Register, Vol 70 No. 85 23305 - 23774)

Dear Dr. McClellan:

Sarasin Consulting welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Inpatient Prospective Payment System (PPS) and calendar year 2006 Rates, as published in the May 4, 2005 Federal Register.

Our comments are as follows:

I support the CMS Post Acute Care Transfer Policy to reduce hospital payment when patients are transferred for post acute care following a short inpatient hospital stay since I believe the Medicare program should not be paying for the same services twice. However, I would like to comment on the following issues regarding this policy:

- Further Expansion of the Post Acute Care Transfer DRG List,
- DRGs with Increase in Post Acute Care Utilization - Increase in Geometric Mean Length of Stay, and;
- Freestanding and Outpatient Hospital Physical/Occupational Therapy.

Further Expansion of the Post Acute Care Transfer DRG List:
CMS is proposing to significantly expand the list of DRGs subject to the post acute care transfer policy, and I believe that prior to expanding the list any further, CMS should perform more current audits that incorporate previous expansions of the list of DRGs subject to the payment policy AND perform more comprehensive audits to include a review of medical records from both the hospital and the transfer facilities providing post acute care.

Previous OIG audits have reviewed the transfer policy based on the initial list of 10 DRGs utilizing claims data only (CWF), and with the assumption that the transferring facility is reporting the appropriate level of care (i.e. SNF) the patient received. As a coding consultant, I tend to agree

with the conclusions drawn from these audits because the vast majority of patients in the initial DRG transfer list (CVAs and hip/knee surgeries) generally did receive post acute care (i.e. physical and occupational therapy) in SNFs, Rehabs and through home health agencies.

However, there have been no audits performed on the expanded list of transfer DRGs, and the first expansion included some of the most common medical conditions treated in the acute care hospital (i.e. pneumonia, dehydration, COPD, CHF, UTI). These common conditions, unlike the initial list of transfer DRGs, are not conditions that routinely require post acute care. Therefore, conclusions drawn from these audits on the initial DRG transfer list and current claims analysis alone should not be used to support a continued expansion of the policy without performing more comprehensive audits. A more comprehensive audit would include claims review AND medical record reviews of both the hospital and the transfer facility by the OIG. Focusing the audits on DRGs that were added to the list in 2003 could provide the additional data needed to fully evaluate expansion of the transfer list. Following are SNF and home health issues I have concerns about.

1. Skilled Nursing Facilities: Previous OIG audits indicate that approximately 20% of the discharge status discrepancies were transfers to SNFs. It would seem that with the expansion of the list in 2003 that this percentage might increase significantly since the DRGs added (CHF, COPD, dehydration, UTI) are much different from the initial list (CVAs, hip/knee surgery); discharges to SNFs may increase. As CMS is aware, many SNF facilities have diversified and provide multiple levels of care (i.e. SNF, rehab, hospice, custodial, assisted living). In addition, CMS regulates these facilities by requiring the following:

- the various levels provided are "distinct parts" of the main facility,
- a 3 day hospital admission is required for Medicare coverage of a SNF admission, and;
- the level of care billed is the level of care provided and documented in the medical record.

With transfer facility diversification and the above requirements for SNFs, how can the OIG make the assumption that the level of care reported by SNF facilities is correct? The potential payment impact on all the previous audits is, to say the least, significant, and warrants a much closer inspection.

I would also like to know whether the post acute care transfer payment reduction is supposed to occur when a SNF stay is deemed non-covered due to lack of an acute care hospital 3 day stay.

2. Home Health Services: Previous audits indicate that approximately 55-60% of discharge status errors were for home health services but the audits did not indicate that diagnosis review was performed to determine whether the transfer services were related to the inpatient stay, and since these services can begin up to 3 days following discharge, it is possible some of these services were not related to the inpatient stay. Since hospitals do not have access to home health claims data, how can they determine that home health initiated after discharge is related to the patient's hospital stay? Hospitals can certainly work more closely with home health agencies or implement social service follow up calls to patients to determine whether services were provided but diagnostic data submitted by the home health agency may not be provided leaving the hospital to assume that the services were related. Keeping track of post-discharge home health services can be a very labor intensive process.

DRGs with Increase in Post Acute Care Utilization and Increase in Geometric Mean Length of Stay:
The data in the table may demonstrate potential discharge status coding issues since many of the DRGs identify surgical procedures that are generally performed in outpatient surgery (DRGs 6, 40, 42, 51, 55, 118, 223, 319) and would not generally require complex post acute care. It is possible that hospitals inappropriately reported some of these cases as a SNF discharge when the patient was actually a custodial level resident returning to the facility. Previous OIG audits on

transfer DRGs focused on the discharge status of "home", and consistently identified significant discrepancies by hospitals. Therefore, one could speculate that audits of other discharge status codes such as SNF or intermediate care would yield similar results. Large scale discrepancies may lead to significant reductions in hospital payment as more DRGs are added to the post acute care transfer list. My experience in reviewing hospital discharge status demonstrates there to be many reasons hospitals misreport discharge status, and they include the following:

- Hospital validation of discharge status may be based on the name of the transfer facility rather than the level of care the patient is transferred to (i.e. custodial/resident, SNF, hospice, assisted living),
- Hospital may use an incomplete list of discharge status codes (i.e. codes for home and facility hospice,
- Hospital's list of discharge status descriptions that coders select from may cross over to an incorrect code (i.e. custodial crosses over in the information system to SNF),
- Hospitals may inappropriately believe that a transfer back to a facility for custodial care should be reported as SNF, and;
- The medical record may provide limited documentation by Social Service/Utilization Review to ascertain the appropriate discharge status code.

DRG 15 (Nonspecific CVA...) may have increased due to the QIO's focus on correct ICD-9-CM coding of CVAs with and without infarction and TIAs; this has been an ongoing education effort for the past 3-5 years.

CMS should perform coding and utilization audits on a small sample from each of these DRGs on both inpatient claims and post acute care claims. This would give CMS an idea of how accurate the coded data and documentation are since there is nothing worse than making policy based on bad data.

Freestanding and Outpatient Hospital Physical/Occupational Therapy:
CMS should consider including freestanding and outpatient hospital physical therapy performed independent of a home health agency since this is another area where the Medicare program may be duplicating payment for post acute care services.
Why are patients who receive post acute care from freestanding physical therapy and hospital outpatient physical therapy not included in the post acute care payment policy? These services are not always provided by home health agencies and appear to have been inappropriately left out of the policy.

Considering the variables that would impact the data given in the OIG audits it would seem prudent for CMS to re-review the Post Acute Care Transfer Policy after conducting more thorough auditing with data that is more current.

Further, we look to CMS to provide clear definitions of existing discharge status codes with examples. For instance,

- What distinguishes a patient discharge to intermediate care versus a patient discharge to a skilled level of care?
- When is a discharge status of home IV assigned versus home health?
- What if a patient is receiving both home PT and IV services – what is the appropriate discharge status?
- If a patient is discharged to the swing bed of a critical access hospital is the discharge status swing bed or critical access hospital?
- What is the appropriate discharge status for the discharge of a custodial/nursing home patient?
- Does the discharge of a patient whose home is assisted living constitute a discharge to home?
- Is there a hierarchy that applies to discharge status when more than one is applicable?

Attachment to #832

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Hospital Inpatient PPS. If Sarasin Consulting can provide any further information, or if there are any questions or concerns with regard to this letter, please contact either Anita McAuley, RHIA (210) 590-8688 or Needacoder@aol.com.or myself Christi Sarasin, CCS at (410) 286-8678 or CDSarasin@aol.com
Sincerely,

Anita McAuley, RHIA
Healthcare Consultant

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KNIGHT
SEIFERT
KRAEMER
TREITEL
BODDEN
HAMMEL
WALZ
HART
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RUIZ
COLLINS
MOREY
SMITH
ROMANO
HEFTER
HARTSTEIN

Submitter : Mr. Timothy Eckels

Date: 06/24/2005

Organization : Trinity Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-830-Attach-1.DOC

MB/H
LABOR S/H
Q DATA
WI/OM
CBSA
WI/Bd
TRANSFERS
DRG/GEN
NT
IME
CAH/RELOC
PMT RTS/OUTLIER
SPH
CAH/LUGAR

Attachment to #830

June 24, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1500-P

RE: Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and fiscal year 2006 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

I write on behalf of Trinity Health regarding the proposed fiscal year 2006 Medicare Inpatient Prospective Payment Regulations, which appeared in the May 4, 2005 *Federal Register*, Vol. 70, No, 85, pp. 23306-23673.

Trinity Health is an integrated health care system that provides acute hospital, long term, hospice, home health and related care services in **California** (Fresno); **Idaho** (Boise and Jerome); **Indiana** (Mishawaka, Plymouth and South Bend); **Iowa** (Clinton, Dubuque, Mason City, New Hampton, Primghar, and Sioux City); **Maryland** (Silver Spring); **Michigan** (Ann Arbor, Battle Creek, Cadillac, Grand Rapids, Grayling, Howell, Livonia, Macomb County [Clinton Township], Muskegon, Oakland County [Pontiac], Port Huron, and Saline); and **Ohio** (Columbus and Westerville). Our services extend from large inner city to remote rural areas. The following comments derive from this perspective.

HOSPITAL MARKET BASKETS; PROPOSED UPDATE FOR HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (PPS) RATE

Trinity Health is very appreciative that CMS is proposing a FY 2006 inpatient PPS rate increase equal to the full market rate -- a measure of hospital inflation -- for those hospitals submitting the required 10 quality measures. Such an increase is crucial to maintaining our ability to serve, and to being competitive in recruiting and retaining health care professionals.

LABOR RELATED SHARE

Trinity Health 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, the 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, the 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. We are troubled that the agency would initially 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.

HOSPITAL QUALITY DATA

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

OCCUPATIONAL MIX ADJUSTMENT

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS, in order to construct an occupational mix adjustment to the wage index. The adjustment is to control for the effect of hospitals' employment choices – such as the use of registered nurses versus licensed practical nurses or the employment of physicians – rather than geographic differences in the costs of labor.

In 2004, CMS said hospitals could correct or revise occupational mix data previously submitted. CMS reports that 20 hospitals took advantage of this option. CMS also notes in the rule that it removed those hospitals that have converted to CAH status since the data originally was collected and those hospitals that had no corresponding cost report data for the FY 2006 wage index. CMS has survey data from nearly 95 percent of hospitals.

CMS proposes no changes to the methodology used in FY 2005. This consists of determining an adjustment for each of the seven general occupational categories and applying each adjustment separately to the wage index. CMS indicates that nearly one-third of rural areas and over one-half of urban areas would see a decrease in their wage index as a result of the adjustment. The largest negative impact for a rural area would be 1.9 percent, while the largest negative impact for an urban area would be 4.3 percent.

Given the potential financial impact on hospitals, CMS is proposing to again limit the use of occupational mix adjustment at 10 percent. Thus, 10 percent of the wage index would be based on an average hourly wage adjusted for occupational mix, and 90 percent would be based on an average hourly wage unadjusted for occupational mix. Due to the concerns CMS expresses in the proposed rule, Trinity Health is supportive of this moderated implementation of the occupational mix adjustment.

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, we believe the agency should identify the rationale for this adjustment and communicate it to hospitals via a proposed rule prior to putting it into place. Trinity Health 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.

REMEDYING AN INORDINATE WAGE INDEX IMPACT ON BATTLE CREEK HEALTH SYSTEM (BCHS)

On behalf of Battle Creek Health System (BCHS), a member of Trinity Health in Calhoun County, Michigan, we request that CMS consider remedying the severe and unparalled wage index impact created for the facility by the newly established Battle Creek (12980) Core-based Statistical Area ("CBSA").

Background. Before October 1, 2004, Calhoun County was a part of the Kalamazoo-Battle Creek Metropolitan Statistical Area. For fiscal year 2004, the Kalamazoo-Battle Creek wage index was 1.0500. For fiscal year 2005, the final wage index for the Battle Creek CBSA plummeted to 0.9345 (before consideration of the blended rate). This 11 percent decrease was the highest decrease experienced by any hospital that was redistricted from one metropolitan area into a newly created metropolitan area throughout the United States, with the exception of Madison County, Indiana. However, the Madison County hospitals were designated as a part of a Combined Statistical Area ("CSA") that also included Indianapolis, and those hospitals, we understand, have been reclassified into the Indianapolis CBSA for wage index purposes effective October 1, 2004. As such, Calhoun County was the most negatively impacted metropolitan area for federal fiscal year 2005 of any of the newly designated single county metropolitan areas that were split off from an existing MSA as a result of the adoption of the 2000 CBSA based Census designations.

According to CMS's own data from 2004, only 45 urban hospitals experienced a wage index decrease of more than 10 percent as a result of the new metropolitan area designations. See 69 *Fed. Reg.* at 49,032. However, according to CMS, these were primarily hospitals that were moved to rural areas. The Centers for Medicare & Medicaid Services (CMS) very generously provided hospitals that were redistricted out of metropolitan areas into rural areas hold-harmless protection for three years to give those hospitals the opportunity to either seek geographic reclassification or adjust to a lower wage index level. Hospitals that were moved to new urban areas that experienced these high-end reductions, such as the Battle Creek CBSA hospitals, received no such hold harmless protection. Although the Battle Creek hospitals were given a blended rate based on 50 percent of the Kalamazoo wage index and 50 percent of the new Battle

Creek wage index for federal fiscal year 2005, that transition protection expires September 30, 2005.

Requested Remedy. Trinity Health believes that the hospitals that experienced a wage index decrease of more than 10 percent, regardless of whether the decrease resulted from these hospitals being relocated into rural areas, should also receive hold-harmless protection. There is no justifiable basis for treating these hospitals differently, simply on the basis that they remained urban. CMS protected hospitals that were relocated to rural areas no matter how small their potential wage index drop. Hospitals that remained in urban areas, but that nonetheless experienced dramatic wage index decreases should be treated comparably to the hospitals that were relocated out of urban areas. As such, we urge CMS to provide hold-harmless protection to all hospitals that experienced a wage index decrease of more than 10 percent, regardless of whether the hospital remained urban or rural.

If CMS does not accept this hold harmless proposal, we request that CMS extend the blended rate to hospitals that experienced a wage index decrease of more than 10 percent for at least another two years to further ameliorate the impact of the new metropolitan area changes.

Alternatively, CMS could resolve this problem by treating Kalamazoo and Battle Creek as a CSA. Specifically, CMS could determine that a single county MSA that was redistricted out of a nearby metropolitan area and incurred a decrease in the raw wage index for federal fiscal year 2005 of at least 10 percent, to be considered a part of a CSA with the metropolitan area to which they were previously associated. In the case of Battle Creek, we specifically propose that the Kalamazoo and Battle Creek CBSAs be considered a CSA such that the two hospitals in Calhoun County (Battle Creek Health System and Oaklawn Hospital) could seek a group reclassification for wage index purposes to the Kalamazoo-Portage CBSA. As an alternative, CMS could instead consider hospitals in this situation as exempt from satisfying the "same CSA" requirement at 42 C.F.R. § 412.234.

We believe that CMS has the authority to implement any of the changes suggested above under Social Security Act § 1886(d)(5)(I)(i), which provides the Secretary with broad authority to make adjustments and exceptions under the inpatient prospective payment system.

POSTACUTE CARE TRANSFERS; PROPOSED EXPANSION OF POSTACUTE CARE TRANSFER POLICY

Trinity Health opposes the proposed revisions of the selection criteria for including a DRG within the post acute care transfer policy and urges CMS to withdraw these criteria, which appear to be founded solely on cost/utilization parameters, rather than clinical grounds. We feel CMS's institution of its post acute transfer policy is in direct conflict with CMS's rationale for implementing DRGs -- i.e., paying hospitals based upon average costs and lengths of stay, thereby providing a built-in incentive to be more efficient and reduce unnecessary inpatient days. Yet, the post acute transfer policy does just the opposite -- it penalizes hospitals for such care efficiency, and creates an incentive to retain inpatients longer, rather than expedite their transfer to a more appropriate, less costly post-acute care setting. As such, Trinity Health opposes any expansion of the

number of DRGs subject to CMS's post-acute transfer policy, with related comments provided below.

If adopted in the final rule, according to CMS, the proposed revision would expand the number of DRGs subject to the transfer payment policy from the current list of 30 DRGs to 231 existing DRGs as well as another 47 proposed DRGs. CMS projects that such a change would reduce aggregate payments to hospitals about $880 million per year, which is a 1.1 percent reduction in total hospital payments.

Background: The statute gives the Secretary of the Department of Health and Human Services (DHHS) the authority to make a DRG subject to the postacute care transfer policy based on a "high volume of discharges to postacute care facilities and a disproportionate use of postacute care services." Accordingly, in the FY 2004 IPPS final rule, CMS adopted qualifying criteria providing that to be included in the transfer-DRG list, a DRG must have, for both of the two most recent years for which data are available:

- At least 14,000 postacute care transfer cases;
- At least 10 percent of its postacute care transfers occurring before the geometric mean length of stay;
- A geometric mean length of stay of at least 3 days; and
- If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent 5 year period of at least 7 percent.

In the FY 2005 IPPS NPRM, CMS proposed alternative eligibility criteria for DRGs that failed to meet the above criteria. According to CMS, the alternative criteria were developed to address situations where there remained substantial grounds for inclusion of cases within the postacute care transfer policy, although one or more of the original criteria may no longer apply.

In response to this proposal, on July 12, 2004, our national association – the Catholic Health Association (CHA) -- commented that it was "very concerned about the arbitrary manner in which this approach was developed and applied." CHA went on to say that:

> "[The proposal] has all the appearances of essentially backing into a policy by the use of criteria which seem to fit the situation. There is no analytical support for the new criteria. CHA is left to wondering what CMS will do the next time it feels a certain DRG should be subject to the postacute care transfer policy, but doesn't meet the primary criteria or the "alternative criteria," if adopted. Will there be another iteration of the "alternative criteria" approach? CMS should provide analytical support and rationale for the new criteria – otherwise the apparent arbitrary nature of such an alternative policy will become more firmly grounded in providers' perception."

In the FY 2005 final rule, however, CMS elected not to adopt the proposed alternative criteria. Instead, CMS adopted a policy of simply grandfathering, for a period of two years, any cases that were previously included within a DRG that has split when the split DRG qualified for inclusion in the postacute care transfer policy for both the previous 2 years.

FY 2006 Proposed Expansion. The dramatic proposed expansion of DRGs subject to the post-acute transfer policy, from the current 30 to 231, reflects a quantum relaxation of CMS's criteria for determining which DRGs qualify:

- The DRG has at least 2,000 postacute care transfer cases;
- At least 20 percent of the cases in the DRG are discharged to postacute care;
- Out of the cases discharged to postacute 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 3.0 days;
- 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.

CMS has not provided the requisite underlying justification for how these criteria satisfy congressional statutory intent in identifying DRGs with high post-acute transfer rates. What is lacking is a scientific, clinically sound basis for setting these criteria, rather than CMS's bias of basing them solely on utilization, average length of stay, and cost. Regrettably, these proposed criteria in no way reflect the efficiency and quality of care rendered. In Trinity Health's opinion, this is a major oversight.

Ensuring that patients receive the right care in the right setting at the right time should be the primary driver of Medicare's inpatient reimbursement system, not arbitrary utilization cut-offs that yield a predetermined level of savings—at the possible expense of quality. As such, Trinity Health respectfully urges CMS to withdraw the proposed expansion of the postacute care DRG transfer list until it can analytically and clinically support such an expansion and is in keeping with the statutory guidance.

DRG RECLASSIFICATIONS; DRG REFINEMENT; ALL-PATIENT REFINED DRGs AND SEVERITY CASES.

While not an issue in the FY 2006 IPPS NPRM, nevertheless given the recent Medicare Payment Assessment Commission's (MedPAC's) endorsement of a refined inpatient classification system that better reflects severity variations followed by your submitted testimony May 14, 2005 before the House Energy and Commerce Committee in which you wrote, "CMS will propose changes to the DRGs to better reflect severity of illness." Trinity Health believes it is worthwhile to clearly signal our mixed concerns about such an effort. On the one hand we support and encourage refinements to the inpatient DRG system that better captures cost variations among Medicare patients. On the other hand, we are very concerned about the redistributive implication such an effort would have on the Medicare payments to hospitals. As such, Trinity Health feels it is critical that CMS evaluate DRG case mix severity outside a "budget neutrality" environment.

As regards the latter concern, we are encouraged by your above noted testimony, in which you acknowledged that a refined DRG system "could have a substantial effect on all hospitals, [and that] CMS believes we must thoroughly analyze these [DRG refinement] options and their impact before advancing a proposal."

We strongly urge that this process be open and inclusive. In particular, we would like to work with CMS through our hospital associations in this on-going analysis.

We assume that such analysis will include an assessment of the impact of any proposed DRG refinement methodology on different categories of hospitals. Obviously we are very concerned about the potential, detrimental impact on Trinity Health hospitals and the communities we serve. We also assume the evaluation process will thoroughly examine how these proposed changes would achieve the goal of leveling the playing field between full-service community hospitals and single-service specialty hospitals.

Finally, given your advance notice of caution as regard the potential impact of this change on hospitals, we encourage CMS to build in an extended phase-in period of at least five to six years.

NEW TECHNOLOGY PAYMENTS

Section 503 of the Medicare Modernization Act provided new money for add-on payments for new medical services and technologies under the inpatient PPS, and lowering the cost threshold for new technologies to qualify for new technology payments. Trinity Health is disappointed CMS is proposing to reject all eight applications for new technology payments (six new and two reevaluations) and only maintain payment for one currently approved technology. Trinity Health would ask CMS to reconsider its decision to increase the marginal payment rate for new technology to 80 percent rather than 50 percent, which it has the administrative discretion to do.

INDIRECT MEDICAL EDUCATION ADJUSTMENT

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

- For discharges occurring during FY 2005, the formula multiplier is 1.42 (equivalent to a 5.8 percent adjustment).
- For discharges occurring during FY 2006, the formula multiplier is 1.37 (equivalent to a 5.55 percent adjustment).

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

CRITICAL ACCESS HOSPITALS; PROPOSED POLICY CHANGE RELATING TO DESIGNATION OF CAHS AS NECESSARY PROVIDERS.

Trinity Health urges that CMS delete the timing thresholds from the criteria used to determine whether a relocated CAH with a grandfathered "necessary provider" designation should be allowed to retain such a designation.

Background. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) terminated, effective January 1, 2006, a State's authority to waive the location requirements for a CAH by designating the CAH as a necessary provider. CAHs that were designated by a State as necessary providers prior to January 1, 2006 would be grandfathered. However, the statute does not address the situation where the CAH is no longer the same facility due to replacement, relocation, or cessation of business.

In light of this, CMS is proposing a two-part test to determine whether a CAH designated by the state as a necessary provider before January 1, 2006 and which relocates after January 1, 2006 may retain such designation.

Part 1 -- Determination of the Relocation Status of CAH.

1. Replacement in the Same Location. CMS proposes, in situations in which the replacement of a CAH is at the same location or on land that is within 250 yards of the current CAH, that the necessary provider designation would continue to apply regardless of when the construction work commenced and was completed. Such a replacement of the same provider is not considered relocation.

2. Relocation of a CAH. CMS wants to ensure that the provider who relocates (i.e., does not build at the same location or within 250 yards of the existing location) is essentially the same provider in order to operate under the same provider agreement. If CMS determines a rebuilding of the facility in a different location to be a relocation, the provider agreement would continue to apply to the CAH at the new location.

3. Cessation of business at one location. If the CAH relocation results in the cessation of furnishing services to the same community, CMS would not consider this to be a relocation, but instead would consider it a cessation of business at one location and establishment of a new business at another location.

Part 2 – Relocation of a CAH Using a Necessary Provider Designation to meet the Conditions of Participation (CoP) for Distance.

If CMS determines that a CAH has relocated, in order to retain its necessary provider designation it must meet several proposed conditions:

1. The relocated CAH must have submitted an application to the State for relocation prior to the January 1, 2006 sunset date.

2. Such an application must include:
    a. Demonstration that the CAH will meet the same State criteria for the necessary provider designation that were established when the waiver was originally issued.
    b. Assurances that after the relocation the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff. This would require the CAH to demonstrate that it is servicing at least 75 percent of the same service area, with at least 75 percent of the same services offered and staffed by 75 percent of the same staff.
    c. Assurances that the CAH will remain in compliance with all of the CoPs in the new location.
    d. And, a demonstration that construction plans were "under development" prior to the effective date of MMA – December 8, 2003.

The requirement that a CAH with a grandfathered necessary provider designation must have submitted an application for a relocation prior to January 1, 2006 and that it must also be able to demonstrate that construction plans were "under development" prior to the passage of the MMA (December 8, 2003) in order to retain such a designation does not adequately reflect the real world pressure confronting such CAHs.

Consider a typical example: A CAH with a necessary provider designation that is still 5 or more years from the need to replace itself. Such a CAH wouldn't have undertaken development plans by December 8, 2003 or submitted a relocation application to the state by January 1, 2006. Yet it is committed to serving essentially the same community with generally the same service profile provided by essentially the same staff. The problem confronting the hospital and the community it serves is that without the necessary provider designation it would no longer qualify as a CAH and hence the higher Medicare reimbursement rates. Such a consequence would obviously have to be weighed in balance with other replacement factors, but the loss of the higher Medicare reimbursement could make the relocation economically unfeasible. The loss to the community of a new facility would arbitrary deny the rural community the quality of care benefits such a new facility would bring.

Limiting the continuation of the necessary provider designation to only those CAH that replace themselves (as opposed to relocating) essentially takes away the option for these facilities to relocate at a different site, regardless of the fact that such a relocation could enhance the availability and accessibility of the CAH's necessary health care services to the Medicare beneficiaries in the communities it serves. Such a perverse incentive would also mean that the accessibility of the CAH's health care services would be severely limited, if not unavailable during the time it takes to build the on-site replacement facility. Construction of a new facility can take up to two years.

Finally, the proposed time line conditions unfairly penalize CAHs that have delayed replacement plans due to poor financial resources that the recently improved CAH payment policies were designed by Congress to address.

Accordingly, we urge that CMS delete the timing thresholds from the criteria used to determine whether a relocated CAH with a grandfathered necessary provider designation should be allowed to retain such a designation. We feel the remaining

conditions will more than adequately ensure that such CAHs are not moving to new markets without seeking new CAH approval.

OUTLIERS; ACCURATE PROJECTIONS OF OUTLIER SPENDING

The statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating IPPS payments. Since the inception of the IPPS, outlier payments as a proportion of total operating IPPS has varied above and below this standard, sometimes significantly. CMS has recently taken two steps to reduce this variability – one addressed the problem stemming from how a hospital specific cost-to-charge was determined and the second provided a more timely methodology for determining the outlier threshold. As a result of these changes, in August 2004 CMS finalized an FY 2005 IPPS outlier threshold of $25,800 after proposing $35,085 in the May 18, 2005 FY 2005 IPPS NPRM. In the FY 2006 IPPS NPRM CMS estimated that outlier payments for FY 2005 would be approximately 4.4 percent of actual DRG payments.

For FY 2006, using an even more timely methodology (compared to the methodology used for determining the FY 2005 threshold) for determining the outlier threshold, CMS proposes that the FY 2006 outlier threshold be set at $26,675. If finalized, this proposed threshold would be a 3.4 percent increase compared to FY 2005. CMS projected that this proposed threshold would result in outlier payments that would equal about 5.1 percent of total DRG payments.

In light of the new threshold determination methodology along with a preliminary CMS estimate that FY 2005 outlier payments will be about 4.4 percent of total DRG payments, we are concerned that the proposed FY 2006 outlier threshold will again result in total outlier payments for FY 2006 that are less than 5.0 percent of total DRG payments.

Accordingly, Trinity Health urges CMS to better ensure that the proposed outlier threshold more closely results in outlier payments that meet the statutory requirements in terms of total DRG payments of at least 5 percent but no more than 6 percent.

RECTIFYING TIMING ISSUE ASSOCIATED WITH HOSPITALS THAT QUAILIFY UNDER MMA'S SECTION 508

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

Specifically, CMS needs to direct us as to whether our hospitals should apply in September 2005 or September 2006, and when reclassification requests made during one of these reclassification cycles will become effective. We propose that CMS resolve this matter by allowing Section 508 hospitals to apply either September 1, 2005 or

September 1, 2006 for a reclassification to be effective beginning April 1, 2007. CMS should likewise make reclassifications sought under this exception effective for 2.5 years, rather than the usual 3 years, so as to return these hospitals back to the usual reclassification cycle.

This clarification is necessary because our hospitals' pending reclassifications will expire in the middle of a federal fiscal year, on March 31, 2007. Unless CMS establishes an accommodation for Section 508 hospitals, we will be confronted with a difficult dilemma. If we apply September 1, 2005 for reclassification to be effective October 1, 2006, we may be forced to forfeit six months worth of our Section 508 reclassification (*i.e.*, for the period October 1, 2006 through March 31, 2007). If we apply September 1, 2006 for reclassifications to be effective October 1, 2007, we will be without a reclassification for the six months between March 31, 2007, when our Section 508 reclassifications expire, and October 1, 2007, when our new Subpart L reclassifications activate. Both outcomes carry significant financial consequences, and neither is practical. We urge CMS to implement a solution that does not force our hospitals to make this difficult choice, and which provides them with the full benefit of their Section 508 reclassification, as intended by Congress.

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

MEDICARE DEFINITION OF A HOSPITAL IN CONNECTION WITH SPECIALTY HOSPITALS

Pursuant to this component of the proposed rule, Trinity Health commends CMS's decision (announced by Dr. McClellan at a May 12, 2005 congressional hearing) to suspend, for at least six months, the issuance of new Medicare hospital provider numbers to limited-service hospitals while the agency reviews its procedures for evaluating such requests. The goal is to ensure limited-service hospitals fully meet the Medicare definition of a hospital. Trinity Health is hopeful these steps by CMS will help protect community hospitals' ability to provide a full range of services, including critical emergency care as well as provide a safety net for the uninsured.

In closing, Trinity Health thanks you for the opportunity to comment on the proposed hospital inpatient Prospect Payment System rule. We look forward to working with you on the above issues.

Sincerely,

Timothy J. Eckels
Vice President, Public Policy

TJE/slg
CMSFinal2006IPPS 2 062305.doc

CMS-1500-P-829
and CMS-1500-P824

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HARTSTEIN
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Submitter : Mr. William Armstrong **Date:** 06/24/2005

Organization : Mercy Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-829-Attach-1.DOC

TRANSFERS
WI/IBd
Q DATA
MB/H
PYMT RTS/OUTLIERS
DRG/GEN
CBSAs
WI/OM

Attachment to #829

June 24, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, *Federal Register* 70, no. 85 (May 4, 2005): 23306–23673. [CMS-1500-P]

Dear Dr. McClellan:

On behalf of Mercy Medical Center, I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2006 inpatient prospective payment system (PPS).

Our principal recommendations this year are:

1. Post-acute care transfers. We strongly oppose CMS's proposal to expand the post-acute care transfer policy. We believe that the entire policy is wrong and that there is absolutely no justification for decreasing aggregate Medicare payments as a result.

2. Wage index. We oppose CMS's decision to discontinue the blend of the MSA and CBSA wage indices for hospitals that were disadvantaged by the change to CBSAs, and recommend that the MGCRB designate the old New York City MSA as a core urban area within the new CBSA and reimburse providers in or reclassifying to the core urban area based on a wage index derived solely from the hospitals located in the old MSA. We also urge CMS to implement 100% of the occupational mix adjustment.

3. Labor share. We believe that CMS should not update the cost category weights in the hospital market basket unless it also designates professional liability insurance as a labor-related cost.

4. Outliers. We are very disturbed that CMS has not been able to estimate the cost outlier threshold to a reasonable degree of accuracy, noting that the Agency estimates it did not spend 31% of the outlier pool in FY 2004.

5. Hospital quality data. We believe that the current flaws in the data validation process are so fundamental that CMS should not tie the full payment update to that process in FY 2006.

6. DRG reclassifications. We support CMS's proposals for DRG refinement and request that the agency also create new DRGs for a) ischemic stroke treatment with a reperfusion agent, which would only include strokes that were caused by clots and treated with tissue plasminogen activator, and b) cardiac defibrillator implant without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies.

More detailed comments about these issues are provided below.

Post-acute Care Transfers

During the 1990s, the national average length of stay decreased by about 2% per year, coincident with the expansion of managed care. One of the mechanisms hospitals used to decrease length of stay was to discharge patients to post-acute care. CMS and the Medicare Payment Advisory Commission (MedPAC) became concerned that the Medicare program was being exploited because spending was increasing rapidly for post-acute care services, but hospital payments were not adjusting fast enough to sufficiently offset some of the post-acute care increase. This was because diagnosis-related group (DRG) weights are based on two-year-old data.

Therefore, through the Balanced Budget Act of 1997 (BBA), Congress directed CMS to begin reimbursing short-stay discharges to post-acute care in 10 DRGs as transfer cases. Transfer cases receive only partial DRG payment. In hindsight, this directive was too late because length of stay stabilized early in this decade. Therefore, the DRG weights based on two-year-old data are no longer imbalanced. Nonetheless, in FY 2004, CMS extended its post-acute care transfer (PACT) policy to 29 DRGs and now, for FY 2006, the Agency is proposing to fully implement the policy by extending it to 231 DRGs, which are virtually all the DRGs to which the policy could reasonably be applied.

We strongly opposed the FY 2004 expansion of the PACT policy and more strongly oppose it now because the patients to whom it applies cannot legitimately be construed as transfer cases. The cases to which the policy is now—and would be—applied are merely cases with a shorter-than-average length of stay. Therefore, reducing the payment for these cases should be recognized as a form of case-mix refinement and, if it were done, should be budget-neutral. There is absolutely no justification for CMS taking savings from this policy, whether it is expanded or not.

The question then becomes whether this form of case-mix refinement is desirable. We feel strongly that this policy is inappropriate because it characterizes a low length of stay as an indicator of a clinically inappropriate discharge, which conflicts with the more contemporary and more prevalent characterization of a low length of stay as an indicator of efficiency. In fact, length of stay is probably the most common measure of efficiency. We have worked very hard to reduce length of stay through better care coordination. Deeming a stay incomplete merely because the length of stay is shorter than the geometric mean minus one day is arbitrary and undermines our efforts. Furthermore, refining the DRGs to pay less for shorter-stay cases also undermines the incentive built into the case payment methodology, which is that hospitals would be rewarded for efficiency.

Hospital Wage Index: Core-Based Statistical Areas

After the 2000 census, the Census Bureau and the Office of Management and Budget (OMB) changed the definition of many of the nation's metropolitan statistical areas (MSAs) and renamed them "core-based statistical areas" (CBSAs). Most MSA boundaries were not affected; however, some were tightened and others were expanded. CMS proposed to use the new CBSAs in place of the old MSAs as wage index labor markets starting in FY 2005, which would have generated gains for some hospitals and huge losses for other hospitals, including hospitals located in the old New York City MSA. We, along with many other disadvantaged facilities, opposed this proposal on policy and fiscal impact grounds and, in response, CMS agreed to compute area wage indices based upon a blend of the old and new labor market definitions for disadvantaged hospitals during FY 2005.

Since then, CMS has proposed to implement the new boundaries for its other prospective payment systems without a transition, and has proposed to end the blend in the inpatient PPS in FY 2006. This action would unjustly harm the minority of providers located in areas whose statistical boundaries were expanded. The U.S. Government Accountability Office and MedPAC have both criticized the indiscriminate use of MSAs (and CBSAs) as hospital labor markets because some are obviously too large to effectively discriminate between separate hospital labor markets.

Therefore, just as CMS has used the Medicare Geographic Classification Review Board (MGCRB) in the past to correct flaws in the hospital labor markets as defined by MSAs, we now urge CMS to 1) use the MGCRB to designate the old New York City MSA as a core urban area within the New York City CBSA, 2) base the wage index of the core urban area solely on the wage index data of hospitals located in that area, and 3) apply that wage index to all providers located in or reclassifying to the core urban area.

Hospital Wage Index: Occupational Mix Adjustment

CMS conducted its first occupational mix survey in a highly compressed time frame in early 2004 and did not have confidence in the validity of the results. For that reason, the agency implemented a 90%-10% blend of the unadjusted area wage index and the occupational mix-adjusted area wage index, respectively, in FY 2005. For the past year, hospitals have had the opportunity to correct any mistakes they may have made in their original submissions, so CMS

should have greater confidence in the validity of the current occupational mix adjustments. Nonetheless, CMS has proposed to continue the blend in FY 2006 in the same proportion as the blend used in FY 2005. We do not believe that continuing the blend is appropriate and urge CMS to fully implement the occupational mix adjustments in FY 2006.

Hospital Market Basket

The sum of the labor-related hospital market basket cost category weights represents the portion of the standardized amount that is wage-adjusted. The current labor share is 71.1% and it is based on FY 1992 data. CMS would have updated the weights in FY 2003 based on FY 1997 data, but declined to do so because the update would have increased the labor share to 72.5%, which would have hurt rural and other low-wage hospitals. Now CMS is proposing to update the weights based on FY 2002 data, which would reduce the labor share to 69.7% and hurt high-wage urban hospitals. This change would not materially help rural and other low-wage hospitals because their labor share was fixed at 62% in the Medicare Modernization Act of 2003.

We can make a good case on behalf of relatively high-wage hospitals that CMS should not update the cost component weights in FY 2006 to make up for not updating the weights in FY 2003. However, we would support CMS updating the weights in FY 2006 *if* the Agency also designated professional liability insurance as a labor-related cost. These costs are clearly wage-related—indeed, they are reported in the wage index—and are clearly locally determined. We believe that the failure to include professional liability insurance in the wage-adjusted portion of the standardized amount in the past was a grave oversight. Including this important cost component in the labor share would bring it up to 71.3%, which is virtually the same as the current labor share of 71.1%.

Outliers

CMS estimates that outlier payments in FY 2004 made up only 3.5% of total inpatient PPS payments, which is 31% less than the amount of funding that the hospitals contributed to the pool. We are compelled to express, once again, our concern about the Agency's inability to estimate the outlier threshold to a reasonable degree of accuracy.

Hospital Quality Data

The health care industry is in the very early stages of implementing electronic health records and the national health information infrastructure. Moving forward is analogous to a baby learning to walk because the systems—and financing—are very weak and the path is strewn with obstacles. Therefore, we agree with Congress and CMS that the appropriate way to implement "pay-for-performance" at this stage is to pay for data submission.

For FY 2006, however, CMS has proposed to make full payment of the annual Medicare inpatient PPS update also contingent on hospitals passing a data validity test. We believe that data validity is very important and appreciate the opportunity to work with IPRO (our quality improvement organization) and CMS on the data validation process. However, we believe that the current data validation process is, itself, not yet sufficiently valid to be tied to the payment.

The problems are so fundamental that we believe they must be resolved before CMS penalizes hospitals financially. Therefore, we recommend that CMS not yet tie the full payment update to data validity.

The Greater New York Hospital Association has thoroughly catalogued the flaws in the data validation process and we fully support the Association's series of recommendations to correct these flaws.

DRG Reclassifications

We believe that continuous DRG refinement is very important because it allows hospitals to implement new technologies, pharmaceuticals, and treatment protocols while minimizing systematic risk. Therefore, we support CMS's proposed DRG refinements for FY 2006, with two modifications.

First, with respect to the stroke DRGs, 14 and 15, we support the second suggestion made by the representatives of several hospital stroke centers with which CMS consulted regarding recognition of the high cost of tissue plasminogen activator (tPA). This suggestion was to create a new DRG entitled "Ischemic Stroke Treatment with a Reperfusion Agent," which would only include strokes that were caused by clots and treated with tPA, as identified through the procedure code 99.10. Furthermore, we recommend that CMS implement the new DRG in FY 2006 rather than waiting for more data to accumulate, since the incremental cost and effectiveness of this thrombolytic agent are well documented.

Second, with respect to the DRGs involving the implantation of an automatic implantable cardioverter/defibrillator, CMS is proposing to regroup cases without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies (EPS), from DRGs 535 and 536 to DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization. CMS's data show that the average cost of cases with EPS is significantly higher than the cost of cases without EPS and that the volume of cases with EPS is also significant. Therefore, we recommend that CMS create a new DRG for cases with cardiac defibrillator implant without cardiac catheterization, but with EPS.

Thank you for considering these comments.

Sincerely,

William C. Armstrong
Senior Vice President and CFO
Mercy Medical Center

Submitter : Mr. William Armstrong **Date:** 06/24/2005

Organization : St. Francis Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

See CMS-1500-P-829
(# 521)

522

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : Ms. Debbie Lombardi

Organization : Florida Hospital Neuroscience Institute

Category : Hospital

Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DRG/OPEN

CMS-1500-P-827-Attach-1.DOC

Attachment to #827

June 24, 2005

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

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

Dear Dr. McClellan:

The Neuroscience Institute (NSI) at Florida Hospital (FH) is pleased to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates. Florida Hospital is a seven campus, 1,782 bed system, and has one of the largest Medicare discharge rates in the country. Our NSI physicians treat more than 2,400 stroke and TIA patients and perform more than 2,200 neurosurgeries per year. The NSI is certified by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as a Primary Stroke Center.

The following comments are submitted on behalf of the NSI:

I. DRG Reclassifications

A. MDC 1 (Diseases and Disorders of the Nervous System)

1. Strokes

Florida Hospital believes that the DRG classification system should segregate stroke patients that receive reperfusion agents such as tPA because of the significant additional cost associated with this intervention. Although CMS proposed that this is not necessary due to the small number of cases, we believe that this number will increase as hospitals add resources and processes that will allow them to offer tPA as a lifesaving, disability reducing treatment much more frequently. Florida has been a pacesetter in the development of stroke centers, with a 2004 law to establish rapid identification and treatment of stroke victims. This is in concert with a national call for the designation of stroke centers in order to bring acute stroke interventions, such as tPA, to more stroke victims.

As of July 1, 2006, Florida law will require emergency medical services (EMS) to transport stroke patients to facilities certified as Primary Stroke Centers if certain parameters are met. This rapid response system facilitates identification of patients potentially eligible for treatment with reperfusion agents, thereby increasing the number of patients receiving the life saving and disability reducing agent. The consideration of similar initiatives across the country will likely have a direct impact on the number of patients qualifying for tPA.

Although ICD-9-CM code 99.10 is used to identify agents such as tPA, it is not a driver for the DRG and is therefore underreported. The cost of this treatment is not recognized in the DRG payment. NSI data indicate that charges for this treatment are substantially higher than other charges within DRGs 14 and 15. These charges exceed the others by $35,000-$40,000 per case. If there were a separate DRG classification to capture these charges, CMS would have better data available to analyze the true number of beneficiaries receiving this treatment. It is recommended that CMS reverse its position and create a new DRG classification for the administration of reperfusion agents. Those facilities that make significant investments in additional resources and processes to operate as a stroke center deserve appropriate compensation. The long term implications of expeditiously treating patients with reperfusion agents are increased outcomes and decreased costs to the Medicare program.

2. Unruptured Cerebral Aneurysms

Florida Hospital believes that unruptured cerebral aneurysms should be reclassified to a unique DRG. CMS review of the MedPAR data revealed that charges for unruptured cerebral aneurysms were slightly, but not significantly higher in comparison to other charges within DRGs 1 and 2. Our data indicate there is a need for a separate DRG to distinguish treatment of unruptured cerebral aneurysms. At Florida Hospital, 12% of our DRG 1 and 2 cases were for unruptured cerebral aneurysms. A significant disparity was noted within DRG 1, where the average charges for unruptured cerebral aneurysms were $35,000 higher than other cases within the DRG. This difference may be attributable to the devices (e.g., coils, clips, etc.) required to treat these cases. A separate DRG is needed to understand the true weight of these procedures and to establish reimbursement that recognizes the cost of the medical devices used to perform the procedures. As a result, CMS is urged to reconsider reclassification of unruptured cerebral aneurysms into a new DRG that recognizes the higher costs associated with these cases.

B. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

1. Multiple Level Spinal Fusions

Florida Hospital believes that creating a new DRG for spine fusions with a principal diagnosis of curvature of the spine and malignancies is appropriate. Our experience indicates that the cost associated with a spine fusion for these diagnoses significantly exceeds the current Medicare reimbursement.

We hope CMS will strongly consider our recommendations.

Respectfully Submitted,

Debbie Lombardi
Administrative Director

523

COLLINS
MOREY
SMITH
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HARTSTEIN

CMS-1500-P-825

Submitter : Mr. Curtis Maier **Date:** 06/24/2005

Organization : St. Benedicts Family Medical Center

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Comments are submitted as an attachment letter

CMS-1500-P-825-Attach-1.DOC

CAH/LOC

Administration

Attachment to #825

Care of the Sick must take priority over everything else, for in them Christ is served.

June 24, 2005

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

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

Dear Sir/Madam:

On behalf of St. Benedicts Family Medical Center, I am writing in regard to the Critical Access Hospital (CAH) sections contained in the Proposed Changes to the Medicare Hospital Inpatient Prospective Payment Systems and FY06 Rates. The proposal relative to the relocation of necessary provider CAH's is extremely concerning to St. Benedicts Family Medical Center and the other CAH facilities in the state.

Medicare Modernization Act

The Medicare Modernization Act (MMA) eliminates the state's ability to designate necessary provider status as of January 1, 2006. A provision was also included in the MMA to allow current CAH facilities to maintain their necessary provider status providing they were designated prior to the January 1, 2006 date. The intent of the MMA was to exempt current CAH facilities from losing their waiver as a necessary provider. However, the restrictive provisions in the MMA for relocation are contradictory to the intent of the MMA.

The December 8, 2003 date restriction proposed by CMS appears to have no foundation and is unreasonable because the necessary provider exemption has no time restrictions for expiration. St. Benedicts would suggest removing this arbitrary date.

St. Benedicts was constructed in 1952 and is in desperate need of updating its facilities. The facility is aged and doesn't function well in today's environment. Rebuilding is necessary to improve safety and quality of care (including fire and safety codes, infrastructure to support utilities and telecommunications upgrades to support technology). These improvements will result in higher quality care and better patient outcomes.

709 North Lincoln
Jerome ID 83338
208.324.4301
Fax: 208.324.3878
www.sbfmc.org

Administration

Attachment to #825

St. Benedicts is landlocked in the current location and the population served in our primary service area has shifted. In addition, construction costs are decreased on a "green field" site.

Moving St. Benedicts to a new location a few miles away does not imply that we have ceased business nor should we be considered a new provider. Movement to our proposed site demonstrates our commitment to better serve the needs of our primary service area and population, which has changed over the last several years. St. Benedicts is an integral and necessary part of the Jerome Community. Like the American Hospital Association (AHA), we believe that CMS should consider any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.

If a facility is moving further than five miles, we would recommend an approach similar to the 75 percent test described by CMS (same population, same staff and same services) with criteria to address any future changes. St. Benedicts has purchased an option for land, which is greater than five miles from the current location but central to our primary service area.

St. Benedicts is in agreement with the AHA in recommending that CMS alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show that a new facility on another site would be less expensive than rebuilding at the current location, only two other measures should need to be satisfied. Regardless of the criteria selected, CAH's should be aware of the expectations with advance notice of the standards to which they will be held.

St. Benedicts Family Medical Center would strongly encourage CMS to expand and utilize the criteria recommended above and to rescind this restrictive policy and allow necessary provider CAH's to rebuild and/or relocate as needed to improve the quality of care and health care needs of the local community.

Sincerely,
ST. BENEDICTS FAMILY MEDICAL CENTER

Curtis Maier
Chief Operating Officer

709 North Lincoln
Jerome ID 83338
208.324.4301
Fax: 208.324.3878
www.sbfmc.org

524

BROOKS
FAGAN
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KELLY
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HARTSTEIN
Walz
Hart

Submitter : Mr. Ford Kyes

Date: 06/24/2005

Organization : St. Anthony's Health Care

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-823-Attach-1.PDF

TRANSFERS

DRG/GEN

ATTACHMENT TO # 823

June 24, 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 Dr. McClellan:

On behalf of St. Anthony's Health Care located in St. Petersburg, Florida, I am writing to express our serious concerns regarding the May 4, 2005 proposed changes to the hospital inpatient prospective payment system (PPS) proposed rule. The rule recommends an expansion of the "transfer policy" to roughly half of all diagnosis related groups (DRGs). This is the third set of new criteria the Center for Medicare and Medicaid Services (CMS) has proposed for inclusion in the transfer policy in the last three years. The proposed rule inhibits the ability of St. Anthony's Health Care's clinicians to determine the best setting for patients based on their distinct medical needs.

St. Anthony's is committed to providing a unique model of efficient care for residents in the communities we serve. As such, we are troubled by Medicare's current transfer policy that defines patients in 30 DRGs who are discharged to a post acute setting, such as a skilled nursing facility or a rehabilitation facility, as a "transfer" rather than as a discharge when their acute care length of stay is at least one day less than the national average. Defining these discharges as transfers means that our hospitals are paid at less than the full DRG rate.

Given St. Anthony's pledge to the communities we serve to deliver health care services in the most efficient manner possible, we believe this policy penalizes hospitals for providing the most efficient treatment in the most appropriate setting. CMS' May 4, 2005 proposed regulations would make even more discharges subject to this imperfect policy – despite the fact that the underlying statute as passed by Congress never explicitly proposed adding these new DRGs.

In conclusion, St. Anthony's Health Care opposes any expansion of the transfer policy. We are also hopeful that CMS will establish clear and consistent processes for the submission and validation of quality data and that hospitals will not be penalized when technical issues outside their control impede data reporting.

Thank you for your consideration of these comments.

Sincerely,

Ford N. Kyes

Ford Kyes
President and Chief Executive Officer

525

BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HABSTEIN

CMS-1500-P-822

Submitter : **Mr. Stephen McMillan** **Date: 06/24/2005**

Organization : **AstraZeneca Pharmaceutcals LP**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

DRG Reclassifications

See Attachment

DRG/GEN

CMS-1500-P-822-Attach-1.DOC

Attachment to #822

AstraZeneca

June 24, 2005

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

Re: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, 70 Fed. Reg. 85, 23306 (May 4, 2005) [File Code: CMS-1500-P]

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit comments on the proposed rule issued by the Centers for Medicare & Medicaid Services ("CMS") to implement Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates (the "Proposed Rule"), 70 Fed. Reg. 85, 23306 (May 4, 2005). We appreciate this opportunity to share our views on the important changes proposed to the DRG structure for stroke care.

Stroke and its long-term consequences are significant public health issues, and are of particular import for the Medicare program. On average, every 45 seconds someone in the United States has a stroke, which equates to nearly 700,000 new or recurrent events each year. Stroke is a leading cause of serious, long-term disability and ranks third in all causes of death behind heart disease and cancer.[1] In 2005 the estimated direct cost of stroke is $35 billion, with nearly $15 billion in hospital services alone.[2] Congress has recognized stroke as a public health issue and there exist bills in both the Senate and the House of Representatives to address stroke through more robust early identification activities and interventions as well as preventive measures.[3] In general, stroke care has traditionally been in the form of active palliation, with a focus on stabilizing the patient and then following quickly with an aggressive rehabilitation program. While these efforts are necessary, there is a trend toward more aggressive treatment of the acute event. Reperfusion agents and a number of new pharmacological and procedural interventions are currently in development, with the common aim of minimizing the damage to brain tissue from the ischemic event.

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1 American Stroke Association, *Heart Disease and Stroke Statistics – 2005 Update*, pp. 16-18.

2 American Stroke Association, *Heart Disease and Stroke Statistics – 2005 Update*, p. 53.

3 Stroke Treatment and Ongoing Prevention Act, S.1064. and H.R.898.

AstraZeneca is one of the world's leading pharmaceutical companies, engaged in the research and development of new medicines. Through its leadership in the cardiovascular, oncology, neuroscience, gastrointestinal, and respiratory areas, AstraZeneca is committed to the discovery of drugs that will allow Medicare beneficiaries to lead longer, healthier, and more productive lives. In keeping with this commitment, AstraZeneca has a long-standing drug development program targeted at effective therapies for stroke, and presently is conducting Phase III trials of a stroke drug candidate which, if approved, will be subject to the payments provided to hospitals under the Inpatient Prospective Payment Systems (IPPS). As such, AstraZeneca applauds CMS's consideration of the adequacy of payment for stroke cases.

AstraZeneca understands that several hospital stroke centers have proposed using tissue plasminogen activator (tPA) as a proxy to identify patients with severe strokes. Representatives of these centers have stated that these tPA cases generate higher charges than other stroke cases because of the higher hospital resource utilization they entail. CMS performed an analysis of Medicare stroke case charges, and has found that the average standardized charges for cases treated with tPA are more than $16,000 and $10,000 higher than those of all other cases in DRGs 14 and 15, respectively.[4] The hospital stroke centers offered two alternatives for rearranging the stroke DRGs. The first would group ischemic reperfusion cases in a renamed DRG 14, with all other ischemic and hemorrhagic cases grouped into DRG 15. The second would leave DRGs 14 and 15 as they currently exist, and group ischemic reperfusion cases in a new DRG. AstraZeneca further understands that CMS is not proposing any changes to the stroke DRGs at this time, because the charge differential is based on a small number of reported tPA stroke interventions.

The following comments address a number of specific considerations raised by the suggested changes in the Proposed Rule. We are available to provide additional information about any of these items or answer any questions you may have.

Summary of AstraZeneca's Position on the Proposed Stroke DRG Change

First, AstraZeneca supports in general any changes to the DRG system that would facilitate beneficiary access to improved stroke care, by enabling more rapid diffusion of worthy treatments and hospital reimbursement for stroke cases that is more commensurate with their costs. As such, we believe that the stroke centers' proposal is worthy of serious consideration by CMS.

However, AstraZeneca believes that the proposed stroke DRG changes are too limited as written. The proposed descriptor, "reperfusion agent", is not broad enough to encompass other promising pharmacotherapies for stroke that are in late stages of clinical development. These novel therapies include GP IIb/IIIa inhibitors and neuroprotectants for ischemic stroke, and recombinant Factor VIIa for hemorrhagic stroke. By broadening the title for the proposed new DRG to include a wider range of acute pharmacotherapies, CMS could accelerate more appropriate payment for stroke cases including any such newly approved therapies. In contrast, implementing the proposed narrowly-defined change would require further modification of the stroke DRGs, potentially in the near future, to facilitate full

[4] 70 Fed. Reg. 85, 23316 (May 4, 2005).

beneficiary access by ensuring adequate reimbursement to the institutions that may use these therapies if approved.

AstraZeneca believes that creating a new, broader DRG for stroke pharmacotherapy is an appropriate step for three reasons. First, the development of these pharmacotherapies for acute stroke treatment signals a paradigm shift in stroke management, not dissimilar to the paradigm shift in heart attack management decades ago. It reflects an emerging medical understanding of the pathophysiological process of the stroke itself and represents a shift of care from active palliation of symptoms to aggressive intervention to minimize or avoid functional losses. As such, all of these pharmacotherapies exhibit a clinical coherence that is greater among them, than between each therapy and the remainder of stroke cases. They, like reperfusion agents, are intended to actively treat the acute event in order to change the natural course of the damage being inflicted on the brain tissue. Second, while the actual case expenses for each of these developing therapeutic options are not presently known, cases involving any of these agents might be expected to be relatively costly. Similar to the situation for tPA, the increased costs of these cases are likely to be quite different from those strokes involving only active palliation. Third, while CMS has expressed concern that there may be insufficient thrombolytic cases to justify the proposed change in stroke DRGs, enabling the future addition of these emerging technologies could effectively broaden the treatable case population in the new DRG considerably. Thus, a new, broader DRG for stroke pharmacotherapy likely would meet CMS's DRG criteria of clinical coherence among cases, internal charge coherence with a significant difference from other, related DRGs, and a sufficient number of cases to warrant separation in a different DRG.

Therefore, AstraZeneca endorses either of the suggested stroke DRG rearrangements, provided that the title of the proposed DRG for reperfusion cases was changed to the following: "Ischemic or Hemorrhagic Stroke Treatment with Acute Pharmacologic Intervention."

Limitations of the Stroke DRG Change Proposal Would be Addressed by Broadening the Title

The current proposal, while admirable in its attempt to ensure clinically-appropriate access to tPA therapy for stroke, nevertheless has a number of significant shortcomings:

- Because only a minority of stroke cases is eligible for treatment with tPA, the proposed change would improve access to therapy for only a small fraction of all stroke patients.

- Because only a single type of reperfusion agent is presently approved for stroke treatment, the proposed change would create a DRG that is, *de facto*, product specific.

- The proposed change addresses case charge disparities associated with the use of a particular therapeutic option, but fails to address the clinical coherence intrinsic to the variety of emerging pharmacotherapeutic options for stroke treatment currently under development.

- Implementing such a narrowly-defined change may necessitate further changes to the stroke DRGs in the near future to ensure patient access to emerging drug therapies once approved.

In contrast, implementing the stroke DRG change proposal with a broader title would address these shortcomings:

- Allowing for additional acute pharmacologic interventions to be added to the "reperfusion" DRG would, by definition, increase the number of patients for which the new DRG would enhance access to appropriate stroke therapy. Although the group of patients receiving tPA therapy may, by itself, be too small to justify realigning the stroke DRGs, this group plus those potentially receiving GP IIb/IIIa inhibitors, clotting factors, or neuroprotectants likely would constitute a "critical mass".

- Broadening the title of the proposed "reperfusion" DRG would, by definition, make the new DRG not product specific.

- Broadening the title of the proposed DRG to encompass a variety of pharmacotherapies would acknowledge the intrinsic clinical coherence of acute pharmacologic intervention cases. Before the approval of tPA for stroke, all strokes were managed similarly, regardless of type (ischemic vs. hemorrhagic) – first by stabilizing the patient, and then by initiating a rehabilitation program as soon as feasible. Thus, because virtually all strokes were managed in a similar fashion, the primary driver of clinical coherence was the etiology of the stroke. The emergence first of tPA (FDA-approved indication in 1996), and then of several other potential therapeutic options (currently in clinical investigations to document safety and efficacy), for treatment of stroke represents a paradigm shift in the clinical approach to these cases. Under this new paradigm of aggressive intervention, the primary driver of clinical coherence among stroke cases has changed from etiology to the type of case management – interventional vs. palliative.

- Implementing a more broadly defined stroke DRG change at present would allow CMS to efficiently accommodate future, deserving pharmacotherapies without subsequent DRG changes. Moreover, to include other pharmacotherapies, CMS would only need to map the ICD-9-CM procedure codes for their administration to the DRG. Because CMS retains complete control over i) the creation of ICD-9-CM procedure codes, ii) their mapping to the newly defined DRG, and iii) the definition (through Coding Clinic) of how each code may be used, there is essentially no risk of upcoding or inappropriate mapping of cases to the DRG. In fact, ICD-9-CM codes already exist for thrombolytic administration (99.10), GP IIb/IIIa inhibitor administration (99.20), and neuroprotectant administration (99.75). There are relatively few other infused agents currently identified by a specific ICD-9-CM procedure code.

Additional Benefits that Could Accrue From a Broader DRG Title

Medicare beneficiaries and CMS would experience additional benefits from the facilitation of more appropriate reimbursement for a wider range of drug treatments for stroke.

- More appropriate reimbursement for effective pharmacotherapies may lead to significant cost offsets in subsequent healthcare utilization for stroke patients. Medicare incurs significant costs for skilled nursing, rehabilitation, and clinical management of stroke sequelae. Acute pharmacologic interventions in development offer the promise of reducing the impact of these downstream cost drivers.

- More appropriate reimbursement for acute pharmacologic interventions will improve the hospitals' ability to maintain adequate stocking levels of these agents and thereby facilitate patient and physician access in the acute timeframe necessary for their use.

- Private payers that use DRG-based or similar case-rate hospital prospective payment systems often look to CMS for guidance in the structure of their systems. By taking the lead in providing more appropriate DRG-based reimbursement for effective stroke pharmacotherapies, CMS could influence similarly appropriate payment by private payers. Such leadership by CMS could have the effect of reducing the number of younger stroke victims entering the Medicare program because of their disability.

A Broader DRG Title is Timely and Appropriate

In addition to tPA, which is already approved and marketed for stroke treatment, multiple other pharmacologic options that may be suitable for a broad range of patients may be nearing clinical use. Such options include, but are not limited to, the following:

- Hemorrhagic stroke – recombinant Factor VIIa: NovoSeven® is routinely used in the United States for the treatment of spontaneous and surgical bleedings in hemophilia A and B patients with antibodies (inhibitors) against factors VIII (FVIII) and IX (FIX), respectively. A recently completed Phase 2b dose-ranging study demonstrated that treatment with recombinant Factor VIIa resulted in less hematoma volume growth, a reduction in the number of patients with moderately severe disability, and a reduction in mortality at day 90.[5]

- Ischemic stroke – GP IIb/IIIa inhibitors: Reopro®, which is approved for cardiological uses, has shown promising results in a Phase IIb trial for up to six hours after symptom onset.[6] A larger, 1,500-patient Phase III trial is now underway.

- Ischemic stroke– neuroprotectants: NXY-059, an investigational compound proposed to work by free-radical trapping, in a first analysis of data from one of the two Phase IIb/III SAINT trials involving more than 1700 patients, showed a reduction versus placebo on the primary outcome of disability after an acute ischemic stroke (p= 0.038), as measured by the Modified Rankin Scale.[7]

While additional research is underway to truly define the role of these potential therapies, it is likely that none of them are expected to be approved for use in stroke during Medicare's FY 2006. Nevertheless, all are progressing steadily through clinical trials for acute stroke, and two have been previously approved for other indications. Thus, CMS has a rare opportunity to take an action in advance that will prepare the agency to facilitate beneficiary access if and when these drugs are approved, without any material risk on the agency's part.

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[5] Mayer SA, Brun NC, Begtrup K, et al. Recombinant activated factor VII for acute intracerebral hemorrhage. N Engl J Med 2005; 352:777-85.

[6] AbESTT Investigators: Effects of Abciximab for Acute Ischemic Stroke: Final Results of Abciximab in Emergent Stroke Treatment Trial (AbESTT). Stroke 2003; 34: 253.

[7] Data on file, AstraZeneca; Presentation of SAINT I results, European Stroke Conference, Bologna, Italy, May 28, 2005

* * * * *

Again, AstraZeneca appreciates the opportunity to comment on the Proposed Rule. We look forward to working with CMS to promote high-quality stroke care for Medicare beneficiaries. Please do not hesitate to contact me at (202) 350-5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,

Stephen D. McMillan
Director, Government Reimbursement

Cc: Marc Hartstein

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CMS-1500-P-820

Submitter : Mr. Kenneth Raske **Date:** 06/24/2005

Organization : Greater New York Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-820-Attach-1.PDF

CMS-1500-P-820-Attach-2.PDF

TRANSFERS
WI/Bd
MB/H
Q DATA
MEDPAC
DRG/GEN
CBSAs
WI/OM
MB/H
Labor/S
Paym't Rates/Update

ATTACHMENT 1 TO #820

Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246 – 7100 / (212) 262 - 6350
Kenneth E. Raske, President

June
Twenty-four
2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, *Federal Register* 70, no. 85 (May 4, 2005): 23306–23673. [CMS-1500-P]

Dear Dr. McClellan:

On behalf of the more than 250 hospitals, skilled nursing facilities, and certified home health agencies, both voluntary not-for-profit and public, that make up the membership of the Greater New York Hospital Association (GNYHA) and the Continuing Care Leadership Coalition (CCLC) at GNYHA, I appreciate this opportunity to comment upon the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2006 inpatient prospective payment system (PPS).

The following is a brief summary of our most important comments and recommendations. They are discussed in much greater detail in the attached text. In addition, our detailed comments are presented in the order in which their topics appear in the proposed rule in order to facilitate their distribution within CMS.

SUMMARY OF KEY RECOMMENDATIONS

1. Post-acute Care Transfers. We believe that CMS's post-acute care transfer (PACT) policy is anachronistic now that lengths of stay have stabilized, and we believe it represents poor policy because 1) it contradicts the contemporary and pervasive view that reduced length of stay indicates efficiency, and 2) it undermines the incentive to improve efficiency in the case payment system. Therefore, we strongly urge CMS to roll back the PACT policy to the

greatest extent possible, and certainly not to expand it. If the Agency is intent upon preserving this policy, then it should recognize it as a form of case-mix refinement and implement it in a budget-neutral way.

2. Hospital Wage Index. Just as CMS and the Congress have used the Medicare Geographic Classification Review Board (MGCRB) to correct shortcomings in the use of metropolitan statistical areas (MSAs) to denote hospital labor markets, so should CMS use the MGCRB to correct shortcomings in the use of core-based statistical areas (CBSAs). Specifically, we recommend that CMS develop criteria that would allow areas within CBSAs to qualify as core urban areas and for all providers located in those areas to receive their own wage indices. We also recommend that CMS fully implement the occupational mix adjustment.

3. Hospital Market Basket. We strongly urge CMS to recognize professional liability insurance as a labor-related cost and to update the market basket weights only if this change is made.

4. Hospital Quality Data. We believe that there are currently too many flaws in the data validation process to tie validation to the annual payment update in FY 2006, so we urge CMS to tie the update solely to the continuous submission of quality data.

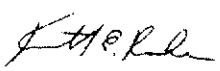
5. MedPAC Recommendations. With respect to four recommendations that pertain to diagnosis-related group (DRG) refinement and the computation of DRG weights, we discourage CMS from implementing these provisions administratively because of the potential for a significant redistribution of funding among hospitals that is certainly not anticipated or understood. We also encourage the Agency to request that Congress not require implementation of these provisions.

We are also providing comments in the attached text on DRG reclassifications and outliers. A separate letter will provide our comments on proposed graduate medical education payment policies.

We acknowledge the great intelligence and care that CMS staff have brought to bear on these issues and, again, we greatly appreciate the opportunity to provide our analysis and comments. If you or your staff have any questions or would like to discuss our comments further, please do not hesitate to contact Karen S. Heller, Senior Vice President and Executive Director of The Health Economics and Outcomes Research Institute (THEORI) at GNYHA. She can be reached at (212) 506-5408 or at heller@gnyha.org.

My best.

Sincerely,



Kenneth E. Raske, President

Attachments

Greater New York Hospital Association's Comments on the Centers for Medicare & Medicaid Services' Proposed Rule for the Federal Fiscal Year 2006 Inpatient Prospective Payment System

DRG RECLASSIFICATIONS

DRG refinement updates the inpatient acute care reimbursement system by recognizing the effect on cost of new technologies, pharmaceuticals and treatment protocols. Advancements in medical and surgical care are sought to improve the health status of Medicare b eneficiaries a nd the overall efficiency of the Medicare program by reducing disability levels. We believe that continuous DRG refinement is very important because it allows hospitals to implement advanced interventions while minimizing systematic risk.

Adoption of the International Classification of Diseases, Tenth Revision (ICD-10) would facilitate CMS's ability to appropriately refine the DRGs, so we urge the Agency to move toward ICD-10 implementation as quickly as possible. To that end, we support CMS's proposed DRG refinements for FY 2006, with two recommended changes. Both of our recommendations emanated from discussions among our members' clinical staff who participate on GNYHA's Outcomes Research Committee.

Recommendations:

1. Stroke cases. With respect to the stroke DRGs, 14 and 15, we support the second suggestion made by the representatives of several hospital stroke centers with whom CMS consulted regarding recognition of the high cost of tissue plasminogen activator (tPA). This suggestion was to create a new DRG entitled "Ischemic Stroke Treatment with a Reperfusion Agent," which would only include strokes that were caused by clots and treated with tPA, as identified t hrough t he p rocedure code 99.10. F urthermore, o ur m embers r ecommend t hat CMS implement the new DRG in FY 2006 rather than waiting for more data to accumulate, since the incremental cost and effectiveness of this thrombolytic agent are well documented.

2. AICD cases. With respect to the DRGs involving the implantation of an automatic implantable cardioverter/defibrillator (AICD), CMS is proposing to regroup cases without cardiac catheterization, but with cardiac electrophysiologic stimulation and recording studies (EPS), from DRGs 535 and 536 to DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization. Our members recognize that cases without cardiac catheterization do not belong in the cardiac catheterization DRGs; however, CMS's data show that the average cost of cases with EPS is significantly higher than the cost of cases without EPS and that the volume of cases with EPS is also significant. Therefore, we recommend that CMS create a new DRG for cases with cardiac defibrillator implant without cardiac catheterization, but with EPS. Essentially, DRG 515 would become two DRGs, one with and one without EPS.

HOSPITAL WAGE INDEX

The comments and recommendations that follow are in addition to the objections and recommendations that we put forward in our comment letter dated July 12, 2004, regarding the FY 2005 inpatient PPS proposed rule, as well as the arguments set forth in the litigation that has been brought by many GNYHA members with respect to CMS's adoption of the new CBSAs and the partial implementation of the occupational mix adjustment, all of which we renew and incorporate by reference for the purposes of this comment letter.

CBSAs

At the direction of Congress, CMS adjusts Medicare reimbursement rates to providers to account for regional variation in wage levels. The adjustment is based on each hospital's area wage index, which is computed as the ratio of the average hourly wage rate in each hospital's labor market to the national average hourly wage rate. Lacking data to define hospital labor markets at the inception of the inpatient PPS, the Health Care Financing Administration (HCFA) used the Census Bureau's metropolitan statistical areas (MSAs) as a proxy.

The MSAs were defined for the sole purpose of reporting statistical data unrelated to Medicare reimbursement, and problems with their use as hospital labor markets immediately emerged. In response, Congress established the Medicare Geographic Classification Review Board (MGCRB) and directed HCFA to develop criteria under which hospitals could apply for reclassification into a more appropriate labor market. The reclassification guidelines have continued to evolve and therefore represent the most current policy determinations of Congress and CMS. One of the most important features of the reclassification process is that increased payments to reclassifying hospitals are financed through a modest across-the-board contribution by all hospitals and not by the hospitals located in the areas to which the reclassifying hospitals are reassigned. This preserves the integrity of the higher regional adjustment made on behalf of the hospitals located in the higher-wage urban area.

After the 2000 census, the Census Bureau and the Office of Management and Budget (OMB) changed the definition of many of the nation's MSAs and renamed them "core-based statistical areas" (CBSAs). These changes were based upon population migration and general industry commuting patterns. Most MSA boundaries were not affected; however, some were tightened and others were expanded. The New York City MSA is an example of a statistical area that was expanded. OMB cautioned agencies not to use the CBSAs for purposes unrelated to statistical reporting unless the new boundaries were studied and found to be appropriate.

CMS sought to reflect the updated statistical areas in its definition of hospital labor markets and proposed to use them in place of the old MSAs. We thought this was inappropriate because it was arbitrary. The CBSAs were based on general commuting patterns rather than on hospital workforce commuting patterns and, therefore, in certain situations, resulted in "reclassifications" that would not have met MGCRB criteria. Furthermore, because the changes were made to the underlying structure of the hospital labor markets rather than through the reclassification process, increased payments to hospitals benefiting from the changes were not financed by all hospitals, but by the minority of hospitals disadvantaged by the changes. So, for example, hospitals located

in or reclassifying into the old New York City MSA would transfer about $1 billion over 10 years to hospitals newly added to the MSA. (Ten years is the length of time statistical area boundaries remain in effect. They may change again after the 2010 census.)

GNYHA and many hospitals located throughout the United States formally opposed CMS's proposal to replace the MSAs with the new CBSAs. We would have preferred that CMS somehow incorporate the new boundaries into the reclassification process. We did not object to conferring new benefits on additional hospitals per se; our objection was, rather, to the method of financing those new benefits—i.e., at the expense of a minority of hospitals. In response, CMS agreed to compute area wage indices based upon a blend of the old and new labor market definitions for disadvantaged hospitals during FY 2005. We were very appreciative of that accommodation. Nevertheless, CMS subsequently proposed to implement the new boundaries for its other prospective payment systems without a transition, and has proposed to end the blend in the inpatient PPS in FY 2006.

This course of action would unjustly harm the minority of hospitals and other health care providers that are located in areas whose boundaries were changed for Federal statistical reporting purposes. It is particularly unfair to disproportionately cut payments to providers located in areas whose statistical boundaries were expanded, because a significant problem with using MSAs or CBSAs as proxies for hospital labor markets—as expressed on several occasions by the U.S. Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC)—has been that they are too large to effectively discriminate between separate hospital labor markets.

Therefore, just as CMS has used the MGCRB in the past to correct flaws in the hospital labor markets as defined by MSAs, we now urge CMS to use the MGCRB to correct flaws in the hospital labor markets as defined by the new CBSAs.

Recommendations:

1. Core urban areas. CMS should develop and propose MGCRB criteria through which hospitals located in counties within CBSAs could apply for designation as a "core urban area" within the CBSA. Such criteria could incorporate hospital workforce commuting data and could include factors such as the county having been disadvantaged by an expansion of its MSA when the CBSAs were adopted.

    a. The wage index applied to hospitals located in a core urban area would be based solely upon their wage index data.

    b. The core urban area wage indices would also apply to other providers located in the core urban areas, including inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs), inpatient psychiatric facilities (IPFs), skilled nursing facilities (SNFs), and certified home health agencies (CHHAs).

c. CMS would also develop and propose MGCRB criteria through which hospitals not located in the core urban area, but within the same CBSA, could apply for reclassification into the core urban area.

d. The wage index data of the hospitals located in or reclassifying into a core urban area would continue to be used for the purpose of computing the wage index of the broader CBSA.

2. Hospital commutation data PUF. CMS should create and post a public use file (PUF) on its Web site that contains the hospital workforce commutation data that the Agency used to develop the out-migration adjustments that were established under Section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The purpose of making these data available would be to enable researchers to work collaboratively with the Agency to develop MGCRB criteria for designating core urban areas.

3. Continuation of blended wage index. CMS should continue to provide the blended MSA/CBSA wage index to hospitals disadvantaged by their location in MSAs that were expanded when the CBSAs were adopted as hospital labor markets. The blend should continue until the process is in place for hospitals to reclassify into a core urban area. This policy should also apply to IRFs, LTCHs, IPFs, SNFs, and CHHAs.

Occupational Mix Adjustment

CMS conducted its first occupational mix survey in a highly compressed time frame in early 2004 and did not have confidence in the validity of the results. For that reason, the Agency implemented a 90%-10% blend of the unadjusted area wage index and the occupational mix-adjusted area wage index, respectively, in FY 2005.

One of the biggest challenges for hospitals completing the survey was that it requested contract labor information that had not been provided to the hospitals in the format in which CMS wanted to receive the data. Not only did the contract labor vendors not report the data in the required format, but, in many cases, they could not reconstruct it in the required format. This meant that once the initial survey instrument was finalized, the hospitals had to negotiate with their vendors to obtain reports in the required format and the survey had to be prospective. Since CMS had only a few months to conduct a prospective survey, review the data, and analyze the results, the survey had to be whittled down to a four-week period or conducted retrospectively for a year if the hospital could gather the required data. The short time frame for the prospective survey coupled with the difficulty hospitals would have gathering retrospective data—assuming they even had such data—contributed to the lack of confidence in the results.

For the past year, though, hospitals have had the opportunity to correct any mistakes they may have made in their original submissions, so CMS should have greater confidence in the validity of the current occupational mix adjustments. CMS has based some of its continued concern on the fact that approximately one-third of rural hospitals have a disadvantageous adjustment, which the Agency did not expect. However, we predicted this outcome from an analysis of the

registered nurse and licensed practical nurse data that are made available every year from the American Hospital Association's annual survey of hospitals. Therefore, the unexpected outcome is not the result of the data. Nevertheless, CMS has proposed to continue the blended wage index in FY 2006 in the same 90%-10% proportion that was used in FY 2005. We do not believe that continuing the blend is appropriate, and we urge the Agency to implement the occupational mix adjustments fully.

In order for CMS to have confidence in the validity of the data derived from the next round of the survey, we believe that the Agency will also have to conduct that survey prospectively. Again, the problem will be obtaining contract labor data in the format—and for the time frame—that CMS requires. Once the Agency distills the contract labor information that it will want on an ongoing basis, the hospitals can arrange to receive regular reports from their vendors, which will enable the occupational mix survey to be conducted retrospectively, or even built into the Medicare cost report.

Since Congress directed CMS to update the occupational mix adjustment every three years, the Agency will be expected to implement the first update in FY 2008, which begins on October 1, 2007. If CMS wanted to collect a year's worth of reliable data from the hospitals on a prospective basis, it is probably already behind schedule. Given that the proposed rule would have to be issued on or about May 1, 2007, and that time must be scheduled for 1) CMS to propose and finalize a survey instrument, 2) the hospitals to prospectively collect and submit the data in the new instrument's format, 3) the fiscal intermediaries to review the data, and 4) CMS to analyze the data and compute occupational mix adjustments, the best that the Agency could hope for would probably be six months' worth of data.

Recommendations:

1. Implementation in FY 2006. CMS should implement the occupational mix adjustment in FY 2006 fully.

2. Prospectivity. CMS should plan to conduct the next occupational mix survey prospectively in order to ensure that hospitals can obtain accurate and reliable data on contract labor.

3. Time frame. In addition, in order to maximize the timeframe during which the survey would be conducted, CMS should issue a proposed survey instrument as soon as possible.

HOSPITAL MARKET BASKET

The current hospital market basket cost category weights reflect FY 1992 data, and the cost categories designated as labor-related are wages and compensation, employee benefits, professional fees, postal delivery, and all other labor-intensive services. The sum of the weights of the labor-related cost categories represents the portion of the standardized amount that is wage-adjusted, which is 71.1% today.

In FY 2003, CMS presented the results of updating the cost category weights to reflect FY 1997 data and removing postal delivery from the list of cost categories that are considered labor-

related for the purpose of wage-adjusting the standardized amount. Updating the weights would have increased the labor-related share from 71.1% to 73.4%, while re-designating postal delivery would have reduced the updated labor-related share from 73.4% to 72.5%. Therefore, the net effect of the two changes would have been an increase in the labor-related share from 71.1% to 72.5%. Because this change would have redistributed money from rural to urban hospitals at a time when Congress wanted to increase payments to rural hospitals, CMS declined to change the hospital market basket in FY 2003.

A year later, Congress enacted the MMA, which essentially capped the labor-related portion of the standardized amount at 62% for relatively low-wage hospitals. Therefore, future updates to the cost category weights in the hospital market basket would affect only relatively high-wage hospitals.

For FY 2006, CMS has proposed to update the cost category weights in the hospital market basket to reflect FY 2002 data. This would have the effect of reducing the labor-related share from 71.1% to 69.7%. The savings generated by this reduction would be used to increase the standardized amount; thus, a portion of the savings would be redistributed to rural and other relatively low-wage hospitals.

We can make a good case on behalf of relatively high-wage hospitals that CMS should not update the cost component weights in FY 2006 to make up for not updating the weights in FY 2003. However, we would support CMS updating the weights in FY 2006 *if* the Agency were also willing to re-designate professional liability insurance as a labor-related cost. These costs are clearly wage-related—indeed, they are reported in the wage index—and are clearly locally determined. We believe that the failure to include professional liability insurance in the wage-adjusted portion of the standardized amount in the past was a grave oversight. Including this important cost component in the labor share would bring it up to 71.3%, which is virtually the same as the current labor share of 71.1%.

Summary of Updates to the Cost Category Weights and Labor-related Designations

	Basis of Cost Weights		
	FY 1992	FY 1997	FY 2002
Effect of rebasing			
Wages and salaries	50.2%	50.7%	48.2%
Employee benefits	11.1%	11.0%	11.8%
Professional fees	2.1%	5.4%	5.5%
Postal delivery	0.3%	0.9%	1.3%
Other labor-related services	7.3%	5.4%	4.2%
Total labor-related	71.1%	73.4%	71.0%
Effect of redesignating labor components			
Removal of postal delivery		-0.9%	-1.3%
Total labor-related		72.5%	69.7%
GNYHA recommendation			
Professional liability insurance			1.6%
Total labor-related			71.3%

Recommendations:

1. Labor Share. CMS should re-designate professional liability insurance as a labor-related cost.

2. Updating Weights. CMS should not update the hospital market basket cost component weights unless it also includes professional liability insurance in the labor-related portion of the standardized amount.

POST-ACUTE CARE TRANSFERS

A patient's stay in an inpatient acute care hospital can be viewed as having three phases: stabilization, treatment, and recovery. CMS has had a long-standing policy of providing only partial inpatient PPS reimbursement on behalf of patients who do not complete the treatment phase of their care. These are patients who are transferred to another acute care hospital once they are stabilized because the first hospital could not provide the acute care services they required. More recently, CMS began to expand the concept of a transfer patient to also include patients with a relatively short recovery phase.

Under the post-acute care transfer (PACT) policy, patients are deemed to be transfers if they are discharged to an IRF, an IPF, a SNF, or to home care. Post-acute care transfer cases are reimbursed according to the regular transfer payment methodology. Under this methodology, the inlier payment is divided by the geometric mean length of stay of the DRG to which the patient is assigned in order to derive a per diem payment. Then the hospital receives the lower of the per diem payment multiplied by the actual length of stay plus one day, or the full DRG amount. In certain DRGs, the hospital receives a blended PACT payment, which is an equal share of the transfer payment and the DRG payment.

The PACT policy originated in the mid-1990s when CMS, MedPAC, and the Congress became concerned that some hospitals were "gaming the system" by discharging their patients inappropriately early to post-acute care services that they owned in order to collect the full acute care case payment plus per diem or per visit post-acute care payments. Even though the DRG weights are recalibrated every year so that they reflect updated practice patterns, the annual recalibration is based on two-year-old data. Therefore, during the years in which lengths of stay were declining steadily, there was some basis for the concerns expressed by CMS and others. Thus, through the Balanced Budget Act of 1997, Congress directed CMS to apply the PACT policy to 10 DRGs, starting in 1999.

The period in which lengths of stay declined every year turned out to be short-lived. The national average length of stay decreased by about 2% per year during the 1990s, coincident with the expansion of managed care, but has stabilized since then. Therefore reimbursing discharges to post-acute care as transfers is no longer warranted. Nonetheless, in FY 2004, CMS extended the PACT policy to 29 DRGs and now, for FY 2006, the Agency is proposing to fully implement the policy by extending it to 231 DRGs, which are virtually all the DRGs to which the policy could reasonably be applied.

We strongly opposed the FY 2004 expansion of the PACT policy and more strongly oppose it now because the patients to whom it applies cannot legitimately be construed as transfer cases. That construction is now anachronistic. The cases to which the policy is now—and would be—applied to are merely cases with a shorter-than-average length of stay. Therefore, reducing the payment for these cases should be recognized as a form of case mix refinement and, if it were done, should be budget-neutral. There is absolutely no justification for CMS taking savings from this policy, whether it is expanded or not.

The question then becomes whether this form of case mix refinement is desirable. Even though New York hospitals have the longest lengths of stay in the United States, and are therefore less affected by the PACT policy than hospitals in other areas, we and our members feel strongly that this policy is inappropriate. We object to the PACT policy because it characterizes a low length of stay as an indicator of a clinically inappropriate discharge, which conflicts with the more contemporary and more prevalent characterization of a low length of stay as an indicator of efficiency.

In fact, length of stay is probably the most common measure of efficiency. Most hospitals have worked very hard to implement protocols that minimize the period of hospitalization through better management and care coordination. Deeming a stay incomplete merely because the length of stay is shorter than the geometric mean minus one day is arbitrary and undermines these efforts. Furthermore, refining the DRGs to pay less for shorter-stay cases also undermines the incentive built into the case payment methodology, which is that hospitals would be rewarded for efficiency.

Recommendations:

1. Opposition to PACT Policy. We strongly urge CMS to roll back its PACT policy and apply it only to the extent required by law—i.e., only to the first set of 10 DRGs—and definitely not to expand the policy.

2. Budget Neutrality. If CMS is intent upon continuing and expanding its PACT policy, then it should ensure budget neutrality by applying a factor either to the standardized amount or to all of the DRG weights.

HOSPITAL QUALITY DATA

Section 501 of the MMA reduced the inpatient PPS update by 0.4 percentage points for FY 2004–2007, but allowed hospitals to recoup the cut in exchange for submitting chart-abstracted data that are needed to compute 10 process measures related to the quality of care for three conditions: acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PNE). These measures are a subset of up to 26 measures for which hospitals are voluntarily submitting data under CMS's 7th Scope of Work. The 7th Scope of Work includes a fourth condition as well, surgical infection prevention (SIP). CMS is reporting the results of an expanded subset of 17 measures pertaining to the first three conditions on its *Hospital Compare* Web site.

For FY 2006, CMS is proposing that the data submission requirement be broadened to include the continuous submission of quarterly data and a determination that the data submitted are valid. "Valid" means that the information the hospitals provided is supported in the medical records. CMS determines validity by collecting a random sample of five medical records that were accepted into the Quality Improvement Organization (QIO) Clinical Warehouse from each hospital every quarter, re-abstracting the information that the hospitals submit, and computing a match rate. The match rate is the percentage of data elements for which the information provided by the hospital and the information obtained during re-abstraction match. CMS is proposing to deem a hospital's data to be valid if the 95% confidence interval around the match rate includes or exceeds 80%.

At the outset, we want to commend CMS—and Congress—for taking the proper approach to paying for performance at this time. It is heartening that our most important payer, Medicare, understands that evaluating hospitals must be viewed in the context of our national mission to develop electronic health records and the national health information infrastructure. As we hope you are aware, moving forward is analogous to a baby learning to walk: while transmitting and validating data will become routine in the future, developing the systems and processes to do so is very difficult and the path is strewn with obstacles.[1]

Yet having an adequate amount of data that are both appropriate and valid is the pre-requisite to having valid performance information. So we are very pleased that CMS is focusing on collecting and validating data at this juncture. Furthermore, we have no problem with the metric that CMS is proposing to determine validity—i.e., that the 95% confidence interval around the match rate must include or exceed 80%. We have studied the methodology that CMS will use to compute the confidence intervals, as described by William G. Cochran in *Sampling Techniques*, and believe it is appropriate.

Nevertheless, we do not believe that CMS should tie the full payment update to data validity this year. In the context of our Quality Steering Committee and our Outcomes Research Committee, we have spent a great deal of time working with our members to identify and resolve problems pertaining to the entire CMS data submission and validation process. We believe we have made great progress working with the hospitals, IPRO (our QIO), and CMS. Nonetheless, significant implementation problems remain. These problems are so fundamental that we believe they must be resolved before CMS penalizes hospitals financially.

The key problems pertain to the appeals process, training, ambiguous data elements, missing data elements, and validity scoring.

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[1] GNYHA has undertaken three projects in the past several years and so has observed firsthand how difficult it is to implement informatics-related initiatives. The three projects are:

a. The Quaesitum Measurement System (QMS), begun in 1997, which develops and juxtaposes quality and efficiency outcome measures for inpatient hospital services.
b. The Connectivity Project, begun in 2002, which is implementing the HIPAA transaction sets between our member hospitals and payers, starting with claims status.
c. The New York Clinical Information Exchange (NYCLIX), begun in 2004, which seeks to build a clinical data exchange, starting with emergency room information.

Appeals Process

Currently, hospitals are not allowed to appeal mismatches once they have achieved a passing validity score. This policy is unwise and unfair. It is unwise because it is necessary for hospitals and their reviewers to discuss areas in which they disagree in order to gain insight and education about the emerging specialty of chart abstraction and validation. For this reason, we also request that all appeals be reviewed by a clinician.

The policy of cutting off appeals once the hospital passes the 80% threshold in any quarter is unfair because CMS allows hospitals to pool more than one quarter's worth of data in situations in which they have a low—i.e., less than 80%—match rate in a particular quarter. In order to offset a low match rate in one quarter, hospitals must maximize their match rates in other quarters. We appreciate CMS's flexibility in allowing the pooling of quarterly data, especially since low scores can occur for benign reasons, as discussed below.

Training of CMS and Hospital Chart Abstractors

Abstracting medical record data according to CMS's standards is not as straightforward as it would seem, especially when it pertains to data elements that are open to a certain amount of interpretation. Most of our hospitals have assigned clinical staff, such as registered nurses, to do the abstractions, and many of those staff have noted that there are different ways to read a medical record. The intellectual and clinical judgment these staff bring to the task apparently introduces inefficiencies into the process and sometimes even "wrong" answers. This makes the process more expensive than it needs to be and can compromise the validity scores.

What would be most helpful would be for CMS to 1) describe the credentials of the staff the Agency uses for chart abstractions, 2) describe the training those staff receive, and 3) facilitate the development of materials that hospitals could use to hire and train their own personnel. It is wasteful for every hospital, or group that represents hospitals, to reinvent the wheel. The analogy to the type of help we seek is a program that helps students prepare for standardized college admission tests. Many students struggle over different plausible ways to answer certain questions, which can reduce their score and under-represent their knowledge and intelligence. Yet with training in how to interpret and answer the questions, they can take the test much more efficiently and their score will more accurately reflect their academic achievement. Assistance of this sort to hospitals would greatly improve the efficiency and effectiveness of the Reporting Hospital Quality Data for Annual Payment Update data abstraction process.

Another way to improve the abstraction process would be for CMS to have clinical staff study the inter-rater reliability of its own abstractors' determinations, to make those results public, and to continually refine its own training. This process would also include reporting the proportion of appealed decisions that were overturned.

Ambiguous Data Elements

Upgrading the validation process would require distinguishing between data elements that can lend themselves to interpretation and data elements that are unambiguous. Once this was

accomplished, CMS could compute an overall validity score as well as a validity score for only the unambiguous data elements. The score associated with unambiguous data elements would be tied to the payment update, while the overall score would be used for continuous education and training.

We did a brief review of the validated data elements with our Outcomes Research Committee and identified 14 out of 83 that could be subject to interpretation, as shown in the following table. Data elements such as admission source can be incorrect because if the patient both resides in a nursing home and was admitted through the emergency room, different abstractors could note either one as the source. We have encountered this phenomenon many times and resolved the problem in our outcomes research by using the urgent/emergent flag in the claims data to note true emergency admissions rather than the admission source code. We welcome and are willing to participate in a more thorough review to identify data elements subject to interpretation.

Validated Data Elements That Can Be Subject to Interpretation

Admission Source
Transfer From Another ED
Discharge Status
Pneumonia Working Diagnosis on Admission
Compromised
Antibiotics Prior to Arrival
Antibiotics PTA
Initial ECG Interpretation
Pre-Arrival LDL-Cholesterol Test
Pre-Arrival LDL-Cholesterol Value
Pre-Arrival LDL-Cholesterol Qualitative Description
Plan for LDL-Cholesterol Test
Reason for No LDL-Cholesterol Testing
Blood Cultures Prior to Arrival

On the same subject, we had difficulty compiling a list of the validated data elements. What we finally did was obtain the inclusion list from the QualityNet Exchange Web site, which we found at **qnetexchange.org/public/docs/hdc/datavldtn/InclusionList.pdf**, and reformat it to show on a single page the full list of unduplicated data elements validated in 2004 or 2005. This spreadsheet—which is attached—also provides a crosswalk from each element to the condition(s) in which it applies and indicates whether the element is used for one of the 10 starter measures. We respectfully request that CMS review this list and let us know if it is accurate. Since we have had numerous requests for such a list, we offer it to CMS to post on its Web site.

Missing Data Elements

Perhaps the most frustrating flaw in the validation process is that hospitals are penalized when certain data are in the medical record but were not submitted to CMS because the vendor software precluded the hospital from entering the data. This situation occurs when there is a "parent/child" relationship among data elements. For example, in all of the programs that our

members reviewed with us, which are virtually all of them, if the hospital says that pneumonia was not a working diagnosis on admission, then the software jumps to the next case and the hospital cannot enter additional information. This is even a feature of CART, CMS's own abstraction and reporting tool.

However—continuing with the same example—if upon re-abstraction CMS believes that the hospital should have said that pneumonia was the working diagnosis on admission, then the Agency scores as incorrect all of the elements for which data were not submitted. This is clearly unfair. CMS should score only one wrong answer in that situation. Then, if the reviewer believes that there are insufficient data elements in the hospital's validation record, the Agency should request an additional case.

Validity Scoring

CMS has proposed to compute the match rate confidence interval (C.I.) based on all validated data elements, but to then compute a match rate C.I. for the subset of elements pertaining to the 10 starter measures if the hospital fails the first validation. Again, we appreciate CMS's flexibility and recommend that the Agency go one step further. In addition to restricting the match rate C.I. for payment purposes to the unambiguous data elements, we believe that CMS should automatically compute the match rate C.I. for this set and for the subset that pertains to the 10 starter measures only. Then CMS should automatically assign the higher score to the hospital, even if both are passing rates.

Summary of Recommendations

1. Payment Update. CMS should not tie the FY 2006 payment update to the validation process because there are currently too many flaws in the process to assume that an inadequate score is a true reflection of invalid reporting.

2. Appeal Process. CMS should allow hospitals to appeal every mismatch determination with which they disagree and to have the appeal reviewed by a clinician.

3. Training. CMS should assist hospitals in their staffing and training by:
   a. publishing the credentials of the personnel it uses to abstract medical records,
   b. publishing the training information it provides to its abstractors,
   c. facilitating the creation of training materials that hospitals can use,
   d. conducting inter-rater reliability tests of its own abstractors,
   e. reporting the results of its inter-rater reliability tests,
   f. reporting the rate at which appealed decisions are overturned, and
   g. reporting on changes the Agency makes in its training techniques to improve accuracy and consistency.

4. Ambiguous Data Elements.

   a. CMS should ensure that mismatches are the result of invalid reporting rather than ambiguity by:

i. convening an expert panel to review the data elements used in the validation process in order to determine which could be subject to interpretation,
ii. computing separate validation scores for the entire set of data elements and for the subset that represents unambiguous data elements, and
iii. using the score on the subset of unambiguous data elements to determine eligibility for the full payment update.

b. In addition, we request that CMS review the list we compiled of the data elements that are validated and post an official list on its Web site.

5. Missing Data Elements. CMS should not penalize hospitals when data are missing because the vendor software precluded the hospital from entering the data because of information related to a prior data element.

6. Validity Scoring. Based on the subset of unambiguous data elements, CMS should automatically compute two validity scores, one for the entire subset and another for the smaller set of elements pertaining to the 10 starter measures, and automatically assign the higher of the two scores to the hospital.

MEDPAC RECOMMENDATIONS

This year, the Medicare Payment Advisory Commission (MedPAC) made four recommendations that pertain to the computation of DRG weights in the inpatient PPS and that have been included in Senate bill S. 1002, the *Hospital Fair Competition Act of 2005*, which was sponsored by the Chairman and Ranking Democratic Member of the Senate Finance Committee. They include:

1. computing DRG weights based on cost instead of charges,
2. computing DRG weights based on the hospital-specific relative value (HSRV) methodology,
3. eliminating statistical *and payment* outliers prior to computing the DRG weights, and
4. further refining the Medicare DRGs.

MedPAC believes that these proposals would improve payment accuracy and would, thus, reduce the potential for specialty hospitals to profit by targeting patients with low relative acuity. It is believed that specialty hospitals skim the most profitable patients from general hospitals, thus leaving the latter with less opportunity to break even by serving a representative mix of high- and low-acuity patients within each DRG. Unfortunately, the Senators proposed to require these changes in the absence of a comprehensive empirical analysis to test whether MedPAC's theory is correct.

We have undertaken such an analysis, although it is not yet completed because of the enormous scope and complexity of the project. To do this study, we are using the FY 2002 Medicare Provider Analysis and Review (MedPAR) file, the Hospital Cost-Reporting Information System (HCRIS) file, and several public use files that CMS has made available on its Web site. We are matching MedPAR data with cost-report data that covered the quarter in which each patient was discharged. We excluded critical-access hospitals, all-inclusive rate hospitals, hospitals with too few cases, and cases within each Medicare DRG that are statistical outliers.

So far, we have completed studying the effects of the HSRV methodology and further refining the Medicare DRGs. We used the All Patient Refined DRG (APR-DRG) grouper (Version 20), a product of 3M Health Information Systems, to study the effect of systematically refining the DRGs based on software that was developed from all-payer data. (We have already endorsed CMS's current, incremental approach.) To test the impact of using APR-DRGs, we standardized the charges of each case by the hospital's weighted wage index, indirect medical education (IME) adjustment, and disproportionate share hospital (DSH) adjustment, with all the parameters based on FY 2006 payment policy. Then we followed CMS's standard procedure for deriving DRG weights.

To test the impact of using the HSRV methodology, we first computed a set of weights for each hospital, then we averaged the weights within each DRG across all hospitals, derived a case-mix index for each hospital, case-mix adjusted each hospital's weights, and recalculated national average weights for each DRG. We repeated this process 10 times to ensure that the number of iterations was sufficient to stabilize each hospital's case-mix index.

In the context of studying the HSRV methodology, we derived weights based on three different sets of case-level data: total charges not standardized, total charges standardized, and cost estimated by applying a hospital-wide ratio of cost to charges (RCC) to total charges (the outlier method of estimating cost). We did this in order to prove our theory that the weights would not change because each adjustment is essentially a hospital-wide scalar. Since this is true, the only way in which weights based on cost would differ from weights based on charges—again, in the context of the HSRV methodology—would be if cost per case were estimated using routine and ancillary department-level RCCs.

The time lag between the cases used to compute the DRG weights and the cases to which the weights are applied is currently two years because the weights are based on charges. If CMS wanted to base the weights on cost instead, then in order to ensure accuracy, it would have to reduce charges to cost using RCCs from the cost report that matched the quarter of each case's discharge. Assuming that the Agency would want to minimize the lag, we assume it would use tentatively settled cost reports, as it currently does to estimate RCCs for outlier payments. Since there is a certain amount of inaccuracy associated with tentatively settled cost reports, we doubt there would be much value in layering cost-based weights onto the HSRV methodology. Regardless, we will estimate cost per case using department-level RCCs in order to test the impact based on the current methodology for computing DRG weights.

With respect to the two provisions that we have modeled—i.e., the HSRV methodology and APR-DRGs—we were surprised by some of the results. First of all, as shown in the table below, if CMS implemented these provisions in a budget-neutral way, they would be likely to redistribute almost $1 billion among the nation's hospitals. Second, the groups of hospitals with a disproportionate share of losses would probably be rural hospitals, public hospitals, and major teaching hospitals. We were surprised by the results because we assume that Congress would not intend to cut payments to rural hospitals and because the stated purpose of the legislation is to strengthen the position of general hospitals providing tertiary services relative to specialty

hospitals. Public hospitals and major teaching hospitals are prime examples of the type of institutions that the legislation would aim to protect.

We will continue our research by modeling the effects of the other two provisions and by studying our data to determine the causes of the results. If CMS were considering implementing any of these provisions administratively, we would certainly recommend that the Agency first conduct a full-scale analysis of its own.

Recommendations:

1. CMS should not implement any of these MedPAC recommendations administratively and should discourage Congress from requiring such implementation in statute.

2. If CMS and Congress are interested in pursuing these ideas, they should first conduct a full-scale fiscal impact analysis.

Fiscal Impact of HSRV Methodology and APR-DRGs (in FY 2002 Dollars)

				% of Total Hospitals		Disproportionate
	Total	Winners	Losers	Winners	Losers	Losers
Number of hospitals by area/type:						
Total	3,448	1,619	1,829	100%	100%	
Urban	2,369	1,225	1,144	76%	63%	
Rural	1,079	394	685	24%	37%	✓
Public	585	198	387	12%	21%	✓
Voluntary	2,114	1,040	1,074	64%	59%	
Proprietary	749	381	368	24%	20%	
Major teaching	274	96	178	6%	10%	✓
Other teaching	757	419	338	26%	18%	
Non-teaching	2,417	1,104	1,313	68%	72%	✓
$ Change in payment (millions) and share of total:						
Total	(0)	930	(930)	100%	100%	
Urban	54	847	(794)	91%	85%	
Rural	(54)	82	(136)	9%	15%	✓
Public	(83)	73	(155)	8%	17%	✓
Voluntary	22	674	(651)	72%	70%	
Proprietary	61	183	(123)	20%	13%	
Major teaching	(238)	123	(361)	13%	39%	✓
Other teaching	145	370	(224)	40%	24%	
Non-teaching	93	438	(344)	47%	37%	
% Change in payment and index to national average:				Index to the National Avg.		
Total	0.0%	2.7%	-2.8%	1.00	1.00	
Urban	0.1%	2.7%	-2.7%	1.01	0.97	
Rural	-0.7%	2.5%	-3.3%	0.94	1.18	✓
Public	-1.1%	2.5%	-3.4%	0.93	1.21	✓
Voluntary	0.0%	2.6%	-2.7%	0.97	0.95	
Proprietary	0.6%	3.2%	-2.9%	1.19	1.03	
Major teaching	-1.6%	2.7%	-3.6%	1.01	1.27	✓
Other teaching	0.6%	2.6%	-2.1%	0.96	0.76	
Non-teaching	0.3%	2.8%	-2.8%	1.03	0.98	

OUTLIERS

CMS estimates that outlier payments in FY 2004 made up only 3.5% of total inpatient PPS payments, which is 31% less than the amount of funding that the hospitals contributed to the pool. We are compelled to express, once again, our concern about the Agency's inability to estimate the outlier threshold to a reasonable degree of accuracy.

ATTACHMENT 2 TO # 820

Data Elements that are Validated

Data Category		Data Elements	Element Code Names	10 Starter Measures: AMI 2004	AMI 2005	HF 2004	HF 2005	PNE 2004	PNE 2005	SIP 2004	SIP 2005	Total 2004	Total 2005	All Measures: AMI 2004	AMI 2005	HF 2004	HF 2005	PNE 2004	PNE 2005	SIP 2004	SIP 2005	Total 2004	Total 2005
		Total data elements		16	18	7	7	15	16	4	5	28	29	33	37	15	15	26	28	21	21	76	78
1	Administrative	1 ICD-9-CM Principal Diagnosis Code	PRINDX	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
2	Demographics	2 Admission Source	ADMSNSRC	√	√	-	-	√	√	-	-	√	√	√	√	-	-	√	√	-	-	√	√
2	Demographics	3 Transfer From Another ED	TRANSFERED	√	√	-	-	√	√	-	-	√	√	√	√	-	-	√	√	-	-	√	√
2	Demographics	4 Discharge Status	DISCHGSTAT	√	√	√	√	√	√	-	-	√	√	√	√	√	√	√	√	-	-	√	√
2	Demographics	5 Arrival Date	ARRVLDATE	-	√	-	-	-	√	-	-	-	√	-	√	-	-	-	√	-	-	-	√
2	Demographics	6 Arrival Time	ARRVLTIME	-	√	-	-	-	√	-	-	-	√	-	√	-	-	-	√	-	-	-	√
3	Diagnosis	7 Pneumonia Working Diagnosis on Admission	WORKINGDX	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
3	Diagnosis	8 Comfort Measures Only	COMFORTMX	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
3	Diagnosis	9 Compromised	COMPROMISED	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
3	Diagnosis	10 ICU Transfer or Admission Within First 24 Hours	ICU24	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
3	Diagnosis	11 Pseudomonas Risk	PSEUDOMONALRISK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Patient Education	12 Adult Smoking History	ADSMKHIST	-	-	-	-	-	-	-	-	-	-	√	√	√	√	√	√	-	-	√	√
4	Patient Education	13 Adult Smoking Counseling	ADSMKCOUNS	-	-	-	-	-	-	-	-	-	-	√	√	√	√	√	√	-	-	√	√
4	Patient Education	14 Discharge Instructions Address Activity	DSINSTADAC	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
4	Patient Education	15 Discharge Instructions Address Diet	DSINSTADDI	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
4	Patient Education	16 Discharge Instructions Address Medications	DSINSTADMD	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
4	Patient Education	17 Discharge Instructions Address Follow-Up	DSINSTADFU	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
4	Patient Education	18 Discharge Instructions Address Weight Monitoring	DSINSTADWT	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
4	Patient Education	19 Discharge Instructions Address Symptoms Worsening	DSINSTADSW	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	√	√
5	Medications	20 Contraindication to Aspirin on Arrival	CTRASPRNAR	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	21 Aspirin Received Within 24 Hours Before or After Hospital Arrival	ASPRN24HRS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	22 Contraindication to Aspirin at Discharge	CTRASPRNDS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	23 Aspirin Prescribed at Discharge	ASPRNRXDIS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	24 ACEI Clinical Trial	CLNCLTRIAL	√	√	√	√	-	-	-	-	√	√	√	√	√	√	-	-	-	-	√	√
5	Medications	25 Contraindication to ACEI at Discharge	CTRACEI	√	-	√	-	-	-	-	-	√	-	√	-	√	-	-	-	-	-	√	-
5	Medications	26 Contraindication to Both ACEI and ARB at Discharge	CTRACEI	-	√	-	√	-	-	-	-	-	√	-	√	-	√	-	-	-	-	-	√
5	Medications	27 ACEI Prescribed at Discharge	ACEIRXDCHG	√	-	√	-	-	-	-	-	√	-	√	-	√	-	-	-	-	-	√	-
5	Medications	28 ACEI or ARB Prescribed at Discharge	ACEIRXDCHG	-	√	-	√	-	-	-	-	-	√	-	√	-	√	-	-	-	-	-	√
5	Medications	29 Beta Blocker Prescribed at Discharge	BBLKRRXDIS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	30 Contraindication to Beta Blocker on Arrival	CTRBBLKRAR	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	31 Beta Blocker Received Within 24 Hours After Hospital Arrival	BBLKR24HRS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	32 Contraindications to Beta Blocker at Discharge	CTRBBLKRDS	√	√	-	-	-	-	-	-	√	√	√	√	-	-	-	-	-	-	√	√
5	Medications	33 Thrombolytic Administration	THROMADMIN	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
5	Medications	34 Thrombolytic Administration Date	THROMDATE	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
5	Medications	35 Thrombolytic Administration Time	THROMTIME	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
5	Medications	36 Lipid Lowering Agent Prescribed at Discharge	LIPIDPREDC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Medications	37 Reason for No Lipid Lowering Therapy	REASONNOLIPD	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
5	Medications	38 Pneumococcal Vaccination Status	PNEVACSTATUS	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
5	Medications	39 Influenza Vaccination Status	FLUVACSTATUS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
5	Medications	40 Antibiotic Received	ANTIBIRCVD	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
5	Medications	41 Antibiotics Prior to Arrival	ABX24PTA	-	-	-	-	√	√	-	√	√	√	-	-	-	-	√	√	-	√	√	√
5	Medications	42 Antibiotics Administered During the First 36 Hours after Arrival	ATBX36	-	-	-	-	√	-	-	-	√	-	-	-	-	-	√	-	-	-	√	-
5	Medications	43 History of Antibiotic Allergy	HXABXALL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
5	Medications	44 Antibiotic Allergy	ANTIALLERGY	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Medications	45 Antibiotic Name	NAMEABX	-	-	-	-	√	√	√	√	√	√	-	-	-	-	√	√	√	√	√	√
5	Medications	46 Antibiotic Administration Date	DTABX	-	-	-	-	√	√	√	√	√	√	-	-	-	-	√	√	√	√	√	√
5	Medications	47 Antibiotic Administration Time	TMABX	-	-	-	-	√	√	√	√	√	√	-	-	-	-	√	√	√	√	√	√
5	Medications	48 Antibiotic Administration Route	ROUTEABX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√	√	√
5	Medications	49 Antibiotics PTA	ANTIPTA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
5	Medications	50 Oral Antibiotics	ORALANTIBIOTIC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
5	Medications	51 Antibiotics During Stay	ANTIDURSTAY	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
5	Medications	52 Prophylactic Antibiotic	PROABX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
6	Diagnostic Tests	53 LVSD	LVSD	√	√	√	√	-	-	-	-	√	√	√	√	√	√	-	-	-	-	√	√
6	Diagnostic Tests	54 Initial ECG Interpretation	INITECGINT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√
6	Diagnostic Tests	55 In-Hospital LDL-Cholesterol Test	INHOLDLTST	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	56 Pre-Arrival LDL-Cholesterol Test	PRARLDLTEST	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	57 Pre-Arrival LDL-Cholesterol Value	PRARLDLTVALU	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	58 Pre-Arrival LDL-Cholesterol Qualitative Description	PRARLDLTQUDS	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	59 Plan for LDL-Cholesterol Test	INHOLDLTPLAN	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	60 Reason for No LDL-Cholesterol Testing	REASONNOLDLT	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	61 In-Hospital LDL-Cholesterol Test Within 24 Hours After Hospital Arrival	INHOLDLTST24	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	62 First In-Hospital LDL-Cholesterol Value	INHOLDLTVALU	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	63 First In-Hospital LDL-Cholesterol Qualitative Description	INHOLDLTQUDS	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	√	√
6	Diagnostic Tests	64 First PCI Time	PCITM	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
6	Diagnostic Tests	65 First PCI Date	PCIDT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
6	Diagnostic Tests	66 LVF Assessment	LVEFEVAL	-	-	√	√	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√
7	Laboratory Testing	67 Pulse Oximetry Done	PULOXDONE	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
7	Laboratory Testing	68 ABG Done	ABGDONE	-	-	-	-	√	√	-	-	√	√	-	-	-	-	√	√	-	-	√	√
7	Laboratory Testing	69 Blood Cultures Prior to Arrival	BLOODPRIORAR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
7	Laboratory Testing	70 Initial Blood Culture Collection Date	INITBLOODCDT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Laboratory Testing	71 Initial Blood Culture Collection Time	INITBLOODCTM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
7	Laboratory Testing	72 Blood Culture Collected After Arrival	BLOODCAFTRAR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	√	√
8	Surgery	73 Surgery Performed During Stay	SURGPERFORM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	74 Infection Prior to Anesthesia	INFECPTA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Surgery	75 Type of Surgery	TYPESURGERY	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	76 Surgery Start Date	SURGSTARTDT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	77 Surgical Incision Time	SURGINCISTM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	78 Surgery End Date	SURGENDDT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	79 Postoperative Infections	POSTOPINFECT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	80 Date of Infection	DTINFECTION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	81 Surgery End Time	SURGENDTM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	82 Admission Diagnosis of Infection	ADMDX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√
8	Surgery	83 Other Surgeries	OTHERSURG	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	√	√

Source: http://qnetexchange.org/public/docs/hdc/datavldtr/inclusionList.pdf
Prepared by The Health Economics and Outcomes Research Institute (THEORI). May 2005

527 KENLY HEFTER HARTSTEIN T. Jones Miller Seifert Knight Walz Hart Kraemer

CMS-1500-P-817

Submitter : Mr. Daniel Lohr **Date:** 06/24/2005

Organization : The William W. Backus Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-817-Attach-1.DOC

HOSP REF
CBSA
WI/GEN
Labor/S
TRANSFERS
IMPACT

Attachment to #817

June 24, 2005

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

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

Dear Sir or Madam:

The William W. Backus Hospital appreciates the opportunity to provide these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates [CMS-1500-P].

Hospital Redesignations and Reclassifications (Pages 23376 – 7)

Under Section 1886(d)(8)(E) of the Act, an urban hospital can apply for redesignation as a rural hospital. Under the proposed rule, the "hold harmless" provisions that occur under section 1886(d)(8)(B) and section 1886(d)(10) when a hospital is granted reclassification, will now be applied when hospitals are approved for redesignation. The William W. Backus Hospital supports this appropriate extension of the "hold harmless" protection, which is particularly important to many Connecticut hospitals. The William W. Backus Hospital thanks CMS for addressing this issue in the proposed rule.

Other Provisions

There are several provisions of the proposed rule that remain harmful to many Connecticut hospitals. The William W. Backus Hospital opposes the following provisions:

- Moving to wage indices based on 100% of the new CBSAs, rather than retaining the 50% blend;
- Reductions to the labor share;
- Expansion of the transfer policy

Of particular concern is the proposed expansion of the transfer provision, which is projected to result in a reduction in Medicare funding to Connecticut Hospitals of $23,895,000 million in FFY 2006, a reduction the hospitals simply cannot afford.

Finally, we ask that CMS consider a minimum guaranteed rate of increase of 2% for hospital providers and a one-time increase of 3.8% to correct for the consistent under-forecasting of the hospital market basket that occurred in seven of the last eight years. Granting such an increase, while not correcting for the past under funding, will offer great relief by bringing the current rates to their proper level. Setting a minimum increase of 2% will prevent what happened last year when 48 hospitals in the country were paid less in 2005 than 2004; 14 of the 48 were in Connecticut. If the various proposed changes go into effect for FFY 2006, nine hospitals in Connecticut will receive less in 2006 than they received in 2005. We believe CMS should develop and implement a minimum increase for hospitals similar to that developed for Health Plans (i.e. 2% minimum annual increase).

We appreciate your consideration of these comments.

Sincerely,

Daniel E. Lohr
Senior Vice President & CFO

By mail and e-mail
June 24, 2005

528 WALZ HART HEFTER HARTSTEIN

CMS-1500-P-816

Submitter : **Mr. James Walker** **Date: 06/24/2005**

Organization : **Phillips Metropolitan CME**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

TRANSFER

CMS-1500-P-816-Attach-1.DOC

Attachment to #816

June 23, 2005

The Honorable Mark B. 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: Post-acute Care Transfers; Proposed Changes to the Hospital Inpatient Prospective Payment System and FY'06 Rates; Proposed Rule

Dear Administrator McClellan:

I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft rule on the Medicare Hospital Inpatient Prospective Payment System, as published in the May 4, 2005 *Federal Register.* We are particularly Concerned about CMS' reported request to expand the number of DRGs subject to The post-acute transfer policy from the current 30 to 223.

The current Medicare transfer payment policy requires that cases assigned to one of 30 DRGs be paid as transfers when patients are discharged to psychiatric or rehabilitation hospitals or units, children's, long-term care or cancer hospitals, and skilled nursing facilities or home health agencies. Under this policy, payment is per diem.

I strongly oppose expanding the transfer policy to encompass additional classes of patient cases. We believe this would fundamentally weaken the incentives inherent in the inpatient PPS. A new transfer policy covering 223 DRGs would effectively uproot and incentive-based system fueled by per-case control, to one inordinately focused on per diem costs.

Any expansion of the inpatient transfer policy would most assuredly not be in the best interest of patients or providers. The proposed policy would undermine clinical decision-making and penalize hospitals for providing patients with the most appropriate care in the most appropriate settings.

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

Sincerely,

Rev. James B. Walker

CMS-1500-P-813

529 KENLY HEFTER HARTSTEIN T. Jones Miller

Submitter : Mr. DAVID GLYER

Organization : COMMUNITY MEMORIAL HOSPITAL OF SAN BUENAVENTURA

Category : Hospital

Date: 06/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-813-Attach-1.PDF

HOSP REDES CBSA

ATTACHMENT TO #813

CMH

Community Memorial Hospital of San Buenaventura

June 24, 2005

Via E-mail: Http://www.cms.hhs.gov/regulations/ecomments

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services

Re: Comments to Inpatient May 4, 2005 Proposed Rule

We are pleased that CMS is proposing to allow counties that are included in a Combined Statistical Area (CSA) to reclassify to a contiguous metropolitan division of the CSA using the 2000 standards.

We believe that this is appropriate public policy and acknowledges the realities of areas such as Ventura County, that are just outside major areas such as Los Angeles and must meet the competitive salary scales in order to attract and retain competent professionals to provide needed hospital services in areas just outside these major metropolitan areas throughout the United States.

Presently, hospitals in Ventura County are potentially eligible for urban county group reclassification. Under current regulations, for all hospitals in an urban county to be reclassified as a group, all hospitals in the county are required to apply for reclassification. One hospital in this county is currently reclassified under section 508 and is receiving its own wage index, a wage index higher than that available under group reclassification criteria. In order for the group to be considered for reclassification, the Medicare Geographic Classification Review Board, requires a section 508 hospital to terminate its existing reclassification in order for the group to reclassify. Under section 508 qualifying hospitals are reclassified for the three year period beginning April 1, 2004 and ending March 31, 2007.

It is unfair to require the Section 508 hospital to terminate the existing reclassification. Section 508 is not budget neutral, and there is a statutory additional $900 million budget. If hospitals withdraw it could reduce payments to less than what Congress intended. We recommend that CMS implement an exception to the existing regulations that would allow hospitals that file an urban county group reclassification request and are determined to meet all applicable reclassification requirements to be reclassified, even if one or more hospitals that are in the group are reclassified under Section 508. The exception would allow the group to be reclassified and would allow the Section 508 hospitals to retain their reclassification until it expires (presently March 31, 2007). Effective upon expiration, the former section 508 hospital would then become a part of the existing group reclassification. The exception would be applicable in the limited circumstances involving an urban county groups with one or more section 508 hospitals in the county. We believe Congress did not intend to prevent group reclassifications simply because one or more hospitals in the county were granted a 508 reclassification.

Should you have any questions regarding the above comments please do not hesitate to contact us.

Sincerely,

David B. Glyer, CPA
Vice President Finance

530

BROOKS
GRUBER
FAGAN
KELLY
HUE
TREITEL
WALZ
KNIGHT
SEIFERT
HART
MOREY
COLLINS
SMITH
HEFTER
HARTSTEIN

CMS-1500-P-811

Submitter : Mr. Donald Koenig **Date:** 06/24/2005

Organization : Catholic Healthcare Partners

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. McClellan

On behalf of Catholic Healthcare Partners (CHP) and our affiliated twenty-seven acute care hospitals and four Critical Access Hospitals, we welcome the opportunity to comment on the proposed rule for the 2006 Medicare Prospective Payment System (PPS) for inpatient admissions. We appreciate CMS willingness to provide clarifications to existing definitions, policies, and coding practices that are problematic and to seek viable solutions that improve overall operations and delivery of quality care to patients. The proposed 2006 Inpatient Prospective Payment System changes provide a mixed-bag of changes in relation to our affiliated providers. Specifically we wish to comment regarding the following proposed changes:

1) Annual DRG Reassignment and subsequent ICD-9 procedure revisions
2) New Technology Criterion regarding the Substantial Improvement definition
3) Hospital Market Basket
4) Postacute Care Transfers
5) Provider-Based Entities regarding Technical and Clarifying Changes to 413.65
6) Critical Access Hospitals

Attached you will find our specific comments and recommendations on the topics contained within the proposed rule. Catholic Healthcare Partners appreciates the opportunity to submit comments for your consideration. If your staff has any questions about these comments, please feel free to contact me at 513-639-2833 or Cheryl Rice,Corporate Compliance Coding and Reimbursement Analyst at 513-639-0116 clrice@health-partners.org.

/s/ Donald E. Koenig, Jr
Vice President , Corporate Responsiblity & Assistant General Counsel

See Attachment

CMS-1500-P-811-Attach-1.DOC

DRG/GEN
NT
MB/H
TRANSFERS
PBE/CLAR
CAH/RELOC
PBE/NICU

June 24, 2005

Mark McClellan, M.D. Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 443-G
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

Dear Mr. McClellan:

On behalf of Catholic Healthcare Partners (CHP) and our affiliated twenty-seven acute care hospitals and four Critical Access Hospitals, we welcome the opportunity to comment on the proposed rule for the 2006 Medicare Prospective Payment System (PPS) for inpatient admissions. We appreciate CMS willingness to provide clarifications to existing definitions, policies, and coding practices that are problematic and to seek viable solutions that improve overall operations and delivery of quality care to patients. The proposed 2006 Inpatient Prospective Payment System (IPPS) changes provide a "mixed-bag" of changes in relation to our affiliated providers. Specifically we wish to comment regarding the following proposed changes:

1) Annual DRG Reassignment and subsequent ICD-9 procedure revisions
2) New Technology Criterion regarding the "Substantial Improvement" definition
3) Hospital Market Basket
4) Postacute Care Transfers
5) Provider-Based Entities regarding Technical and Clarifying changes to 413.65
6) Critical Access Hospitals

Attached you will find our specific comments and recommendations on the topics contained within the proposed rule.

Catholic Healthcare Partners appreciates the opportunity to submit comments for your consideration. If your staff has any questions about these comments, please feel free to contact me at 513-639-2833 or Cheryl Rice, Corporate Compliance Coding and Reimbursement Analyst at 513-639-0116 clrice@health-partners.org.

/s/ Donald E. Koenig, Jr.
Vice President, Corporate Responsibility & Assistant General Counsel

Attachment
Clr

2006 Medicare Program: Proposed Changes to the Hospital Inpatient Payment System [CMS-500-P]
70 Federal Register 85, 23306 May 4, 2005
Point of Contact: Cheryl L. Rice, Corporate Compliance Coding and Reimbursement Analyst
Catholic Healthcare Partners, Cincinnati OH 45202 513.639.0116 clrice@health-partners.org

Annual DRG Reassignment and Subsequent ICD-9 Procedure Revisions

Many of the proposed 2006 DRG and ICD-9 procedure changes address historic coding and classification issues that have challenged providers both clinically and operationally. We appreciate CMS willingness to work towards coding solutions that more accurately reflect current medical practice. Specifically, we support the following proposed coding changes:

1. The creation of a new DRG in addition to the existing DRG 14 and 15 in order to differentiate the use of reperfusion or thrombolytic agents during strokes - Option 2 maintains the historic meaning of DRG 14 and 15 (both high volume DRGs for our hospitals) and at the same time, allows for a smoother transition in mapping and tracking of future clinical cases under the newly defined DRG. **We support coding option 2 that creates a separate, new DRG rather than the revision of the existing DRG 14 or 15.**

2. The removal of ICD-9 procedure 37.26 from the list of DRG 535 and 536 Cardiac Cath procedures – Current coding guidelines for 37.26 (cardiac electrophysiologic stimulation and recording studies – EPS) have been an ongoing source of confusion within hospital coding and billing. As more EPS studies are physically performed within cardiac cath suites and cardiology service areas, the proposed changes and new reporting requirements under the National Coverage Determination should improve future coding application and accuracy. **We recommend CMS consider issuing separate coding instructions regarding the proper use of ICD-9 procedure code 37.26 when approved in a separate Program Transmittal and/or Medlearn Matters communication to further support correct coding and charging.**

3. The implementation of eight new ICD-9 procedure codes for multiple stent insertions and multiple vessel treatments along with the proposed deletion of DRG 516 and DRG 526 and subsequent creation of DRGs 547, 548, 549, and 550 - These collective coding changes will allow hospitals to more clearly differentiate cardiac cases involving multiple stents and procedures for future consideration in reimbursement adjustments. **We strongly recommend CMS consider issuing a separate communication beyond the Final Rule reiterating the specific coding guidance outlined in the proposed rule. By providing clear instructions and examples of "how to code" and "how to not code" for the multiple stents and multiple vessels, CMS can ensure that future claims will be coded and billed properly for stent services. This will build reliable future claims data necessary for further ICD-9 coding revisions and movement towards single ICD-9 codes that incorporate the number of stents placed in the vessels.**

4. The deletion of DRG 209 and creation of DRG 544 and DRG 545 to differentiate between original replacement joints and revisions of previous replacement joints - This DRG change will improve clinical tracking of a growing number of Medicare patients who receive joint replacements and revisions annually. Differentiation between revisions and replacements will help providers analyze resource utilization and care delivery differences.

5. The comprehensive review of the complications and comorbidities (CC's) for 2007 – This review should help CMS better reflect resource utilization and severity recognition within the current DRGs and remove CCs that have marginal impact on current clinical care costs.

New Technology Criterion – Substantial Improvement Definition

Although none of our affiliates are medical device manufacturers, we appreciate CMS clarification of the meaning of "substantial improvement" as related to the new technology consideration criteria. This clarification was substantial and specific. It has been several years since CMS released a summary document specifically outlining the new technology criterion and clarifications in their entirety. Currently providers must access several separate resources to obtain all the requirements and definitions. **For enhanced compliance and general re-education of providers on new technology add-on payment criterion and requests for consideration as "new technology", CHP recommends CMS consider releasing a separate comprehensive document that incorporates the new technology requirements, clarifications, and payment policy.**

Hospital Market Basket

The hospital market basket update factor is intended to reflect the average change in the price of goods and services that hospital purchase on behalf of inpatients. The price changes must be able to project forward in order to estimate subsequent year increases and appropriate market based adjustments. The current methodology is prospective and does not reconcile to reflect actual price increases experienced by hospitals. In recent years the prospective projections have been consistently lower than the actual price increases. We are concerned that the current projection methodology used to determine the market basket increases are flawed and fail to provide a reliable estimate of the hospital cost increases. Given a 4.1% cost increase for FY 2005, the projected FY 2006 increase of 3.2% does not seem reasonable. **We request CMS review the methodology and share the details of the calculation with providers so that suggestions on how best to estimate costs can be provided.**

Postacute Care Transfers

CMS proposes to expand the postacute care transfers from 30 DRGs to 231 DRGs. **CHP opposes this proposed expansion.** The expansion of the transfer DRGs impounds additional reductions in DRG payment, some of which are high volume DRGs for our hospitals that are already receiving payment reductions due to the annual DRG recalibration. Specifically DRG 15, 18, 35, 78, 92, 93, 135, 138, 147, 149, 154, 171, 191, 198, 227, 233, 264, 271, 292, 293, 300, 301, 303, 305, 316, 354, 355, 398, 419, 421, 462, 464, 473, 475, 487, 499, 500, 532, 538 and 543 will receive a "double decrease" in overall payment if the proposed transfer rule expansions are adopted. **For our affiliated entities the projected percent impact of the expanded transfer rule to 231 DRGs ranges from -.32% to -1.92% on the overall proposed federal DRG payment. Ten of our facilities will see projected percentage impacts on DRG payments greater than -1%. For fourteen of our facilities this decrease in payment significantly offset and surpasses any of the inflation updates made by the annual IME, labor share and/or wage index adjustments.**

This proposed rule significantly changed two of the four criterions for qualifying as a postacute transfer DRG. Of major concern is the revision to include DRGs with as few as 2000 cases (down from 14,000 cases under current requirements). CMS did not present any evidence that the expanded DRGs with the 2000 case range were cases that upon review were prone to inappropriate transfers or potential "gaming" of payment on the part of providers. For all practical purposes, the proposed expansion of the postacute transfer policy services as an across-the-board reduction in Medicare payments. As a result, our hospitals along with others would be automatically penalized for providing efficient care in the setting that is most appropriate for the patient. **CHP opposes the expansion of the postacute care transfer policy on the grounds that it undercuts clinical decision-making and care coordination for the majority of care providers who are legitimately providing the most efficient, timely, and clinically-appropriate care.**

Provider-Based Entities

We appreciate CMS providing additional commentary, clarification, technical corrections and proposed revisions to the Provider-Based status rules and requirements. **We support the technical and clarifying changes to 413.65. We especially welcome the proposed change to the obligation of hospital outpatient departments and hospital-based entities' notice of coinsurance liability to indicate that the notice is only applicable to services that normally would be subject to a coinsurance payment.** This clarification will improve the general understanding of the provider-based requirements for off-site entities and overall customer service relations.

Critical Access Hospitals

CMS outlined new definitions and proposes to establish a new methodology for determining whether Critical Access Hospitals (CAHs) can continue to be deemed

"necessary providers" if they relocate. CAHs that are currently designated as necessary providers could be in jeopardy of losing their CAH status if the changes as proposed are implemented. The proposed rules would bar any necessary CAH from rebuilding its facilities anywhere other than their current location unless the construction was under development before December 8, 2003. We understand the need to define the terms " relocate", "replace", and "cessation of business" in order to clarify processes and maintain a consistent provider-based status policy. However, CAHs are often the sole providers of inpatient acute-care services within their communities. Many of the CAHs were not able to rebuild older facilities prior to gaining CAH status. Many of our older buildings are either landlocked or need relocation in order to better serve the community that is expanding physically in a different portion of the surrounding community than the original location of the CAH. **We recommend that CMS reconsider other options that allow more flexibility for CAHs that did not meet the construction deadline. We recommend that CMS reconsider the use of the 250-yard rule as the sole criteria for provider-based status, and instead consider providing an additional alternative such as a mileage-radius similar to the hospital provider-based definition. This option would allow CAH to expand on their existing location as well as an alternative site if it is more beneficial to the community. Additionally we recommend CMS limit their 75% restriction criteria to the same criteria posed on provider-based hospitals, that is, 75% of the same population is served by the provider within a given location. The proposed requirement to maintain 75% of the same staff and 75% of the same services is more stringent and does not allow flexibility in care delivery that may be changing within the community and therefore driving the need for expansion or relocation of the CAH.**

531

KNIGHT
SELFERT
HEFTER
HARTSTEIN
Ellington
Treitel

Submitter : James Quirk **Date:** 06/24/2005

Organization : Memorial Sloan-Kettering Cancer Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-834-Attach-1.PDF

NMB/~~EX~~ Hosp

ATTACHMENT TO #834

The Alliance of Dedicated Cancer Centers
Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
City of Hope National Medical Center
Dana-Farber Cancer Institute
Fox Chase Cancer Center
H. Lee Moffitt Cancer Center and Research Institute
M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center
Roswell Park Cancer Institute
Seattle Cancer Care Alliance
Sylvester Comprehensive Cancer Center

June 24, 2005

By E-mail

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:

On behalf of the Alliance of Dedicated Cancer Centers, an alliance of ten nationally recognized institutions focusing exclusively on the care of cancer patients, I am writing to comment on the Proposed Rule that would revise the Medicare prospective payment system for hospital inpatient services, as published in the *Federal Register* on May 4, 2005 (70 Fed. Reg. 23,306) (the "Proposed Rule"). The Cancer Centers, individually listed above, appreciate the opportunity to submit these comments.

BACKGROUND

The Cancer Centers play a pivotal role in the National Cancer Program, which was enacted by Congress in 1971 to improve the detection, prevention, diagnosis, and treatment of cancer. The Centers are the National Cancer Program's cornerstones for deepening the understanding of the causes and cures for cancer, developing new treatments for cancer, and disseminating this knowledge to the provider community at-large. The Centers' state-of-the-art therapies and research activities offer the greatest possibility for successful treatment of cancer patients. Much of the

recent progress in understanding cancer's biology and successful treatment is directly attributable to the work of the Centers.

Within the Medicare Program, the Centers were afforded special status when the inpatient prospective payment system (PPS) was implemented in 1983. In enacting the Social Security Act amendments of 1983, which established inpatient PPS, Congress authorized hospitals "involved extensively in treatment for and research on cancer," Social Security Act Amendments of 1983, § 601(e) (adding 1886(d)(5)(c)(iii)), to continue to be reimbursed under the Medicare reasonable cost system (subject to the TEFRA cost limits). See 48 Fed. Reg. 39,752, 39,782 (Sept. 1, 1983); 49 Fed. Reg. 234, 272-73 (Jan. 3, 1984).

DISCUSSION

The Cancer Centers are concerned about the proposal to use the inpatient PPS market basket to update the target amounts for cancer and children's hospitals reimbursed under the TEFRA cost limits. See 70 Fed. Reg. at 23,395. We do not believe that the inpatient PPS market basket adequately reflects the increases in cost incurred by the Centers and urge CMS to implement a separate market basket for cancer hospitals, similar to those proposed for other classes of hospitals that were historically excluded from PPS, that would recognize the actual cost increases experienced by our institutions.

In the Proposed Rule, CMS has proposed eliminating the existing separate market basket for hospitals that were excluded from inpatient PPS, for both hospitals such as rehabilitation and psychiatric facilities that were formerly PPS-excluded but now are being transitioned to their own PPS, and children's and cancer hospitals that remain subject to the TEFRA cost limits. See 70 Fed. Reg. at 23,394. In particular, CMS has proposed establishing separate market baskets for each facility type that was formerly exempt from PPS. See id. However, rather than also establishing a separate market basket for the currently exempt cancer and children's hospitals, CMS is proposing to apply the inpatient PPS market basket to these providers, purportedly because their cost structure is close to the cost structure of PPS hospitals. See id. at 23,395. We strongly disagree with this proposal.

As noted in the Proposed Rule, the inpatient PPS market basket update generally is slightly lower than the excluded hospital market basket update. See id. Thus, using the inpatient PPS market basket to update the cost limits for cancer and children's hospitals will result in smaller annual updates for these hospitals. As it stands, even the existing excluded hospital market basket updates fall far short of reflecting the annual cost increases actually experienced by the Cancer Centers. Therefore, further reducing the annual update by shifting the Centers to the inpatient PPS market basket update will only exacerbate the significant shortfalls we currently experience.

We have determined that this shortfall is, in part, the result of certain weights and proxies being used to calculate the existing market basket that do not adequately reflect the unique cost structure of the Cancer Centers. Significantly, CMS has specifically recognized that, for excluded hospitals in general, compensation costs and pharmaceutical costs represent a higher percentage of overall costs than for inpatient PPS hospitals. See 67 Fed. Reg. 49,982, 50,042 (Aug. 1, 2002). Cancer hospitals, in particular, incur a number of costs, including pharmaceutical costs, that represent a much larger component of their total costs than that of non-cancer hospitals. Moreover, because of our institutional commitment to provide patients with state-of-the-art cancer therapies, which often involve costly emergent drugs and other technologies, the Centers' pharmaceutical and

many other costs increase at a rate that far outstrips the cost increases recognized under the existing market basket. Using the inpatient PPS market basket will result in even greater disparities between the actual cost increases incurred by the Centers and the update factor.

Therefore, instead of shifting the Centers to the inpatient PPS market basket, the Centers believe we should receive a separate market basket, consistent with CMS's treatment of other excluded hospitals, that more accurately reflects the costs incurred by our facilities. CMS has recognized that the formerly exempt hospitals continue to have separate payment methodologies distinguishing them from other inpatient PPS hospitals because of their different case mixes, practice patterns and inputs composition. See id. Cancer hospitals also have different case mixes, practice patterns, and composition of inputs, which Congress has recognized by affording the Centers a separate payment methodology that reflects these differences. Like the formerly excluded hospitals, cancer hospitals should have a separate market basket to reflect these unique characteristics that more closely tracks the cost increases incurred by our institutions.

CONCLUSION

Thank you for your willingness to consider our views. We are hopeful that CMS will address the concerns described above and make the necessary adjustments to ensure equitable reimbursement for state-of-the-art cancer care. If you have any questions or require additional information, please contact Anthony Diasio of Fox Chase Cancer Center at 215-728-3824.

Sincerely yours,

James S. Quirk

James S. Quirk
Senior Vice President
Memorial Sloan-Kettering Cancer Center

532 MILLER HEPTER HARTSTEIN

Submitter : Ms. Leslie Conner **Date:** 06/24/2005

Organization : East Texas Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

WI/GEN

CMS-1500-P-831-Attach-1.DOC

=

June 23, 2005

Centers for Medicare and Medicaid Services
Attn: Wage Index Team / Division of Acute Care
7500 Security Boulevard
Mail Stop C 4-08-06
Baltimore, Maryland 21244

RE: Comment – Proposed Wage Index Calculation – Overhead Rate applied to Excluded Overhead Salaries.

Provider # 45-0083

Dear Sir or Madam:

East Texas Medical Center (the "ETMC") has reviewed the FFY 2006 Proposed Rule published May 04, 2005. The ETMC notes that there is a change to the wage index calculation relating to the ratio used to allocate overhead costs to excluded-overhead salaries. As you know, the ratio developed by this method is applied to employee benefit amounts reported on WKS S-3 Part II lines 13, 14, and 18 in order to derive overhead costs attributable to identified excluded-overhead salaries. Based on our analysis of the ETMC's wage index calculation, it appears that the excluded-overhead ratio is 33%. This number is dramatically high. We do not believe that the ratio accurately reflects the overhead costs attributable to these salaries. The overall employee benefit ratio for the entire hospital is 24.80% (based on proposed wage index data – total benefits divided by total salaries). We do not believe that applying the 33% amount to excluded overhead salaries accurately reflects overhead costs for those salaries under any reasonable cost allocation methodology. We respectfully request that CMS postpone implementation of this change until a more equitable methodology can be determined.

Sincerely,

Angela Burns Campbell
Director of Financial Services
East Texas Regional Healthcare System

533

Submitter : Mrs. Monica Hemming

Organization : Fairview Lakes Regional Medical Center

Category : Hospital

Q Data

Date: 06/21/2005

Hefler
Hartstein
Bodden
Hammel

Issue Areas/Comments

GENERAL

GENERAL

Fairview Lakes would like to voice their concerns regarding the data validation process. The validation process should only incorporate the data associated with the 10 quality measures. Under the current system, a hospital that submits multiple data sets may earn an overall quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably lower. In this way, payments risk being based on inconsistent calculations and inaccurate data.

534

Q Data

Submitter : Mr. Ken Trester **Date:** 06/21/2005

Organization : Oakwood Healthcare Inc.

Category : Hospital

Hefter
Hartstein
Bodden
Hammel

Issue Areas/Comments

GENERAL

GENERAL

This proposed rule change would add to the significant adverse reimbursement actions that are threatening the viablity of hospitals which bear the brunt of caring for the uninsured and underinsured.

535

Submitter : Mrs. Anke WinklerPrins

Date: 06/21/2005

Organization : University of Michigan Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Issues

DRG Reclassifications

DRG/Gen

Hefler
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 20, 2005

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

Re: File code CMS-1500-P

Dear CMS:

I am writing this letter in strong support of changes proposed within a recent document submitted by CMS in May of this year. The document, indicated as File Code CMS-1500-P, was titled: ?Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.? The section of the document which contains a description of the proposals is ?Section II-f: ECMO.?

The document proposes reassigning ECMO cases procedural reporting code 39.65 (Extracorporeal Membrane Oxygenation) to DRG 541 (Tracheostomy with Mechanical Ventilation) on the basis that the average charges for ECMO cases reflects those of DRG 541 more closely than they do for other O.R. procedures under which ECMO is classified, such as DRG 104 (Cardiac Valve and other Major Cardiothoracic Procedure with Cardiac Catheterization).

The ECMO Program at the University of Michigan Health Systems continues to provide ECMO support for an average of 80-100 patients every year of all ages ? newborns to adults. Our patient population is divided nearly equally across all ages. Advancements in patient care have resulted in relatively fewer neonates requiring ECMO now than in the past. This trend has been recognized nationally. Utilization and demand on resources for pediatric and adult patients, is relatively higher than for neonates. While patient mix has changed drawing more from resources, ECMO charges have not. Data presented in the table within the CMS document reflect our Program?s experience with average charges for reported DRG code 39.65 and agreeably, are better reflected in charges that resemble those of DRG 541. For this reason, our ECMO Program is in support of reassigning ECMO cases reporting code 39.65 to DRG 541 as this would better reflect the cost of the necessary resources utilized in providing such therapy

As a large tertiary medical center, committed to providing advanced critical therapies such as ECMO to our patients, we truly appreciate the attention you have paid to this matter and avidly support passage of the proposed changes.

Robert H. Bartlett, M.D.
ECMO program Director and
Anke WinklerPrins, BA, BSN, RN
ECMO Program Manager
University of Michigan Hospitals
Mott Hospital
1500 E. Medical Center Drive
F 5850 Box 0282
Ann Arbor, MI 48109-0282

536

Submitter : Ms. Linda Rankin **Date:** 06/22/2005

Organization : Children's Memorial Hospital - Chicago

Category : Hospital

DRG/Gen

Issue Areas/Comments

GENERAL

GENERAL

I, as well as our ECMO program at Children's Memorial Hospital - Chicago, support the CMS proposal of reassigning ECMO procedureal code to a higher weighted DRG - specifically DRG 541, (pt.
with a trach on a vent)

Hartstein
Hefter
Brooks
Fagan
Gruber
Kelly
Hue

537

WALZ
HART
TRUONG
LEFKOWITZ
RUIZ
SMITH
HUDSON
ELLINGTON
TREITEL
HEFTER
HARTSTEIN

Submitter : Mr. Andrew DeVoe

Date: 06/23/2005

Organization : University of Pennsylvania Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-689-Attach-1.PDF

TRANSFERS
IME
DSH
CAPITAL
PYMT RTS/OUTLIER

ATTACHMENT TO #689

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Andrew DeVoe
Senior Vice President and
Chief Financial Officer

June 24, 2005

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

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed rule (70 FR 23305-23774, May 4, 2005) for the Hospital Inpatient Prospective Payment System. The University of Pennsylvania Health System (UPHS) serves the Greater Philadelphia area through three teaching hospitals, offering a full range of acute and post-acute services. Combined, our hospitals admit over 15,000 Medicare Beneficiaries on an annual basis and provide training to over 900 interns and residents.

1. OTHER DECISIONS AND PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS AND GME COSTS

a. Post-acute Care Transfers

The modification of the criterion that were established when the post-acute care transfer policy was initiated is not congruent with the statutory directive that CMS focus the policy on DRGs that have a high volume of discharges to post-acute care *and* a disproportionate use of post-discharge services.

Furthermore, expanding the post-acute transfer policy results in penalties to those hospitals that are ensuring that Medicare patients are receiving care in the setting that is most appropriate to

21 Penn Tower • 3400 Spruce Street • Philadelphia, PA 19104-4385 • Phone: 215-662-2992 • FAX: 215-662-7431

their diagnosis and undermines the DRG recalibration process, which takes into account declining lengths of stay, and consequently lower costs within a particular DRG

CMS has approximated that the proposed expansion would result in a 1.1 percent decrease in payments to Hospitals However, we believe that CMS did not include the cumulative effect when the Indirect Medical Education (IME), Disproportionate Share (DSH) , capital and outlier payments are considered. Our three hospitals (which include hospital-based Psychiatry, Rehabilitation and Skilled Nursing Units) would see a decrease of nearly 2% of our total inpatient Medicare payments if the expansion of the DRGs were permitted.

We are fundamentally opposed to the proposed expansion of the post-acute care transfer policy from the existing 30 DRGs to 223 DRGs.

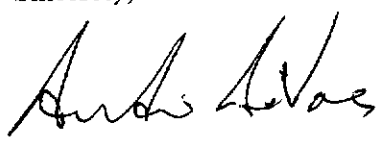
b. Outlier Payment Threshold

CMS is proposing an increase in the fixed-loss cost threshold (used in determining outlier payments) from the current level of $25,800 to $26,675; a 3.4% increase. We fail to understand how CMS can propose to increase the threshold when they are estimating that actual FFY 2005 payments will not reach the target of 5.1 percent of total DRG payments. Since the standardized amount was reduced by 5.1 percent to account for outliers, the threshold set by CMS results in less total Medicare payments to hospitals, which is contrary to the intent of the outlier payment policy. The same can be noted for FFY 2004 when outlier payments were only 3.5 percent of total DRG payments

We believe the proposed fixed-loss cost threshold should be reduced on FFY 2005.

Thank you again for the opportunity to comment on this proposed rule. If you have questions regarding anything I have commented upon, please do not hesitate to contact me at 215-662-2992

Sincerely,



Cc: Mike Leavitt, Secretary of Health and Human Services
Joshua Bolton, Director of Office of Management and Budget
Robert Dickler, Association of American Medical Colleges

538

COLLINS
MOREY
SMITH
HEFTER
[redacted]
HARTSTEIN

Submitter : Mrs. Cherie Taylor **Date:** 06/24/2005

Organization : Northern Rockies Medical Center, Inc.

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

CAH/Reloc

GENERAL

See Attachment

CMS-1500-P-688-Attach-1.DOC

Attchment to 688

Northern Rockies Medical Center, Inc.
802 2nd St. SE
Cut Bank, MT 59427

June 23, 2005

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

Re: The Proposed Construction Ban for a CAH

Dear CMS:

It is the utmost importance for Critical Access Hospitals (CAH's) like Northern Rockies Medical Center, Inc (NRMC) to have the flexibility to relocate our facility in the future. Our facility is a Hill-Burton facility. It will be imperative that NRMC replaces its facility in the next 5 years to continue providing quality healthcare.

Portions of our building were built in 1949. It is very possible that due to the cost of removing asbestos it will be more cost effective to build off-site. It makes no sense to me that the federal government would pass legislation that could increase the costs of capital improvements in rural hospitals. Since a CAH is cost reimbursed, why would CMS want to increase the cost of providing care to Medicare and Medicaid patients?

Our facility is 25 miles from the next hospital. If our facility chose to relocate due to cost effectiveness, it would be within a 1 mile of our current location. A community task force is being formulated to analyze the best alternative for our hospital, which serves Glacier County. Even if the feasibility studies determine a new facility at a different location is the most cost effective solution, the proposed legislation will eliminate the possibility. It is hard for the rural hospital Boards to provide cost effective healthcare, when federal regulations prohibit it. NRMC would have a difficult time relocating within 250 yards of our current facility since the area surrounding it is residential.

NRMC's Necessary Provider designation is associated with its current Medicare provider agreement; which should remain intact unless NRMC ceases its operations or is terminated by Medicare. How can relocation of our hospital within our community be considered a cessation of business and a loss of our provider agreement and number?

I propose CAH's are automatically allowed to relocate within 2 miles of its location because the requirements by CMS would be fulfilled without the cost of proving it. If the

relocation is beyond the mileage requirement, then require assurance "the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff."

Please delete the arbitrary deadline on Critical Access Hospital replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. Thank you for your time and consideration for rural America.

Sincerely,

Cherie Taylor
Chief Executive Officer
nrmcomt@theglobal.net

CMS-1500-P-676

539 WALZ HART HEFTER HARTSTEIN

675
672

Submitter : Mr. Leo Greenawalt **Date:** 06/24/2005

Organization : Washington State Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

TRANSFER

GENERAL

See attached letter from
Leo Greenawalt, President and Chief Executive Officer
Washington State Hospital Association

CMS-1500-P-676-Attach-1.RTF

CMS-1500-P-676-Attach-2.DOC

Attachment 1 to #676

June 23, 2005

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

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

Dear Dr. McClellan:

On behalf of the Washington State Hospital Association, representing about 100 hospitals in the State of Washington, we are writing to provide comments on the fiscal year 2006 inpatient prospective payment system proposed rule.

We are particularly concerned about the proposed expansion of the post-acute care transfer policy and the loss in payments for our members due to this expansion. CMS is proposing to expand the definition of transfers from 30 DRGs to 231 DRGs. These "transfers" are cases where the patient had a length of stay less than the average and received some post acute care. By proposing to classify these cases now as transfers, CMS is proposing to reduce the amount it pays hospitals to care for these patients from the full DRG payment to a per-diem payment based on the length of stay.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient prospective payment system is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

[redacted]
300 Elliott Avenue West
Suite 300
Seattle, WA 98119-4118
Phone 206-216-2500
Fax 206-283-6122
e-mail: leog@wsha.org

We find this proposed policy especially troublesome because Washington hospitals are relatively efficient with short lengths of stay. Our hospitals will be hurt more than the average hospital, since more cases in Washington will fall below the average length of stay. In Washington, this new policy will mean a loss of $19 million in Medicare payments per year.

We urge you to reconsider this proposal. Our hospitals cannot continue to function effectively without adequate and appropriate Medicare payments.

Sincerely,

Leo Greenawalt

Leo Greenawalt
President and CEO

Attachment 2 to #676

Duplicate Attachment

June 23, 2005

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

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

Dear Dr. McClellan:

On behalf of the Washington State Hospital Association, representing about 100 hospitals in the State of Washington, we are writing to provide comments on the fiscal year 2006 inpatient prospective payment system proposed rule.

We are particularly concerned about the proposed expansion of the post-acute care transfer policy and the loss in payments for our members due to this expansion. CMS is proposing to expand the definition of transfers from 30 DRGs to 231 DRGs. These "transfers" are cases where the patient had a length of stay less than the average and received some post acute care. By proposing to classify these cases now as transfers, CMS is proposing to reduce the amount it pays hospitals to care for these patients from the full DRG payment to a per-diem payment based on the length of stay.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient prospective payment system is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

[redacted]
300 Elliott Avenue West
Suite 300
Seattle, WA 98119-4118
Phone 206-216-2500
Fax 206-283-6122
e-mail: leog@wsha.org

We find this proposed policy especially troublesome because Washington hospitals are relatively efficient with short lengths of stay. Our hospitals will be hurt more than the average hospital, since more cases in Washington will fall below the average length of stay. In Washington, this new policy will mean a loss of $19 million in Medicare payments per year.

We urge you to reconsider this proposal. Our hospitals cannot continue to function effectively without adequate and appropriate Medicare payments.

Sincerely,

Leo Greenawalt

Leo Greenawalt
President and CEO

Submitter : **Mr. Leo Greenawalt** **Date: 06/24/2005**

Organization : **Washington State Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter from
Leo Greenawalt, President and Chief Executive Office
Washington State Hospital Association

Submitter : Mr. Leo Greenawalt **Date:** 06/23/2005

Organization : Washington State Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter from
Leo Greenawalt, President and Chief Executive Officer
Washington State Hospital Association

CMS-1500-P-712

540

COLLINS
MOREY
SMITH
KNIGHT
SEIFERT
WALZ
HART
BODDEN
HAMMEL
HEFTER
HARTSTEIN

710
711

Submitter : Mr. David Burd

Date: 06/24/2005

Organization : Nebraska Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-712-Attach-1.DOC

CAH/RELOC

MB/H

TRANSFERS

© DATA

Attachment to #712

NHA Nebraska Hospital Association

June 24, 2005

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

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

Dear Dr. McClellan:

On behalf of the Nebraska Hospital Association (NHA), its 85 member hospitals, and the 35,000 individuals we employ, I appreciate the opportunity to submit comments on the fiscal year (FY) 2006 inpatient prospective payment system (PPS) proposed rule.

While the NHA is supportive of many of the provisions in the proposed rule, we have some concerns about the potential underestimation of the market basket; the proposed expansion of the post-acute care transfer policy; the potential restrictions on the relocation of critical access hospitals (CAHs) with necessary provider status; and the proposed link between meeting the quality data validation requirements and receiving the full market basket update.

Hospital Market Basket

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 however, along with technical adjustments to ensure budget neutrality would result in a proposed average per case payment increase of only 2.5 percent. At the same time, the current estimates of the actual market basket increase for FY 2005 is 4.1 percent. We are concerned that CMS is dramatically underestimating the market basket for FY 2006. **We request that CMS review and revise the methodology used to determine the projected FY 2006 market basket.**

In 2003, 54 percent of hospitals had negative Medicare inpatient margins and one out of every three hospitals was losing money overall. Hospitals cannot continue to receive actual updates that are less than the rate of hospital inflation. **We will continue to urge Congress to provide adequate Medicare reimbursement to hospitals. We also encourage CMS to make the necessary changes that would prevent further decline in Medicare payments.**

Post-Acute Care Transfers

We are very concerned with the proposed rule to further expand the post-acute care transfer policy which would reduce hospital payments nationally by nearly $900 million in FY 2006 alone. **The effect of this proposed change on Nebraska hospitals would be approximately $5.4 million in FY 2006.** Although some other states will be impacted more (in terms of dollars) by this proposed rule change, a payment reduction of this size would still have a very negative financial impact on Nebraska hospitals.

The expansion of the transfer policy goes against the basic principles and objectives of the Medicare prospective payment system (PPS). The Medicare PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. **The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge.**

This 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. **The NHA strongly encourages CMS to withdraw this provision in its final rule.**

Necessary Provider Status Relocations

A state's authority to grant necessary provider status, and thus waive the distance requirement under the CAH program expires January 1, 2006. However, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS' proposed rule would essentially bar necessary providers from ever rebuilding farther than 250 yards from their current location. Appropriate and necessary relocations that will undoubtedly result in higher quality care, better patient outcomes, and more efficient service should be allowed.

Some of the 60 Critical Access Hospitals in Nebraska are housed in old buildings that have not been renovated in decades. There are several reasons why a hospital would want the option of building a new facility versus renovating the old facility. The hospital may be landlocked with no room for expansion. The hospital may also be trying to accommodate community needs by improving patient access and by making safety improvements. **NHA urges CMS to remove the arbitrary date restrictions included in the proposed rule that have no basis in law. NHA also recommends that CMS automatically consider any CAH that moves within five miles of its current location to be the same provider and thus retain its necessary provider status.**

Hospital Quality Data

To determine if a hospital qualifies for its full Medicare market basket update in FY 2006, CMS must determine if a hospital has submitted data on the 10 measures of heart attack, heart failure, and pneumonia care. The proposed rule for FY 2006 states several requirements for data to be considered submitted for purposes of receiving the full market basket update. These requirements include the hospital's continuous submission of quarterly data on the 10 measures,

the submission of the data for patients discharged through the 4th quarter of 2004 by May 15, 2005, and the validation of the hospital's 3rd quarter 2004 data.

The NHA strongly supports the need for validation of the data that are submitted by hospitals. Validation helps ensure that the collected information shows an accurate picture of the quality of care provided in each participating hospital. However, there is evidence of flaws in the validation process. Until the validation process is reliable, NHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update. **The CMS validation process needs to be improved before it is used in determining which hospitals receive full updates.**

The NHA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact David Burd, NHA's Director of Finance, at (402) 458-4900.

Sincerely,

Laura J. Redoutey, FACHE
President

Submitter :

Date: 06/24/2005

Organization :

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

See attached

Submitter : **Mr. David Burd** **Date: 06/24/2005**

Organization : **Nebraska Hospital Association**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

541

TRUONG
LEFKOWITZ
RUIZ
HEFTER
HARTSTEIN

Submitter : Mr. Kenneth Raske **Date:** 06/24/2005

Organization : Greater New York Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from the Greater New York Hospital Association that includes comments on the IPPS FFY 2006 proposed rule.

CMS-1500-P-716-Attach-1.PDF

CMS-1500-P-716-Attach-2.PDF

IME
GME/IRP

ATTACHMENT 1 TO #716

Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

June 23, 2005

VIA ELECTRONIC MAIL

Mark McClellan, MD
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**; Comments on IPPS Proposed Rule, *Section F. Indirect Medical Education Adjustment (Section 412.105)* and *Section I. Payment for Direct Graduate Medical Education (Section 413.79)*

Dear Administrator McClellan:

Greater New York Hospital Association (GNYHA), which represents approximately 100 teaching hospitals in the metropolitan New York region, including hospitals in New York, New Jersey, Connecticut, and Rhode Island, is pleased to provide these comments on *Section F. Indirect Medical Education (IME) Adjustment (Section 412.105)* and *Section I. Payment for Direct Graduate Medical Education (Section 413.79)*, and accompanying proposed regulations, that were included in the Proposed Rule describing changes to the Hospital Inpatient Prospective Payments Systems (IPPS) and Fiscal Year 2006 Rates.

GNYHA comments on other sections of the proposed rule, including proposed changes to the Medicare wage index, are being sent under separate cover.

Indirect Medical Education (IME) Adjustment (Section 412.105)

GNYHA appreciates that the Centers for Medicare & Medicaid Services (CMS) recognizes that there are circumstances in which a hospital that was excluded from the inpatient prospective payment system (PPS) might "convert" to an acute care hospital and be subject to the inpatient PPS, and that a definitive statement from CMS is needed regarding the issue of resident caps. CMS proposes that in the case of an exempt hospital converting to an acute care hospital, the information that was used to determine the hospital's direct GME resident cap during the last cost report period on or before December 31, 1996 be reviewed and based on this review, an IME resident cap be established for the purpose of calculating the hospital's IME payments under the inpatient PPS. In the proposed rule, CMS is silent, however, regarding the applicability of any such methodology to an exempt unit within a hospital that "converts" and becomes subject to the inpatient PPS.

GNYHA strongly believes that 1) any consideration and application of a methodology applies equally to the situation where a unit within a hospital was excluded from the inpatient PPS and becomes subject to the inpatient PPS, and 2) CMS should use a more updated cost reporting period – and in particular should not use the last cost reporting period ending on or before December 31, 1996 – for the establishment of an IME resident cap amount.

GNYHA recognizes that in order for CMS to have a consistent policy with regard to application of resident caps, hospitals that convert and become subject to the inpatient PPS must have an IME resident cap established. GNYHA also believes that consistency in such policymaking regarding "conversions" must extend equally to situations where a unit previously exempt becomes subject to the inpatient PPS as a result of changes in Medicare's rules. In situations where a unit converts, the IME cap established for the converting unit *should be added* to the acute hospital's existing IME cap. Otherwise, the hospital will have inconsistent direct GME and IME resident caps as a result of the conversion. The fact that the residents were included in the direct GME cap in 1996 is acknowledgement by CMS that the residents were there and should be included as part of the resident count. CMS is well aware that the reasons why a unit previously exempt may become newly subject to the inpatient PPS may be a full-blown conversion involving different services or may be a nominal "conversion" in response to new requirements under Medicare. GNYHA believes that in the latter case, the principle behind the establishment of the resident cap for the converting hospital as outlined in the proposed rule argues strongly for extending the principle equally to hospital-based units that convert and are newly subject to the inpatient PPS.

With regard to the period used for the determination of the cap amount (whether for a converting hospital or a converting unit), GNYHA believes it is unnecessary to use nearly ten-year old data for the establishment of an IME resident cap or calculation for adding to the acute inpatient hospital's IME cap. There is ample precedent for CMS to use a more updated data source for establishment of the IME cap for hospitals and units converting to the inpatient PPS without an accompanying legislative change. The inpatient psychiatric PPS developed by CMS established an IME cap for those facilities *and units* based on the most recent cost reporting period prior to November 15, 2004, and the inpatient rehabilitation PPS proposed rule recently published by CMS contemplates the last cost reporting period ending on or before November 15, 2003 for the establishment of an IME cap for those facilities and units. GNYHA strongly recommends that for the sake of consistency, CMS use either or both of these cost reporting periods for the establishment or adding to the IME resident cap in situations where a hospital or unit is converting and will be newly subject to the inpatient PPS.

Direct GME Initial Residency Period (Section 413.79(a)(10))

GNYHA is appreciative that CMS decided to clarify its policy regarding the "clinical base year" in the FFY 2005 inpatient PPS final rule in response to concerns raised by the academic medicine community regarding the illogical way in which this policy was being applied in certain instances. The decision by CMS to change its regulations as of October 1, 2004 – to explicitly state that a resident who entered residency raining through a simultaneous match is eligible for the initial residency period (IRP) associated with the specialty in which the physician

actually intends to practice – was a step in the right direction toward addressing this issue in a way that accommodates the realities of the way in which physicians are actually trained. Similarly, the change discussed in FFY 2006 IPPS proposed rule – to further change the regulations as of October 1, 2005 to allow a resident who matches only to an advanced program without a match to a clinical base year program to be labeled with the IRP associated with the advanced program – is another step in the right direction. GNYHA applauds CMS for proposing this change to expand upon its FFY 2005 final rule change. That said, GNYHA continues to believe that CMS should simply address the issue in the more straightforward manner by implementing a clear *second-year policy* that determines the IRP for those performing a clinical base year based on where the resident is training in the second year. Such a clarification would be well within CMS's authority, would be consistent with statutory intent, and would remove all the complications surrounding this issue.

GNYHA continues to believe that CMS has the authority to clarify its policy based on the recent clear statement of Congressional intent included within the Conference Report accompanying the Medicare Modernization Act (MMA). That statement stated in no uncertain terms that the CMS interpretation of its statutory limitations in applying a sensible policy is a misreading of the statute. As stated by conference report language accompanying section 712 of the MMA:

> 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.

GNYHA urges that CMS interpret the statute to consistent with Congressional intent. This solution will ensure that the administrative complications for teaching hospitals and the fiscal intermediaries inherent in implementing a "match policy" will be removed and a consistent policy is applied across residency training programs. As CMS is aware, not every resident who is in a specialty that requires the clinical base year training matches simultaneously into both specialties, and there is no ACGME requirement that the resident do so. In addition, many residents are admitted to a residency program outside of any residency match, and there are some specialties that do not even participate in a residency match. Such legitimate variations among the specialties and the means of entering residency training confirm that attempts to use "resident matching" for this purpose is extremely inefficient.

As the preamble alludes to regarding the various ways in which a resident may enter training in the first and second years, a resident who performs a separate clinical base year:

- May match simultaneously into both the first and second year, *or*
- May match to the second year without an accompanying first-year match prior to beginning any training, *or*
- May match into the second year during the clinical base year, to which he or she hasn't matched, *or*
- May enter both the clinical base year and the second year completely outside of the matching process.

All scenarios are acceptable by the accrediting bodies and should be acceptable to CMS as well. Plus, CMS has the authority to implement this policy without an associated change in the statute.

As GNYHA noted in its comments last year, the Medicare statute states that the IRP is "determined, with respect to a resident, as of the time the resident enters the residency training program." The statue also states that "the period of board eligibility" is the minimum number of years of formal training necessary to satisfy the requirements for initial Board eligibility in the particular specialty for which the resident is training. Under CMS's current interpretation of the statute, focusing on the program in the first year of training, regardless of the specialty for which the resident is actually training for in that first year within that program, may yield an incorrect labeling of the resident that does not reflect the resident's clear intent with regard to specialty training. To reiterate, the statute requires that the IRP be determined *as of the time* the resident enters the training program, but nowhere does the statute require the assignment of the IRP to a resident *prior to* or *during* the first year of the resident's training. If the statute did mandate that the IRP be determined prior to the beginning of the second year of training, then a resident training in a separately accredited transitional year program would not be eligible to have the IRP determined at that time. CMS' longstanding policy allowing the IRP to be determined at the beginning of the second year for residents who trained in transitional year programs is clear evidence that a second-year policy is permissible under the statute.

In conclusion, while GNYHA supports the proposed change in the regulations within the narrow constraints within which CMS has defined it, GNYHA encourages the agency to exercise its discretion and state clearly and unequivocally that for those residents who perform a clinical base year – and enter that year of training and the following year of training by whatever means the resident chooses – those residents should be assigned the IRP associated with the second year of training, which is a true reflection of the physician's intent with regard to specialty.

Thank you for the opportunity to comment on these proposed regulations. Should you or your staff wish to discuss any aspect of the comments, please feel free to contact Tim Johnson of my staff at tjohnson@gnyha.org or 212-506-5420.

My best.

Sincerely,

Kenneth E. Raske
President

ATTACHMENT 2 TO # 716

Duplicate attachment submitted

GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

June 23, 2005

VIA ELECTRONIC MAIL

Mark McClellan, MD
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**; Comments on IPPS Proposed Rule, *Section F. Indirect Medical Education Adjustment (Section 412.105)* and *Section I. Payment for Direct Graduate Medical Education (Section 413.79)*

Dear Administrator McClellan:

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Indirect Medical Education (IME) Adjustment (Section 412.105)

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GNYHA urges that CMS interpret the statute to consistent with Congressional intent. This solution will ensure that the administrative complications for teaching hospitals and the fiscal intermediaries inherent in implementing a "match policy" will be removed and a consistent policy is applied across residency training programs. As CMS is aware, not every resident who is in a specialty that requires the clinical base year training matches simultaneously into both specialties, and there is no ACGME requirement that the resident do so. In addition, many residents are admitted to a residency program outside of any residency match, and there are some specialties that do not even participate in a residency match. Such legitimate variations among the specialties and the means of entering residency training confirm that attempts to use "resident matching" for this purpose is extremely inefficient.

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Thank you for the opportunity to comment on these proposed regulations. Should you or your staff wish to discuss any aspect of the comments, please feel free to contact Tim Johnson of my staff at tjohnson@gnyha.org or 212-506-5420.

My best.

Sincerely,

Kenneth E. Raske
President

542

TREITEL
WALZ
HEFTER
HARTSTEIN

Submitter : Mr. Charlie Hall

Date: 06/24/2005

Organization : Piedmont Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

NT

GENERAL

See Attachment

CMS-1500-P-750-Attach-1.DOC

Attachment to 750

June 22, 2005

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

RE: New Technology Add-on Payment Application for CHARITE™ Artificial Disc

Dear Sir or Madam:

As a hospital Chief Financial Officer, I am writing in response to the request for public comments on the CHARITE™ Artificial Disc application for new technology add-on payments.

Spinal arthroplasty is an area that is generating considerable interest in the orthopaedic sector and with our surgeons, particularly since the FDA approval of CHARITE in October 2004. However, based on the cost of this and future artificial disc technology, our hospital may have to restrict usage until a more appropriate reimbursement environment is established.

This is why I am now requesting that CMS grant new technology add-on payments for the CHARITE disc. As mentioned above, the cost burden from artificial discs places significant stress on hospital finances. I believe that the granting of add-on payments will help ease this burden for hospitals so that they can provide the technologies that their surgeons want to use.

Thank you for your consideration of this important matter for hospitals. Should you wish to discuss this request, please contact me at 404-605-2439.

Sincerely,

Charlie Hall

Charlie Hall
Chief Financial Officer
Piedmont Hospital

Cc: Robert, Maynard, CEO, Piedmont Hospital
Bob Cross, Director, Government Reimbursement
Michelle Fisher, Project Manager, Management Support
Sherry Thornton, Group Director, Medtronic Sofamor Danek

543

WALZ
HART
MILLER
HEFTER
HARTSTEIN

Date: 06/24/2005

Submitter : Mr. John Manzi

Organization : NJ Chapter HFMA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-812-Attach-1.RTF

TRANSFERS
PYMT RTS/OUTLIER
WI/Bd

Attachment to #812

June 21, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 21244

Re: 2006 Inpatient Prospective Payment (IPPS) Proposed Rule

Dear Mr. McClellan:

The New Jersey Chapter of the Healthcare Financial Management Association appreciates this opportunity to comment on the 2006 IPPS Proposed Rule that was published in the May 4, 2005 Federal Register. We wish to address the following Proposed Rule changes:

Post Acute Care Transfers

The Centers for Medicare and Medicaid Services (CMS) has had a long-standing policy of providing only partial IPPS reimbursement on behalf of patients who do not complete the treatment phase of their care. These are patients who are transferred to another acute care hospital once they are stabilized because the first hospital could not provide the services the patient required. More recently, CMS began to expand the concept of a transfer patient to also include patients who do not complete a reasonable recovery phase. The agency defines "reasonable" based upon the patient's length of stay.

Under the expanded transfer policy, patients are deemed to be transfers if they are discharged to an inpatient rehabilitation facility (IRF), an inpatient psychiatric facility (IPF), a skilled nursing facility (SNF), or a home health agency (HHA). Transfer designation yields two outcomes:

- Transfer cases are reimbursed according to the transfer payment methodology. Under this methodology, the inlier payment is divided by the geometric mean length of stay of the DRG to which the patient is assigned in order to derive a per diem payment. Then the hospital receives the lower of the per diem payment multiplied by the actual length of stay plus one day, or

the full DRG amount. In certain DRGs, the hospital receives a blended transfer payment, which is an equal share of the transfer payment and the DRG payment.

- Transfer cases are weighted at less than 100% for the purpose of computing DRG weights. The substitute weight is the share of the full DRG payment that is represented by the transfer payment. This has the effect of supporting the DRG weight. That is, the lower-cost discharges to post-acute care are not allowed to dilute the DRG weights.

CMS began with the transfer policy by applying it to 10 DRGs in 1999. This was done at the direction of Congress through the Balanced Budget Act of 1997 (BBA). Later, in FY 2004, the agency extended the policy to 29 DRGs. Now, for FY 2006, CMS is proposing to fully implement the policy by extending it to 231 DRGs, which are virtually all the DRGs where significant volume exists.

Expansion of the DRGs subject to the transfer policy will have a significant impact on New Jersey hospitals. Modeling that we have completed has shown that IPPS reimbursement will be reduced by more than 1% based upon this Proposed Rule change. The original intent of this law was to utilize 10 DRGs as qualified transfers, and now the proposed total is 231. The transfer of patients to other Healthcare settings does not lower LOS; thus, this proposal is merely a continuation to reduce hospital payments.

Recommendation: We strongly urge CMS not to implement its proposed expanded post-acute care transfer policy.

Outlier Cost Threshold

The cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that will result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus $26,675 - an increase of 3.4 percent over the FY 2005 of $25,800.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FY 2005 will represent only 4.4 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 3.5 percent of total DRG payments in FY 2004. Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in both of these years, contrary to the intent

of the outlier payment policy.

We believe the FY 2005 fixed-cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays.

Recommendation: We strongly urge CMS not to increase the cost threshold but to reduce in a manner that is consistent with the 2004 and 2005 trend so that 2006 outlier payments will reach the 5.1 percent goal.

Wage Index

We support the continuance of the 508 legislation and request that the Rural Wage Floor be extended.

If you or your staff would like to discuss our comments, please contact John Manzi at (609) 919-0990 ext. 124 or Lee Gordon at (201) 996-3373.

Sincerely,

_____

John Manzi, President

_____

Lee Gordon, Co-Chairperson
Reimbursement/Proactive Committee

_____

Rea Zagaglia, Co-Chairperson
Reimbursement/Proactive Committee

CMS-1500-P-833

544

TREITEL
WALZ
BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Submitter : Ms. Maya Bermingham

Date: 06/24/2005

Organization : PhRMA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see comments attached regarding CMS-1500-P.

CMS-1500-P-833-Attach-1.PDF

NT
SUBSTANTIAL SIMILARITY
DRG/GEN

ATTACHMENT TO #833

PhRMA

June 24, 2005

VIA E-MAIL

http://www.cms.hhs.gov/regulations/ecomments
Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: **CMS-1500-P; Comments Regarding the Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2006 Rates; New Technology Applications and DRG Reclassifications**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the hospital inpatient proposed rule (Proposed Rule) issued by the Centers for Medicare and Medicaid Services (CMS).[1] PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

[1] Medicare Program; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2006 Rates; 70 Fed. Reg. 23306 (May 4, 2005).

PhRMA is deeply committed to research and innovation and achieving the goal that all patients have access to the most appropriate therapies available, in the hospital inpatient (and other) settings. Congress sought to advance this same goal when it created new technology add-on payments and when it subsequently strengthened them with the Medicare Modernization Act. Without new technology add-on payments, the DRG-based payment system could create barriers to access for therapies not yet reflected in DRG payments. Patient access to innovative therapies also depends upon appropriate classification of DRGs and calibration of relative weights.

****

These comments address: (1) CMS's interpretation of the newness criterion used in awarding hospital inpatient new technology add-on payments; (2) the role of "substantial similarity" in awarding these add-on payments and the factors used by CMS to determine whether technologies or medical services are substantially similar; and (3) reclassification of the stroke DRGs.

A. Interpretation of Newness

The statute and the regulations require that technologies satisfy three criteria to receive new technology add-on payments: newness, cost, and substantial clinical improvement.[2] According to the regulations, services and technologies are new "within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new . . . technology become available for DRG calibration)."[3] Satisfying the cost criterion requires showing that the current DRG-based payment for cases involving use of the service or technology is "inadequate" in relation to the technology's cost.[4] Finally, to satisfy the substantial clinical improvement criterion, the service or technology must "substantially improve[], relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries."[5]

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[2] Social Security Act (SSA) § 1886(d); 42 CFR § 412.87.

[3] 42 CFR § 412.87(b). Similarly, the Medicare statute requires CMS to collect data on the costs of a new technology "for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the . . . technology" and to "provide for additional payments to be made . . . with respect to discharges involving [the technology] that occur during [the specified data collection period]." SSA § 1886(d)(5)(K)(ii)(II), (III). "Inpatient hospital code" includes an ICD-9-CM code. Id., § 1886(d)(5)(K)(iii).

[4] 42 CFR § 412.87(b).

[5] Id.

Last year, in our comments on the FY 2005 proposed inpatient rule, we recommended that CMS interpret the newness criterion consistently with the Medicare statute and CMS's implementing regulations. We are disappointed that CMS has instead continued to misinterpret newness this year, stating, for instance, that "the two-to-three year period during which a technology . . . can be considered new would ordinarily begin with FDA approval."[6] As we discussed in our FY 2005 comments, this interpretation cuts off eligibility for new technology add-on payments prematurely, is inconsistent with the Medicare statute and regulations, and may limit patient access to innovative new technologies by inadequately compensating hospitals. For these reasons, we urge CMS to base its final decisions on the pending new technology applications on the newness standard incorporated in the statute and regulations; that is, CMS should start the two-to-three year period a technology may be considered new from the date that the technology is assigned an ICD-9-CM code (if that post dates the FDA approval date).

B. Substantial Similarity

In previous inpatient rules, CMS has described a special policy for analyzing whether "substantially similar" products should receive add-on payments. According to CMS, under this policy, "subsequent new technologies that are substantially similar to a current approved (for special payment) technology should be eligible for special payment as well. Otherwise, our payment policy would bestow an advantage to the first applicant representing a particular new technology to receive approval."[7] CMS has applied substantial similarity both to grant add-on payments (to products that are substantially similar to other products that qualify for add-on payments) and to deny add-on payments (for otherwise new products deemed substantially similar to products that no longer qualify as new).[8]

In the Proposed Rule, CMS discusses three factors that a commenter had suggested using to determine whether products are substantially similar. These factors are whether the technologies or services:

1. "Use the same, or a similar, mechanism of action to achieve the therapeutic outcome";

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[6] Proposed Rule, 70 Fed. Reg. at 23354.

[7] 66 Fed. Reg. 46902, 46915 (Sept. 7, 2001).

[8] For instance, CMS granted OP-1 Putty a new technology add-on payment for use in spinal fusions based on its substantial similarity to another product, InFUSE, which was eligible for add-on payments for this indication. See 69 Fed. Reg. 48916, 49008-09 (Aug. 11, 2004). In the same rule, CMS denied InFUSE add-on payments for use in tibial fractures in part because it was substantially similar to the OP-1 Implant, which was too old to qualify for add-on payments for this indication. Id. at 49011-12.

2. "Are indicated for use in the same population for the same condition"; and

3. "Achieve the same level of substantial improvement."[9]

CMS agreed that the first factor, mechanism of action, "has some relevance in determining whether products are substantially similar."[10] However, CMS concluded that the other two factors are irrelevant for this purpose. In explaining why the level of substantial clinical improvement is not relevant to a substantial similarity determination, CMS stated, "[W]e do not necessarily agree that considerations about the degrees of clinical improvements offered by different products should enter into decisions about whether products are new," thus suggesting that substantial similarity is a sub-factor under the newness criterion.[11]

PhRMA is concerned about CMS's discussion of these substantial similarity factors for two reasons. First, CMS's discussion suggests that a product with the same or a similar mechanism of action as an existing product could be denied add-on payment for that reason alone. This disqualification could limit patient access to therapies that otherwise deserve new technology add-on payments because they are new (not reflected in hospital charge data), costly (significantly increase hospital charges), and offer a substantial clinical improvement over existing products. Products with the same or a similar mechanism of action can have very different clinical effects (either generally or for particular patients), and patients should not be denied access to a new therapy offering a substantial clinical improvement merely because the therapy has the same mechanism of action as an existing treatment.

Second, CMS's discussion of substantial similarity creates confusion about the relationship between substantial similarity and the three add-on payment criteria. Although the Proposed Rule implies that substantial similarity is a sub-factor to the newness criterion, past rules have implied that substantial similarity is a sub-factor to clinical improvement[12] or replaces all three criteria.[13] This creates needless confusion for

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[9] Proposed Rule, 70 Fed. Reg. at 23359.

[10] Id.

[11] Id. (Emphasis added).

[12] CMS has stated that "Applicants [seeking to rely on substantial similarity] would still be required to submit data showing they would be inadequately paid and that the subsequent technology meets the criterion that it be new," which implies that substantial similarity replaces or relates only to a showing of substantial clinical improvement. 66 Fed. Reg. at 46915.

manufacturers that need to invest resources in developing innovative products relying on predictable ground rules.

Given these concerns, PhRMA recommends CMS eliminate substantial similarity from its new technology add-on payment deliberations, and grant add-on payments based solely on whether a product satisfies the newness, cost, and substantial clinical improvement criteria specified in the statute and regulations.

Eliminating substantial similarity would offer several benefits. First, eliminating substantial similarity would eliminate the risk that patients would be denied access to products that offer substantial clinical improvements, such as reduced mortality, recovery times, or hospitalizations, merely because they are deemed to have the same mechanism of action as existing products. Second, eliminating substantial similarity would improve the clarity and predictability of the add-on rules. Third, reliance on only these criteria is better supported by the statutory provisions and CMS regulations on add-on payments because neither of these authorities mentions "substantial similarity." Finally, eliminating substantial similarity would actually serve the goal CMS articulated when it introduced this doctrine -- making technologies that enter the market subsequent to similar products that are currently receiving add-on payments "eligible for special payment as well," and thus not bestowing "an advantage to the first applicant representing a particular new technology to receive approval."[14] If the second applicant is new (because the product is not reflected in the DRG-based payment rates), sufficiently costly, and offers substantial clinical improvement relative to technologies that have already been incorporated into DRG-based payment rates, the second applicant also should receive an add-on payment.

C. Reclassification of Stroke DRGs

CMS in the Proposed Rule also discusses reclassification of DRGs 14 and 15, "Intracranial Hemorrhage or Cerebral Infarction" and "Nonspecific CVA and Precerebral Occlusion Without Infarction," respectively.[15] CMS notes that several hospital stroke centers recommended that these DRGs be modified (or a new DRG created) to recognize

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[13] CMS, in discussing its decision to grant add-on payments for OP-1 Putty for use in spinal fusions, only mentioned the ways in which OP-1 Putty was substantially similar to another product, InFUSE (similar mechanisms of action and indications and their use of "closely related" bone morphogenic proteins), but did not mention whether OP-1 Putty independently met any of the three criteria. See 69 Fed. Reg. at 49008-09. CMS thus implied that substantial similarity in this instance replaced consideration of the three criteria.

[14] 66 Fed. Reg. at 46915.

[15] Proposed Rule, 70 Fed. Reg. at 23315-16.

the higher charges of and resources required by cases that contain the ICD-9-CM code 99.10, "Injection or infusion of thrombolytic agent."[16] According to CMS's analysis of the MedPAR data, charges for cases including code 99.10 are $10,000 to over $15,000 higher (or from over 1.5 to nearly 2 times greater) than cases without the code. Although these charge differences support changing the DRGs, CMS proposes making no changes because of its concern regarding what it deems the "small number of cases" coded using 99.10.[17] CMS requests comments on its proposal and the number of patients currently being treated with reperfusion agents because it suspects that the number of cases involving reperfusion agents may be underreported in the MedPAR data.

PhRMA agrees that cases involving reperfusion agents are likely underreported in the MedPAR data because hospitals currently have no incentive to include code 99.10 on claim forms, since it currently has no impact on reimbursement. While PhRMA understands that other commenters may choose to provide CMS with useful non-MedPAR data on additional cases involving reperfusion agents, PhRMA believes the MedPAR data alone are sufficient to justify reclassifying the stroke DRGs. CMS's analysis shows that there are 2,448 cases in DRGs 14 and 15 that are coded with ICD-9-CM 99.10, and tens of thousands of cases in these DRGs without this code. In a recent inpatient rule, CMS reclassified a pair of DRGs based on 22 cases from MedPAR because it considered the data sufficient for making its decision.[18] Likewise, CMS should reclassify DRGs 14 and 15, which have over one hundred times as many cases.

PhRMA recommends that either DRGs 14 and 15 be modified or a new DRG created, along the lines proposed by the hospital stroke centers, with one qualification.[19] PhRMA recommends that CMS modify or create new stroke DRGs that are broad enough to encompass both existing agents and forthcoming stroke therapies, which currently are in late stage clinical trials. Making this change would assure the clinical coherence of

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[16] Id. at 23315.

[17] Id. at 23316.

[18] CMS reassigned ICD-9-CM codes 49.75 ("Implantation or revision of artificial anal sphincter") and 49.76 ("Removal of artificial anal sphincter") from DRGs 157 and 158 using its analysis of MedPAR data. Six cases with these codes were grouped in these DRGs, and 16 cases with these codes were grouped into other DRGs. Based on these MedPAR cases, CMS reclassified these procedure codes into other DRGs. CMS made this revision despite recognizing that "there were few reports of codes 49.75 and 49.76." See 69 Fed. Reg. at 48934.

[19] The hospitals recommended either renaming DRGs 14 and 15 to "Ischemic Stroke Treatment with a Reperfusion Agent" (which would include only cases coded with ICD-9-CM 99.10 and "Hemorrhagic Stroke or Ischemic Stroke without a Reperfusion Agent" (which would exclude cases coded with 99.10) or creating a new DRG, "Ischemic Stroke Treatment with a Reperfusion Agent." Proposed Rule, 70 Fed. Reg. at 23315.

these DRGs in the years to come and streamline patient access to new treatments for stroke, the third leading cause of death in America.

****

PhRMA hopes that these comments will be useful to CMS in finalizing the Proposed Rule. We look forward to further dialogue on these issues and hope that CMS will not hesitate to contact us with any questions, comments or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research and Strategic Planning

Diane E. Bieri
Vice President and Compliance Officer

545

Submitter : Mr. Chris Batson
Organization : Mission Hospitals
Category : Hospital
Date: 06/24/2005

Transfers

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-818-Attach-1.TXT

Hefter
Hartstein
Walz
Hart
Brooks
Kelly
Fagan
Gruber
Rue

Attachment to #718

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

June 22, 2005

Re: Post- Acute Care Transfers
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates; CMS-1500-P; Proposed Rule; 70 Fed. Reg. et seq. (May 4, 2005)

Dear Sir or Madam:

Please accept these comments regarding the CMS proposal to expand the post-acute care transfer provision "from 30 DRGs to 223 DRGs (later revised to 231), which would reduce hospital Medicare payments by $894 million " "when the effects on disproportionate share (DSH), indirect medical education (IME), capital and outlier payments are"considered. These proposed changes would reduce Mission Hospitals Medicare payments by $1 million annually.

"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. Thus, if a patient has a shorter than average inpatient stay, the hospital is paid less than the full DRG rate."

"Currently to be included in the transfer-DRG list, a DRG must have the following for the two most recent years:"

* "At least 14,000 discharges to post-acute care;"
* At least 10% of its discharges to post-acute care occurring before the geometric mean length of stay;
* A geometric mean length of stay of at least three days; and
* "If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent five year period of at least 7%.

CMS proposes to expand the application of the post-acute care transfer policy to any DRG that meets the following criteria:

* "At least 2,000 discharges to post-acute care;"
* At least 20% of its discharges are to post-acute care;
* At least 10% of its discharges to post-acute care occur before the geometric mean length of stay for the DRG;
* A geometric mean length of stay of at least three 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.

Attachment to #718

Mission Hospitals will continue to object to an expansion of the post-acute care transfer policy, which is not in the best interest of patients or caregivers, for the following reasons:

1. The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals lose if a patient is discharged prior to the mean length of stay, and they lose if patients are discharged after the mean length of stay. This is particularly problematic given that more than 50 percent of hospitals are already losing money treating Medicare inpatients and overall Medicare margins have been dropping every year since 1997 to an estimated negative 1.9 percent.

2. The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the appropriate care at the appropriate time. This proposed expansion disadvantages hospitals that make sound clinical judgements about the best setting of care for patients - and this setting is often outside of the hospital's four walls. Hospitals should not be penalized for greater than average efficiency. Particularly, facilities are disproportionately penalized in regions of the country where managed care has yielded lower lengths of hospital stay for all patients.

3. The post-acute transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and costs of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by the AHA and others show that the majority of patients who use post-acute care have longer - not shorter - hospital stays than patients that don't use post-acute care, demonstrating that these patients are truly 'sicker' and in need of additional care. In FY 2004, for instance, patients that were not transferred to post-acute care had an average length of stay of 4.93 days, while those who did receive post-acute care had an average length of stay of 7.51 days. If the agency is concerned about premature discharges, then we recommend it focus on improving the quality review process rather than further expansion of the transfer provision.

4. Section 1886(d)(4)(J) of the Social Security Act directs CMS to focus on those DRGs that have a high volume of discharges to post-acute care and a disporportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have disproportionate use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to a post-acute care in FY2004. Clearly 88 percent of DRGs with any post-acute care use cannot have disproportionate use. Furthermore, CMS is also capturing DRGs that are not at all high-volume. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2070 discharges to post-acute care as compared to DRG 544 (major joint replacement or reattachment of the lower extremity) which has 349,085 discharges to post-acute care. It cannot be argued that while DRG 473 does not have a high-volume of discharges to post-acute care, it still has disproportionate use. Only 22.7

percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. CMS proposed criteria cast far too wide of a net and captures far more DRGs than appropriate.

We at Mission Hospitals respectfully request that these comments be considered in your final determination of whether to expand the existing post-acute care transfer provision. As stated earlier, this expansion of the post-acute care transfer policy is not in the best interest of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting.

Sincerely,

Joseph D. Damore
President and CEO
Mission Hospitals, Asheville NC

546

Submitter : Mr. Allen Miller
Organization : jewish hospital
Category : Hospital

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-526-Attach-1.TXT

WI | GeN
PBE

Hefter
Hartstein
Miller
Kenly
Morey
Smith

Attachment to #526

Wage Data – Provider Based Clinics

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment to #526

In summary, "Hospital-owned provider-based physician practices" referred to as Provider Based C linics in t he F Y2006 p roposed r ule s hould b e de signated a s IPPS " Excluded Areas" for purposes of IPPS wage index, because these hospital entities are not "departments of the provider", they are strictly outpatient services providers unrelated to the inpatient services of the main hospital, and they are not reimbursed under IPPS. (All similar reasons for the exclusion from wage index of RHCs and FQHCs)

547

Braxton, Shawn L. (CMS)

Q DATA

Heffler
Hartstein
Bodden
Hammel

From: BODDEN, CHERYL L. (CMS)
Sent: Friday, June 03, 2005 11:52 AM
To: Braxton, Shawn L. (CMS)
Cc: Tawnia Olson
Subject: FW: Re: QualityNet Help Desk ticket #0127977 has been assigned to you to resolve.

Attachments: Tawnia Olson.vcf

Tawnia Olson.vcf
(467 B)

Good morning Shawn,

Can you please add the following questions/comments to the list on the proposed rule; please see the below e-mails?

Thanks,

Cheryl

>-----Original Message-----
>From: Tawnia Olson [mailto:TOlson@iaqio.sdps.org]
>Sent: Tuesday, May 31, 2005 3:33 PM
>To: BODDEN, CHERYL L. (CMS); Krushat, William M. (CMS)
>Subject: Fwd: Re: QualityNet Help Desk ticket #0127977 has
>been assigned to you to resolve.
>
>
>Cheryl-
>
>This QIO has tried on several occassions to forward her
>comments to the CMS Federal regulations comments section
>related to the APU 2006 proposed regulations and they won't go
>through. Do you have a way to send these comments to the
>appropriate group?
>
>Thanks,
>
>
>Thanks Tawnia. I have tried again with no luck. It may be best
>if you can forward my questions. Here they are:
>
>1.) How is CMS defining 'publishable' data? Is the validation
>score linked to this definition, for example if a hospital has
>a final validation score of 75%, will this data be considered
>unpublishable?
>
>2.) "Hospitals that fail to receive the required 80%
>reliability after the standard appeals process may ask that
>CMS accept the 4Q2004 validation results as a final attempt to
>present evidence of reliability...hospitals will need to
>submit the charts requested for reabstraction as soon as
>possible but no later than August 1, 2005" . This statement
>doesn't make any sense. If the 4Q2004 validation requests are
>expected to be sent to hospitals around the first week of June
>(~2 wks after data submission deadline), then hospitals only
>have 30 days to get the records in (~first week in July).
>Isn't August 1, 2005 too late for 4Q2004?
>
>

>Kristen Boucher, BSN, RN, CMC
>Communications Coordinator
>HealthInsight
>kboucher@nvqio.sdps.org
>(702) 933-7314
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>
>
>
>Tawnia Olson, R.N.
>Hospital Reporting Program QIOSC Coordinator
>Iowa Foundation for Medical Care
>515-273-8875
>
>
>
>>>> Kristen Boucher 05/31/05 1:46 PM >>>
>Hi Tawnia,
>I have attempted to submit my comments but the site won't
>accept them for some reason. I will try again.
>
>Thanks,
>Kristen
>
>>>> Tawnia Olson 05/31/05 11:34 AM >>>
>Hello Kristen,
>
>The CMS web site is:http://www.cms.hhs.gov/regulations/
>
>Thanks,
>
>HRPQIOSC
>>>> Kristen Boucher 05/31/05 1:29 PM >>>
>Tawnia,
>Thanks for the response. I apologize for keeping this ticket
>open. I plan to submit the questions to CMS for comment. What
>is the link for that?
>
>Go ahead and close the ticket.
>
>Thank you,
>
>Kristen Boucher, BSN, RN, CMC
>Communications Coordinator
>HealthInsight
>kboucher@nvqio.sdps.org
>(702) 933-7314
>
>
>
>Tawnia Olson, R.N.
>Hospital Reporting Program QIOSC Coordinator
>Iowa Foundation for Medical Care
>515-273-8875
>
>
>
>>>> Qnetsupport Help 05/16/05 8:39 AM >>>
>
>
>QualityNet Help Desk
>Phone: 866-288-8912
>Fax: 888-329-7377
>Email: qnetsupport@ifmc.sdps.org
>

>>>> Tawnia Olson 05/16/05 10:09 AM >>>
>Kristen,
>
>We have summited both of these questions to CMS and we do not
>have complete answers to these yet.
>
>Answer to question 1: Based on discussion with CMS, the
>publishable data is not linked to validation.
>Question 2. "... hospitals will need to submit the charts
>requested for reabstraction as soon as possible but no later
>than August 1, 2005", we also have these same questions.
>
>As before we suggest that you forward your comments to CMS un
>the comments section of the federal register. We will be
>talking to CMS soon to get these questions addressed.
>
>Thanks,
>
>HRPQIOSC
>
>
>Issue Desc: >>> Kristen Boucher 05/11/05 12:46 PM >>>
>I have a couple of questions for the 2b QIOSC (if there is an
>answer) based on the proposed regulations in the May 6 Federal
>Register:
>
>1.) How is CMS defining 'publishable' data? Is the validation
>score linked to this definition, for example if a hospital has
>a final validation score of 75%, will this data be considered
>unpublishable?
>
>2.) "Hospitals that fail to receive the required 80%
>reliability after the standard appeals process may ask that
>CMS accept the 4Q2004 validation results as a final attempt to
>present evidence of reliability...hospitals will need to
>submit the charts requested for reabstraction as soon as
>possible but no later than August 1, 2005" . This statement
>doesn't make any sense to me. If the 4Q2004 validation
>requests are expected to be sent to hospitals around the first
>week of June (~2 wks after data submission deadline), then
>hospitals only have 30 days to get the records in (~first week
>in July). Isn't August 1, 2005 too late for 4Q2004?
>
>Thank you,
>
>Kristen Boucher, BSN, RN, CMC
>Communications Coordinator
>HealthInsight
>kboucher@nvqio.sdps.org
>(702) 933-7314
>
>
>QualityNet Help Desk
>Phone: #866-288-8912 (local #515-226-7381)
>Email: qnetsupport@ifmc.sdps.org
>
>Tawnia Olson, R.N.
>Hospital Reporting Program QIOSC Coordinator
>Iowa Foundation for Medical Care
>515-273-8875
>
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>
>----------
>Email messages cannot be guaranteed to be secure or error-free as

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>

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BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

225 North Michigan Avenue
Chicago, Illinois 60601-7680
312.297.6000
Fax 312.297.6609
www.BCBS.com

June 21, 2005

Mr. James Wickliffe
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Office of Strategic Operations and Regulatory Affairs
Security and Standards Group
Office of Regulations Development and Issuances
Room C4-24-02
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2006 Rates; Proposed Rule

Dear Mr. Wickliffe:

We have the following comments on the proposed rule for changes to the hospital IPPS for fiscal year 2006, published in the May 4, 2005, Federal Register.

WAGE DATA

Worksheet S-3 Wage Data for the Proposed FY 2006 Wage Index Update - Page 23371

Beginning with the FY 2007 wage index, hospitals and fiscal intermediaries must ensure that pension, post-retirement health benefits, and other deferred compensation plan costs are reported according Medicare instructions. CMS cited the Provider Reimbursement Manual, Part 1 (PRM-1), Sections 2140, 2141, and 2142, and "related Medicare program instructions for developing pension and other deferred compensation plans." However, CMS was not specific in terms of what the other "related Medicare program instructions for developing pension and other deferred compensation plans" are. We recommend that the final rule include a description of the specific treatment CMS requires for these costs if it differs from the instructions at PRM-1, Sections 2140, 2141, and 2142.

INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT

Section 1886(d)(8)(E) - Teaching Hospitals that Withdraw Rural Reclassification - Page 23433

CMS proposes that, effective with discharges occurring on or after Oct. 1, 2005, hospitals that rescind their rural reclassifications and return to urban status would not be eligible for permanent increases of 130 percent under their IME caps. Any adjustments the provider received to its IME full-time equivalent (FTE) cap would be rescinded. An urban hospital that has been reclassified for graduate medical education (GME) and IME purposes would be eligible to get an add-on to the IME FTE cap for new programs. We request that you clarify whether a provider's IME new program add-on would be rescinded if an urban hospital had been reclassified to rural status.

DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT DATA

General Comment

CMS indicated that beginning with cost reporting periods that include Dec. 8, 2004, MedPAR LDS data will be furnished to a hospital at its request, regardless whether there is a pending appeal. The hospital can then use this data to calculate and verify its Medicare fraction and decide whether it prefers to have the fraction determined on the basis of its fiscal year rather than on a federal fiscal year.

We recommend that CMS establish a time frame to supply this data once it is requested by a hospital. We also recommend that CMS establish a procedure that the provider's request go through the intermediary.

Please clarify the procedures in the situation where a provider selects its fiscal year end. It is our understanding that under 42 CFR 412.106(b)(3), the hospital must request a recalculation, the intermediary will be informed of the updated SSI percentage, and the hospital must accept the result.

Disproportionate Share Hospital (DSH) Adjustment Data - Page 23434

In the Aug. 4, 2004, IPPS final rule on page 49096 of the Federal Register, CMS addressed the treatment of observation bed days in the context of DSH. CMS indicated that observation bed days are to be excluded from the counts of both available bed days and patient days unless the patient who receives outpatient observation services is ultimately admitted for acute inpatient care.

Reimbursement for GME takes into consideration Medicare utilization, which is computed by comparing total inpatient days to Medicare inpatient days. Total days now include observation days. We recommend that the Medicare days be increased as well to reflect this change.

In addition, we recommend that, if total Medicare days are increased to reflect this change, the days included in the Supplemental Security Income (SSI) percentage of the DSH computation be counted consistently. That is, if they are included in the denominator, they should also be included in the numerator.

GEOGRAPHIC RECLASSIFICATIONS

Multicampus Hospitals - Page 23436

A multicampus hospital system that seeks a geographic reclassification to another labor market must allocate its wage data among its individual campuses on supplemental Worksheet S-3. CMS indicates that the fiscal intermediary will be responsible for reviewing the allocation on supplemental Worksheet S-3. We recommend that CMS provide guidance on its recommended allocation methodology, particularly the treatment of shared wage costs. In order for the intermediary to determine whether the allocation was made properly, the intermediary will need further guidance.

URBAN HOSPITALS RECLASSIFIED AS RURAL

General Comment

Under the new Core-Based Statistical Area (CBSA) designation, if a provider is redesignated from rural to urban, the provider can appeal to the Medicare Geographic Classification Review Board (MGCRB) to be reclassified as rural. Please clarify whether, as a rural hospital, the provider can:

- Qualify to receive a certified registered nurse anesthetist (CRNA) exception;
- Receive the higher level of Transitional Outpatient Payment System (TOPS) payments under outpatient PPS; and
- Qualify for swing-bed status.

DIRECT GRADUATE MEDICAL EDUCATION (GME)

General Comment

It is clear that for purposes of determining the total number of FTE residents for GME payment, the time residents spend in research as part of an approved program anywhere in the hospital complex may be counted for direct GME payment purposes.

It is becoming more common for hospitals to have separate buildings for research. This creates a problem because the term "hospital complex" is not defined. We recommend that a definition of a "hospital complex" be included in the regulations, or that an explanation be included in the preamble of how to determine whether a building used for research is part of the hospital complex.

Direct GME Initial Residency Period Limitation: Simultaneous Match - Page 23438

CMS proposes to revise 42 CFR 413.79(a)(10) to state that "when a hospital can document that a resident matched in an advanced residency training program beginning in the second residency year prior to commencement of any residency training, the resident's initial residency period will be determined based on the period of board eligibility for the specialty associated with the advanced program, without regard to the fact that the resident had not matched for a clinical base year training program."

What is the effective date of this change in policy, i.e., will it be effective with residents beginning their training on or after July 1, 2006, or for residents already in the program? For the first year of the residency, please clarify which per-resident amount should be used, the primary care or the non-primary care rate. We recommend that the non-primary care rate be used, consistent with the situation in which a resident has matched for the clinical base year program.

We note that on the IRIS diskette, foreign residents are identified by having a Med School number of 9999, in order to distinguish these from the rest of the residents. In order to properly identify residents in their clinical year, we recommend that they be coded with a Med School number of 8888. This will ensure that such residents are easily identifiable and counted for the clinical year. This will also make it easier to identify them as a non-primary care FTE, to be paid at the specialty per-resident amount.

Also, please provide clarification on how the initial residency period should be determined for a resident who, at the end of the clinical base year, decides to change specialties and go into one that doesn't require a clinical base year.

New Teaching Hospitals' Participation in Medicare GME Affiliated Groups - Page 23440

CMS proposes that new urban teaching hospitals that qualify for an adjustment to their FTE caps for a newly approved program under 413.79(e)(1) may enter into a Medicare GME affiliation agreement under certain circumstances. Specifically, such a hospital may enter into a Medicare GME affiliation agreement, but only if the resulting adjustment to its direct GME and IME caps is a "positive adjustment," i.e., there is an increase in the new teaching hospital's caps as a result of the affiliation agreement.

We recommend that this provision be effective for affiliation agreements entered into on or after Oct. 1, 2005, and be noted in the final rule.

GME FTE Cap Adjustment for Rural Hospitals - Page 23441

Hospitals that became urban in FY 2005 due to the new labor market areas would nevertheless be permitted to retain the adjustments they received for new programs as long as they were rural at the time they received them. Once such hospitals receive a designation as urban, they may no longer seek FTE cap adjustments relating to a new training program.

If a new medical residency program was being established, there are three years to determine the new base year FTE cap. Please clarify how the FTE cap would be determined if the hospital enters into an affiliation agreement in the first or second year of the new program.

PROVIDER-BASED ENTITIES

Limits on Scope of the Provider-Based Regulations - Facilities for Which Provider-Based Determinations Will Not Be Made - Page 23444

CMS now includes Rural Health Clinics (RHCs) affiliated with hospitals having 50 or more beds in the list of facilities for which provider-based status does not have to be made, since these facilities are paid on the same basis as non-affiliated RHCs. What is the effective date of this interpretation that such RHCs would not have to have a provider-based determination?

Critical Access Hospitals (CAHs) are not hospitals, and sometimes are not subject to the same requirements as hospitals. Therefore, we request that CMS clarify if an RHC is affiliated with a CAH, whether the RHC would be exempt from the per visit limits.

Technical and Clarifying Changes to 413.65 - Definitions - Page 23445

CMS proposes to revise the definition of "provider-based" to remove the requirement that the provider-based entity be operating under the name of the main provider. This change will simplify compliance with the provider-based criteria since entities that do not now operate under the potential main provider's name will not be obligated to change their names in order to be treated as provider-based. We recommend that the final rule state that this policy is effective for provider-based determinations made as of Oct. 1, 2005.

Technical and Clarifying Changes to 413.65 - Provider-Based Determinations - Page 23445

CMS proposes to revise the regulations to clarify that if a facility is operated as a joint venture or under a management contract, it may qualify for provider-based status only if it is located on the main campus of a main provider. We recommend that the final rule state that this policy is effective for provider-based determinations made as of Oct. 1, 2005.

Obligations of Hospital Outpatient Departments and Hospital-Based Entities - Page 23446

Beneficiaries will be billed for and will be responsible for paying coinsurance amounts for both the facility portion and the physician portion of a facility billing as a provider-based entity. If a facility is determined to have been billing improperly as a provider-based entity, CMS will determine what the facility should have been paid as a free-standing facility and recoup any overpayments. We note that in such an instance, the beneficiary coinsurance billings will be incorrect as well. We recommend that CMS require the provider to correct the beneficiary coinsurance billings as well as payments to the Medicare program if it incorrectly billed as provider-based.

EXCLUDED HOSPITALS AND UNITS

General Comment - Target Rate Exceptions

We would like clarification concerning how to address provider requests for TEFRA target rate exceptions when the costs in question do not exceed 110 percent of the ceiling.

The relief payment provisions changed, effective Oct. 1, 1997, to allow relief payments only if total Medicare inpatient costs exceeded 110 percent of the TEFRA ceiling. CMS made a corresponding change to the exception/adjustment provisions that would allow only costs exceeding 110 percent of the ceiling to qualify for TEFRA exception/adjustment at 42 CFR 413.40(g). CMS's intention was reiterated on page 26347, of the May 12, 1998, Federal Register, in the final rule for Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates, under Bonus and Relief Payments. CMS stated, "Because section 4415 of the BBA does not provide relief for costs that are within 110 percent of the ceiling, we made a corresponding change to the exception payment provision at §413.40(g)(1) so that qualification for the amount of an exception payment does not encompass costs within 110 percent of the ceiling."

While this was present in the Oct. 1, 1997, regulations at 42 CFR 413.40(g), it was absent in the Oct. 1, 1998, regulations. The current regulations at 42 CFR 413.40(g)(1)(iii), state: "When a hospital requests an adjustment, HCFA makes an adjustment only if the hospital's operating costs exceed the rate-of-increase ceiling imposed under this section." We note that there was no specific discussion of this change in any of the Federal Registers in which the proposed and final rules are issued.

Please clarify whether the omission of the 110 percent rule in the 42 CFR 413.40(g)(1)(iii) was an oversight or whether CMS changed its position on determining a provider's exception request.

Payments to Existing Hospitals and Hospital Units - Page 23448

For existing excluded hospitals and units, for cost reporting periods beginning on or after Oct. 1, 1997, through Sept. 30, 2002, the target amount is the lower of either the hospital-specific target amount or the 75th percentile cap. CMS is clarifying that this limitation only applies to the cost reporting periods beginning on or after Oct. 1, 1997, through Sept. 30, 2002. The target amount for FY 2003 is determined by updating the target amount from FY 2002.

While CMS did clarify that the limitation period ended, as of FY 2003, CMS did not clarify which amount to use as a target amount for FY 2003. CMS should clarify that where the target amount was limited to the 75th percentile cap for FY 2002, that amount should be updated for FY 2003, and not to use the hospital-specific target amount that was not limited.

CRITICAL ACCESS HOSPITALS (CAHS)

Cessation of Business at One Location - Page 23452

Under existing policy, if a CAH relocation is considered a cessation of business, this is a basis for voluntary termination of the provider agreement. The CMS Regional Office may assist the provider in obtaining an agreement to participate under a new provider number. Regulations require that the provider give advanced notice to CMS and to the public regarding its intent to stop providing medical services to the community. There is no appeals process for voluntary termination.

The proposed rule indicates that the provider must notify CMS and the public regarding its intent to stop providing medical services to the community. This would occur if the relocation is considered to be a cessation of business, instead of a relocation of an existing provider. We recommend that a provider be required to notify CMS of any new construction or pending relocation, so that CMS can make the determination of whether this constitutes a relocation or cessation of business.

Relocation of a CAH Using a Necessary Provider Designation to Meet the CoP for Distance - Page 23452

Once it has been determined that construction of a new facility would cause the CAH to relocate, it is necessary to determine whether the CAH that has a necessary provider designation can maintain this after relocation. In order to maintain its necessary provider status, a CAH that intends to relocate must demonstrate to CMS that it will be serving at least 75 percent of the same service area as it does prior to relocation. We recommend that CMS indicate how a provider can demonstrate that it will be servicing at least 75 percent of the same service area.

CRNA Services Performed in a Rural Hospital

We request clarification on a concern raised in the comments to the FY 2003 Prospective Payment System Rates, published in the Aug. 1, 2002, Federal Register.

Under 42 CFR 412.113(c), a rural hospital can qualify and be paid on a reasonable cost basis for qualified non-physician anesthetists, or CRNAs, as long as it can establish before January 1 of each year that it did not provide more than 500 surgical procedures requiring anesthesia services.

Under 42 CFR 412.113(c), the regulations define a "surgical procedure requiring anesthesia services" as a surgical procedure in which the anesthesia is administered and monitored by a qualified non-physician anesthetist, a physician other than the primary surgeon, or an intern or resident.

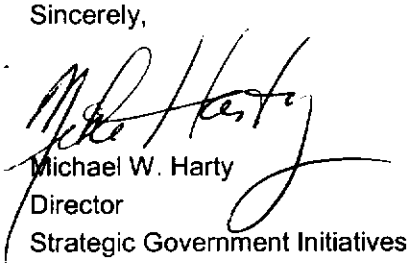
Some of the commenters to the proposed FY 2003 IPPS rates raised a concern about inconsistencies among fiscal intermediaries in terms of counting the surgical procedures. The commenters indicated that some fiscal intermediaries include non-anesthesia ancillary services provided by CRNAs in the count of total surgical procedures, which could make some rural hospitals unable to qualify for the reasonable cost payment. For example, anesthetists may provide therapeutic services for pain management unassociated with a separate surgical procedure, such as the injection of epidural steroids. Although this procedure has a surgical CPT code (CPT 62310), we do not think that it is the type of procedure that should be included in the count of surgical procedures. The procedure does not require a separate surgical physician beyond the individual providing the anesthesia services. Our concern is that some of these procedures that are coded as surgical procedures could be included in the count simply on the basis of the surgical CPT code.

The commenters to the final rule recommended that CMS clarify the types of procedures included in the count with a specific definition of surgical procedures that includes cutting, abrading, suturing and lasering of otherwise physically changing body tissues and organs. We agree with the commenters that a clarification of surgical procedures in relation to this issue would be helpful. In addition, we recommend that procedures that are done by the CRNA alone without an additional procedure performed by a physician (for example, pain management without a surgical procedure) should not be included in the count.

CMS indicated in the final rule for FY 2003 IPPS rates that it agrees that certain steps are needed to improve consistency in counting of surgical procedures. CMS also indicated that it would consider issuing clarifications and instructions on the counting of the surgical procedures to facilitate greater consistency in the manner and criteria used by all intermediaries. Does CMS intend to issue any clarification on the counting of surgical procedures, and if so, what is the status of this?

Thank you for the opportunity to comment on the proposed rule. Please call me at 312.297.5876 if you have any questions on our comments.

Sincerely,



Michael W. Harty
Director
Strategic Government Initiatives

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

Dear Mr. Kuhn,

I am writing on behalf of the American Academy of Neurology in support of the establishment of a new DRG for acute stroke patients treated with reperfusion. The American Academy of Neurology represents the vast majority of Neurologists in the United States. Neurology is the primary medical specialty directing the treatment of stroke patients, who number 750,000 per year in the U.S. Vascular Neurology is the American Board of Medical Specialties (ABMS) accredited subspecialty devoted to stroke care.

The treatment of acute ischemic stroke has undergone a metamorphosis in the past decade. This has been fueled primarily by the finding that early reperfusion treatment of acute stroke patients causes sustained improvement in their functional outcome. However, reperfusion therapy for acute stroke carries with it significant risk that mandates a much more intensive level of patient care. Ultra-fast, but extremely careful patient selection as well as careful patient management post treatment is necessary to minimize serious complications and preserve overall benefit. As a result, appropriate management of acute stroke patients requires significant increases in manpower, neurointensive care or stroke unit services, neuro-imaging tests, pharmacy costs, and is only safe within a finely organized infrastructure. The latter has required considerable strengthening of emergency stroke services throughout the nation.

As the Center for Medicare and Medicaid Services points out in their preliminary ruling, the cost to hospitals of managing acute stroke patients treated with reperfusion therapy is double that of the hospital costs for other stroke patients in DRG 14. The current structure therefore acts as a disincentive for hospitals to organize their emergency services to treat acute stroke patients. We believe that increased cost is one reason for the lower than desired number of patients currently treated with reperfusion therapy. However, we respectfully disagree that the number of patients treated is too small to warrant a change in the DRG structure. Because the thrombolysis code 99.10 was not reimbursable, hospital coders often did not use it. Some hospitals in which reperfusion therapy was commonplace never used this code. The percentage of patients treated with acute reperfusion therapy is therefore grossly underestimated by this method. More direct methods, such as prospective data collection in the Center of Disease Control's Paul Coverdell Stroke Registry indicate that States or cities with an organized system of Stroke Centers have treatment rates as high as 8% of their acute stroke patients.

DIRECT GRADUATE MEDICAL EDUCATION (GME)

General Comment

It is clear that for purposes of determining the total number of FTE residents for GME payment, the time residents spend in research as part of an approved program anywhere in the hospital complex may be counted for direct GME payment purposes.

It is becoming more common for hospitals to have separate buildings for research. This creates a problem because the term "hospital complex" is not defined. We recommend that a definition of a "hospital complex" be included in the regulations, or that an explanation be included in the preamble of how to determine whether a building used for research is part of the hospital complex.

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What is the effective date of this change in policy, i.e., will it be effective with residents beginning their training on or after July 1, 2006, or for residents already in the program? For the first year of the residency, please clarify which per-resident amount should be used, the primary care or the non-primary care rate. We recommend that the non-primary care rate be used, consistent with the situation in which a resident has matched for the clinical base year program.

We note that on the IRIS diskette, foreign residents are identified by having a Med School number of 9999, in order to distinguish these from the rest of the residents. In order to properly identify residents in their clinical year, we recommend that they be coded with a Med School number of 8888. This will ensure that such residents are easily identifiable and counted for the clinical year. This will also make it easier to identify them as a non-primary care FTE, to be paid at the specialty per-resident amount.

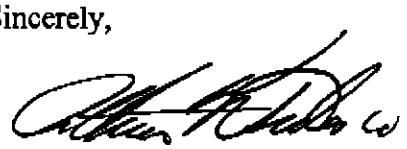
Also, please provide clarification on how the initial residency period should be determined for a resident who, at the end of the clinical base year, decides to change specialties and go into one that doesn't require a clinical base year.

Of particular concern is the proposed expansion of the transfer provision, which is projected to result in a reduction in Medicare funding to Danbury Hospital of $1.7 million in FFY 2006, a reduction this hospital simply cannot afford.

Finally, we ask that CMS consider a minimum guaranteed rate of increase of 2% for hospital providers and a one-time increase of 3.8% to correct for the consistent under-forecasting of the hospital market basket that occurred in seven of the last eight years. Granting such an increase, while not correcting for the past under funding, will offer great relief by bringing the current rates to their proper level. Setting a minimum increase of 2% will prevent what happened last year when 48 hospitals in the country were paid less in 2005 than in 2004; 14 of the 48 were in Connecticut. If the various proposed changes go into effect for FFY 2006, nine hospitals in Connecticut will receive less in 2006 than they received in 2005. We believe CMS should develop and implement a minimum increase for hospitals similar to that developed for Health Plans (i.e., 2% minimum annual increase).

We appreciate you consideration of these comments.

Sincerely,



Arthur N. Tedesco
Senior Vice-President and Treasurer

ANT:kmb
By mail and e-mail, June 24, 2005

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

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

Sincerely,

Gary R Goodman, MD

Gary Goodman, MD
Associate Chair General Surgery, Medical Staff
Providence Hospital
16001 West Nine Mile Road
Southfield, MI 48075

550

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June 24, 2005

Geo Reclass
Hosp Redes

Hefler
Hartstein
Kelly
Jones

Via E-mail: Http://www.cms.hhs.gov/regulations/ecomments

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services

Re: Comments to Inpatient May 4, 2005 Proposed Rule

We are pleased that CMS is proposing to allow counties that are included in a Combined Statistical Area (CSA) to reclassify to a contiguous metropolitan division of the CSA using the 2000 standards.

We believe that this is appropriate public policy and acknowledges the realities of areas such as Ventura County, that are just outside major areas such as Los Angeles and must meet the competitive salary scales in order to attract and retain competent professionals to provide needed hospital services in areas just outside these major metropolitan areas throughout the United States.

Presently, hospitals in Ventura County are potentially eligible for urban county group reclassification. Under current regulations, for all hospitals in an urban county to be reclassified as a group, all hospitals in the county are required to apply for reclassification. One hospital in this county is currently reclassified under section 508 and is receiving its own wage index, a wage index higher than that available under group reclassification criteria. In order for the group to be considered for reclassification, the Medicare Geographic Classification Review Board requires a section 508 hospital to terminate its existing reclassification in order for the group to reclassify. Under section 508 qualifying hospitals are reclassified for the three-year period beginning April 1, 2004 and ending March 31, 2007.

It is unfair to require the Section 508 hospital to terminate the existing reclassification. Section 508 is not budget neutral, and there is a statutory additional $900 million budget. If hospitals withdraw it could reduce payments too less than what Congress intended. We recommend that CMS implement an exception to the existing regulations that would allow hospitals that file an urban county group reclassification request and are determined to meet all applicable reclassification requirements to be reclassified, even if one or more hospitals that are in the group are reclassified under Section 508. The exception would allow the group to be reclassified and would allow the Section 508 hospitals to retain their reclassification until it expires (presently March 31, 2007). Effective upon expiration, the former section 508 hospital would then become a part of the existing group reclassification. The exception would be applicable in the limited circumstances involving urban county groups with one or more section 508 hospitals in the county. We believe Congress did not intend to prevent group reclassifications simply because one or more hospitals in the county were granted a 508 reclassification.

Should you have any questions regarding the above comments please do not hesitate to contact us at 805.955.6202

Sincerely,

C. Larry Pugh
Vice President, Finance

Danbury Hospital

551-0

(3)

June 24, 2005

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

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

Dear Sir or Madam:

Danbury Hospital appreciates the opportunity to provide these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates [CMS-1500-P].

Hospital Redesignations and Reclassifications (Pages 23376-23377)

Under Section 1886(d)(8)(E) of the Act, an urban hospital can apply for redesignation as a rural hospital. Under the proposed rule, the "hold harmless" provisions that occur under section 1886(d)(8)(B) and section 1886(d)(10) when a hospital is granted reclassification, will now be applied when hospitals are approved for redesignation. Danbury Hospital supports this appropriate extension of the "hold harmless" protection, which is particularly important to many Connecticut hospitals. Danbury Hospital thanks CMS for addressing this issue in the proposed rule.

Other Provisions

There are several provisions of the proposed rule that remain harmful to many Connecticut hospitals. Danbury Hospital opposes the following provisions:

- Moving to wage indices based on 100% of the new CBSAs, rather than retaining the 50% blend;
- Reductions to the labor share;
- Expansion of the transfer policy; and
- Reductions to indirect medical education (IME).

Of particular concern is the proposed expansion of the transfer provision, which is projected to result in a reduction in Medicare funding to Danbury Hospital of $1.7 million in FFY 2006, a reduction this hospital simply cannot afford.

Finally, we ask that CMS consider a minimum guaranteed rate of increase of 2% for hospital providers and a one-time increase of 3.8% to correct for the consistent under-forecasting of the hospital market basket that occurred in seven of the last eight years. Granting such an increase, while not correcting for the past under funding, will offer great relief by bringing the current rates to their proper level. Setting a minimum increase of 2% will prevent what happened last year when 48 hospitals in the country were paid less in 2005 than in 2004; 14 of the 48 were in Connecticut. If the various proposed changes go into effect for FFY 2006, nine hospitals in Connecticut will receive less in 2006 than they received in 2005. We believe CMS should develop and implement a minimum increase for hospitals similar to that developed for Health Plans (i.e., 2% minimum annual increase).

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Sincerely,

Arthur N. Tedesco
Senior Vice-President and Treasurer

ANT:kmb
By mail and e-mail, June 24, 2005

Danbury Hospital

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Hosp. Redes.
Geo. Reclass.
CBSA SENT VIA E-MAIL ON JUNE 24, 2005
Labor Share C/N
Transfer
IME
WI/Bdl

HCFHC
Hartstein
Kenny
Jones
Walz
Hart
Miller
Truins
Whitesite
Ruiz

Knight
Kraemer
Seifert
Treitel

June 24, 2005

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

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

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- Expansion of the transfer policy; and
- Reductions to indirect medical education (IME).

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Hartstein
Kenly
Jones
Miller

June 21, 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:

Chilton Memorial Hospital (Chilton) 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).

We pride ourselves on delivering high quality patient care at a reasonable cost. Ensuring an appropriate level of reimbursement from the Medicare program is essential in achieving this objective. Accordingly, please accept the following comments/questions that 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? Chilton 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":** The legislation under section 508 from the Medicare Modernization Act. CMS should continue the legislation **but** require all potential qualifying hospitals as well as those currently reclassed to file an application. This is similar to the traditional reclass requirements of individual and county applications. The 508 should also be continued as this will prevent large shifts in commuting patterns that will create great losses for hospitals.

- **"Hospital Reclassifications":** Chilton 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.

Chilton Memorial Hospital thanks you for the opportunity to submit these comments. Please note that I can be reached directly at (973) 831 – 5202.

Sincerely,

Michael Richetti
Vice President and Chief Financial Officer

(DOHHS-McClellan-6-21-05)

553

1500-P
CMS-~~1290-P~~-12

Trans
DR&I Gen.

Submitter : Mrs. Cecilia Sotomayor **Date:** 06/24/2005

Organization : Harris County Hospital District

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

Undue hardship to hospital industry and its revenue of the Post Acute Transfer Policy limitations. HHC and other type of facility disposition status codes should not be included in this policy due to arguments presented in enclosed letter. Also variations between transferring hospital and receiving facility level of cares should not require recoupments since receiving facility may reassess patient needs and change the level planned.

CMS-~~1290-P~~-12-Attach-1.DOC
1500-P

Hefter
Waxstein
Brook
Fagan
Grover
Kelly
Hue
Walz
Hart

1504 Taub Loop, Houston, TX 77030
(787) 873-2345 Ben Taub General Hospital
(787) 566-5351 LBJ Hospital
Fax (787) 783-2328
Cecilia_Sotomayor@hchd.tmc.edu

Harris County Hospital District

June24, 2005

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

Dear Sirs/Madams:

After reading the proposed changes to the inpatient PPS system, I have a few comments regarding the post acute transfer policy.

Although the publication discusses the decrease of GLOS over 7% and equal or over 14,000 cases/year, in addition to volume and LOS considerations for the expansion from 29 to 223 DRGs included in this policy, the data presented did not reflect specificity as to types of transfers, or documentation issues, and the realities of the discharge planning process.

Transfers to another acute care facility, hospice facility, home hospice, SNF. ICF, LTAC, other Rehab are significant disposition status codes. Transfer to a HHC does not have the same implications for continuation of care than those ones, and should not affect the hospital reimbursement on an inpatient episode that met full inpatient criteria. After discharge planning intervention and family interviews, an attending physician might not deem necessary to refer the patient for HHC. Once discharged some HHC agencies procure discharged patients and "sell" the concept to the patients or relatives directly and the patient obtains a referral for this service from another physician, resulting in initiation of those services within the 3 days post discharge. The same results can happen when the patient, or relatives realize that they can not cope with the circumstances and seek such services. The medical record does not provide any documentation of such coordination and not even an intention of it. This is out of the control of the nursing, clerical, discharge planning, or HIM hospital staff. Recoupments of the charges on these accounts, processing revisions to the disposition status code based solely on the fiscal intermediary claim information, and rebilling these accounts constitute an undue hardship for the hospital industry and its revenue management. I request that this type of disposition status code should not be included in the post acute transfer policy. Transfers to other types of institutions should also follow this same exception (shelter, personal care home, drug abuse program).

In cases in which the physician refers the case for discharge planning or case management and a transfer is coordinated with another institution for SNF, LTAC, Rehab, or ICF, the original plans might suffer changes once the patient is on board at the receiving facility, altering the level of care given and hence their claim. The receiving facility does not communicate to the transferring hospital staff the changes made. It is common to transfer a Medicare patient for a nursing home (ICF) level of care, but the receiving facility reassesses the patient needs and changes services to a SNF level of care. The variations between the hospital claim stating one of these disposition status codes and the

receiving facility should not require a recoupment/rebilling process, as long as one of them is indicated in the hospital claim, and as long as that disposition status code does not reflect other status codes such as home, home hospice, or other type of institution.

These changes would allow for addressing the real issue of negligence/fraud in underreporting transfer status codes that affect the DRG vs. per diem reimbursement process that this policy intends to address.

Your consideration to this request will be deeply appreciated by the hospital industry and its staff that works hard in correcting these issues.

Sincerely,

Cecilia Sotomayor, RHIA, CCS
Reimbursement Coordinator

554

IMPACT

CMS-1500-P-465

Submitter : Mr. Ken Trester **Date:** 06/21/2005

Organization : Oakwood Healthcare Inc.

Category : Hospital

Heflen
Haelstein
Kraemer

Issue Areas/Comments

GENERAL

GENERAL

This proposed rule change would add to the significant adverse reimbursement actions that are threatening the viablity of hospitals which bear the brunt of caring for the uninsured and underinsured.

555

Submitter : Mr. John Gaspelin

Date: 06/21/2005

Organization : Orlando Regional Healthcare

Category : Hospital

Issue Areas/Comments

Issue

Provisions of the Proposed Rule

Post Acute Transfer Policy

Proposed FY 2006 Federal Prospective Payment Rates

Outlier Payment Threshold

CMS-1290-P-11-Attach-1.DOC

Transfers
Outliers

Hartstein
Heffer
Tricel
Walz
Hart

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

Dear Sirs:

Post Acute Transfers

In the 2006 IPPS proposed rule the list of DRG's which the Post Acute Transfer policy will be applied to is expanding from 30 DRG's to 223 DRG's. We feel this change is inappropriate. Our facilities treat patients until they meet the criteria for discharge to another level of care or to home. Changing the Post Acute transfer policy penalizes hospitals for efficient care of patients. The DRG system established a fixed payment per DRG and was designed to reward hospitals for the efficient care of patients. The transfer payment methodology was put in to discourage the gaming of the system by transferring to another Acute Care hospital. This change takes away the incentives for efficient care. We feel the adjustment to the case weights per DRG take Post Acute Transfers into account due to the lower charges on those accounts. We do not feel it is necessary to expand the Post Acute Transfer policy.

Outlier Payment Threshold

Outliers for FYE 2005 are estimated to be at 4.4 % of the total PPS payments. These are funded through a 5.1% reduction in Total DRG payments. Also in 2004 outlier payments only represented 3.5 % of Total DRG payments. Outlier payments have been under-funded in the past two years, therefore we feel it is unnecessary for CMS to raise the threshold from 25,800 to 26,675. We feel it is more appropriate to leave it at the 25,800 level for FYE 2006 to achieve the 5.1% of total DRG payments.

If you have any questions on these comments please contact me at (407)237-6308.

Sincerely,

John Gaspelin
Director of Finance
Orlando Regional Healthcare