

CMS-1533-P-323

**Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter :

Date & Time: 06/11/2007

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1533-P-323-Attach-1.DOC

1987 at the beginning of the IPPS and showed only a 0.8 percent growth in case mix due to coding.

CHA believes that the examples CMS used to justify the coding adjustment are flawed. In the rule, CMS used the experience of Maryland hospitals moving to 3M's All-Patient Refined DRGs (APR-DRGs) as a basis for the behavioral offset. However, MS-DRGs and APR-DRGs are two completely different ways to classify patients, and generalizing from one system to the other is inappropriate.

CMS also drew on the example of the inpatient rehabilitation facility (IRF) PPS to justify the coding adjustment. This is also an inappropriate comparison. The coding changes seen under the IRF PPS were the result of moving from a cost-based system to a PPS, not the marginal difference of moving from the existing CMS-DRGs to the refined MS-DRGs. In addition, coding under the IRF PPS is driven by the IRF Patient Assessment Instrument (IRF-PAI). This provides an incentive for IRFs to code in a way that differs from the IPPS, which does not utilize a patient assessment instrument.

CHA believes that most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding complications or comorbidities (CCs) at high rates for many years. More than 70 percent of claims already include CCs, and more than 50 percent of claims have at least eight secondary diagnoses (the maximum number accepted in Medicare's DRG GROUPER). In addition, it must be recognized that many cases simply do not have additional CCs to be coded. For many claims, additional codes are simply not warranted and not supported by the medical record. Therefore, there is no opportunity for a coding change to increase payment, contrary to what CMS believes.

According to an article in the *Healthcare Financial Management* magazine, the level of coding on claims suggests that the presence of a CC on a bill is not strongly influenced by financial gain. The proportion of surgical cases with a CC code is higher for cases where there is no CC split than on cases where there is a CC split and a corresponding higher payment. Thus, coding is driven primarily by coding guidelines and what is in the medical record rather than by financial incentives.

CHA is also aware of an analysis of the all-payer health care claims databases from California, Connecticut, Florida and Michigan. Unlike the Medicare Provider and Review (MedPAR) files, these databases include all 25 diagnoses reported on the claims. This analysis showed that for California hospitals only 0.20 percent of claims had major complications or comorbidities (MCCs) appear for the first time in positions 10 through 25. Similarly, only 0.30 percent of claims had a CC appear for the first time in positions 10 through 25. This strongly suggests that hospitals will not be able to "re-order" their secondary diagnoses to appear higher on the claim so that CMS will pick them up and pay them a higher rate. Coding experts note that most hospitals use software that automatically re-sorts the secondary diagnoses to ensure that those pertinent to payment are included in positions two through nine.

For these reasons, CHA strongly believes that CMS should not implement a "behavioral offset" at this time. Once the MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment at this time, and should not do so without an understanding of whether there will even be coding changes in the first few years of the refined system. CMS can always correct for additional payments made as a result of coding changes in a later year when there is sufficient evidence and an understanding of the magnitude.

Severity of Illness DRGs

CMS is proposing to implement the MS-DRG using 745 MS-DRGs to replace the current 538 CMS DRGs. In addition, CMS has undertaken an overhaul of today's CC list and created up to three tiers of payment for each DRG based on the presence of a MCC, a CC or no CC.

CMS notes that the MS-DRG proposal addresses concerns and issues raised about the DRG proposal in the 2007 proposed rule. Last year, commenters pointed out that the FY 2007 proposal did not retain the improvements that had been made to the base DRGs over time that recognized advancements in medical technology and practices. Objections were also raised regarding the use of a proprietary classification system not residing in the public domain. CMS was urged to develop a severity-adjusted DRG system within the current DRGs.

CHA supports efforts by CMS to respond to the comments raised during last year's PPS comment period, and supports meaningful improvements to Medicare's IPPS. MS-DRGs represent a reasonable approach to DRG refinement. Although CHA agrees that CMS should move forward with this new approach/system, we have concerns over the potential impact on individual hospital's reimbursement levels, both in the positive and the negative. CHA believes that it would be prudent to provide sufficient time for hospitals to adapt to these changes through a transition period so they are adequately prepared for this significant change. CHA suggests that CMS consider the adoption the MS-DRGs over a four-year transition period, since the implementation of the more extensive classification system, though budget neutral, will redistribute significant dollars among hospitals. In addition, CHA would suggest that this major change in reimbursement could have severe implications and encourages CMS to consider alternative reimbursement strategies to mitigate the dramatic financial impact to rural hospitals in California.

The proposed rule also includes a discussion of the RAND Corporation's interim report on its evaluation of five alternative systems, and invites comments on the preliminary analysis. Although RAND's final report is not expected until September, CMS is still proposing to implement the MS-DRG system beginning October 1, 2007. In the proposed rule CMS indicates its belief that it is premature to propose adopting one of the systems because RAND has not completed its evaluation. CMS states that "Although we are proposing to adopt the MS-DRGs for FY 2008, this decision would not preclude us from adopting any of the systems being evaluated by RAND for FY 2009." CHA is concerned that if another significant change in the DRG payment system were to occur this quickly such variations in payment methodologies could have severe impacts on some hospitals' financial viability. Therefore, CHA suggests that a four-year transition period should be undertaken in a manner that delays implementation in the 2008 fiscal year, followed by a one-third, per-year transition period. This would then provide adequate time

to consider the results of the RAND study without having to completely revise the new MS-DRG system.

Transition From Charge-Based Weights to Cost-Based Weights

CHA recommends that the second year transition from charge-based weights to cost-based weights be delayed until further analysis can be performed to identify and address the data problems associated with this change in methodology, of which some are identified in the FY 2008 proposed regulations. Although CMS agrees that there appear to be potential problems as identified by their contractor RTI, no delay in the transition is being proposed while further analysis is performed to determine the extent of the problem and potential best solutions due to "time available for the development of the proposed rule." CHA believes that a delay in further transition is warranted to prevent inappropriate reduced payments to any hospitals that are unfairly underpaid due to problems, as yet unaddressed, identified in the proposed regulation.

CMS modified the prior system that relied solely upon hospital charge data, and developed an approach that would establish the weights based upon hospital "cost" data. CMS suggested that this type of revision would lead to the creation of DRG weights that more accurately reflect the relative resource use by DRG. Recognizing the financial impact of changes to the weights on some hospitals and the possible need for further refinements, the final rule allowed for a three-year transition using a blend of the "charge-based" system and the "cost-based" system. During the first year of transition, two significant problems have been identified that lead CHA to question the accuracy of the cost-based approach in relationship to the prior charge-based approach.

Mark-up rates by hospitals continue to increase, causing hospitals with higher mark-up rates to have greater influence and resulting in DRG weights with higher ancillary services to be overstated, as discussed in the proposed regulations. This resulting "charge compression" should continue to be evaluated in terms of how much distortion is being caused by combining services with different mark-up rates into one cost center? In effect, high-cost services with lower mark-ups will be undervalued, and vice-versa.

There is a mismatch between the two data sources used in establishing the cost-based weights. These differing data sources, specifically the MedPAR charges and cost report cost to charge ratios, can distort the resulting DRG weights. It is important to note that the cost report was not designed to support the estimation of costs at the DRG level.

Following are CHA's comments in response to the questions posed by CMS in the FY 2008 proposed regulations.

Suggestion to Expand From 13 CCRs to 19 CCRs and Apply a Regression Analysis Approach Where Necessary

Although CHA is concerned that the transition from charge-based weights to cost-based weights does cause a distortion with certain cost centers, especially in the supply related cost centers, it is uncertain whether the recommendations from RTI to expand certain cost categories through a regression analysis is the appropriate solution. CHA would support the expansion of cost cate-

gories using the cost centers that already exist on the cost report, which include the emergency department and blood cost center. In addition, CHA would support the further examination of cost report modifications, as discussed below, as a better approach to capturing the necessary data to allow for improved accuracy when using cost-based weights.

If the goal of converting to a DRG cost-based system is to achieve a DRG weighting system that better reflects resource use by DRG, and therefore, a more accurate system, then it would also be important that appropriate and accurate data be used in the cost-based weight system. CHA is concerned that for the sake of expediency, the use of estimates (a regression analysis approach) as opposed to efforts to collect accurate data at the appropriate cost center level would fail the objective. In addition, CHA is concerned that the use of a regression model may be difficult to validate as the DRG weights are modified on an annual basis.

Address the Mis-Matching of Data Sources Through Increased Cost Report Audit Guidelines, Cost Report Instruction Revisions, Long-Term Cost Report Revisions and Expanded MedPAR Fields

In order to make a recommendation that addresses the problems associated with the use of two different data sources in establishing the cost-based weights, it is necessary to first identify the reasons the problems occur. There are at least two reasons that there is not uniformity in how the data is being reported.

The method used by CMS to group hospital claims for the MedPAR files is different than how hospitals group Medicare charges, total charges and overall costs on the cost report. Hospitals group their Medicare charges, total charges and overall costs in different departments on their cost reports for various reasons that are not inconsistent with the cost reporting instructions.

RTI's recommendation to incorporate edits to reject or require more intensive review by the auditors is not a viable solution if the lack of uniformity in cost reporting is not inconsistent with cost reporting instructions. Currently, cost report instructions included with the CMS Form-339 allow for three methods of reporting Medicare charges. The method selected by each hospital is specific to its information systems and based on the method that most accurately aligns Medicare program charges on Cost Report Worksheet D-4 (Inpatient) and/or Worksheet D, Part IV (outpatient) with the overall cost and charges reported on Worksheets A and C. Many hospitals elect to allocate some or all of the Medicare program charges from the Medicare PS&R to various lines in the cost report based on hospital specific financial system needs. Under this scenario, total hospital cost-to-charge ratios (CCRs) are aligned with program charges, but will not match the charge groupings used in MedPAR. This mismatching may distort the resulting DRG weights under the methodology developed by CMS. Increased edits or cost report rejections would not provide a solution to a problem that is caused by cost report instructions that allow for multiple approaches.

CHA agrees that improvements, both in the short term and long term, to both the cost report instructions and cost reporting forms is worth examining if accurate cost-based weights are to be

used for payment purposes. The instructions and forms should be modified in a manner that all hospitals can prepare their Medicare cost reports so that Medicare charges, total charges and total costs are aligned with each other and with the categories currently utilized in the MedPAR file. This would allow for a consistent grouping of departments within the 13 categories identified in the August 18, 2006, final IPPS rule that are currently used to create the cost-based weights, or if an expansion of categories occurs as well. It must be recognized that the mis-matching problem is not occurring due to the failure of hospitals to prepare their cost reports correctly as appears to be suggested by the RTI study. CMS will need to understand that some hospitals will be better situated than others to adopt certain cost report changes. As a result, it will be more expensive and time-consuming for some hospitals than others to successfully implement a different approach to cost reporting, and therefore, appropriate education, training and timing need to be considered as cost reporting changes are examined.

If CMS believes that the primary function of the cost report should be to support accurate cost-based DRG data, the necessary modifications to the existing cost report instructions to achieve uniformity by all hospitals will achieve this objective. In addition, to address the "cost compression" issue, especially related to the medical supplies department, the addition of the appropriate number of departments on the cost report will achieve that result. However, it is recognized that both these changes will require time to implement, but should be started sooner than later, with the transition delayed until the data is adequate.

Outliers

CHA is aware of a number of different methodologies that could more accurately calculate the outlier threshold, and recommends that CMS consider evaluating and possibly implementing one of these methods to ensure that the outlier payments achieve the 5.1 percent stated goal.

Calculations were done utilizing the same data, parameters and assumptions used by CMS in an attempt to duplicate the calculation done by CMS to estimate the outlier threshold for FY 2008 of \$22,940, revised from the proposed regulations of \$23,015. These calculations indicate that the estimated outlier operating and capital outlier payments would approximate 5.02 percent and 4.98 percent, respectively, and compares reasonably well to the CMS figures of 5.10 percent and 4.87 percent, respectively.

CHA commends CMS for recognizing in FY 2007 that the CCRs should be updated, but believes that it is not appropriate to project all CCRs for a period of one year. CHA believes that for many hospitals the CCRs need to be projected over differing periods of time, either more or less than one year, depending on the hospitals' fiscal year. CHA estimates that this would result in a fixed loss amount of \$22,795 for FY 2008.

Another method, which uses an alternative projection factor for the CCRs, results in a fixed loss factor as low as \$21,850. CMS used the CCRs from the Provider Specific File (PSF) updated through December 31, 2006. CMS estimated the rate of change in CCRs by assuming the relationship between actual costs and the hospital market basket stays constant over time. The ratio of the rate of change in the cost per discharge to the rate of change in the market basket was calculated for three different years (2003-2005). The ratios were averaged and the result multiplied

by the rate of change in the 2006 market basket to estimate the 2006 cost inflation. The estimated 2006 cost inflation was divided by the estimated 2006 charge inflation in order to estimate the annual rates of change at -0.88 percent for operating CCRs and -3.60 percent for capital CCRs. It is not clear if the historical record supports the assumption that costs and the market basket maintain a relatively constant relationship over time. In the 2003-2005 three point data set used by CMS, the lowest change in the cost per discharge (5.29 percent) corresponds to the highest change in the market basket (4.3 percent) and the range between the highest and lowest change in the cost per discharge is proportionally much higher than the corresponding market basket range.

An alternative approach to estimating the rate of change in CCRs is to use a recent historical industry-wide average rate of change as the projection factor, which is exactly the approach CMS uses to project charge inflation. The December 31, 2006 update of the PSF shows the effective dates of changes in the file. This allows comparing the CCRs in effect at different points in time. The two most recent points in time separated by a whole year for which sufficient data were available were October 1, 2005 and October 1, 2006. Data were available for 3,443 out of the 3,535 hospitals used for outlier projections. These hospitals account for more than 99 percent of all MEDPAR cases subject to IPPS. The average change in the operating CCRs between October 1, 2005, and October 1, 2006, weighted by the number of Medicare IPPS cases was 0.9792, a decrease of 2.08 percent. For the capital CCRs the average change was 0.9841, or a 1.59 percent decrease. Using these values as annual projection factors instead of the ones used by CMS, but otherwise maintaining the same assumptions and methodology as CMS, the 2008 fixed loss amount is estimated at \$22,160. If the CCR projection methodology is modified as described above to take into account hospitals' fiscal periods, the 2008 fixed loss amount is estimated at \$21,850.

CHA urges CMS to revise the methodology used to more accurately calculate the outliers thresholds and ensure that outlier payments achieve the stated level of 5.10 percent.

Capital

CHA is opposed to unwarranted reductions in capital IPPS payments without the consideration of how these cuts will impact ongoing maintenance and improvement projects that were undertaken with the expectation that Medicare would continue to pay its fair share. CHA also points out that the reduction does not take into account Medicare operating margins that are not at the same levels as the capital margins.

Medicare reimburses the capital-related costs of inpatient hospital services through a separate capital IPPS. These costs include depreciation, interest, taxes, insurance and similar expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (e.g., MRIs and CT scanners). Under the capital IPPS, capital payments are currently adjusted by the same DRGs for each case, as is done under the operating PPS. Capital PPS payments also are adjusted for indirect medical education (IME), and disproportionate-share hospital (DSH) and outlier payments.

CMS performed an analysis examining the relationship between hospitals' IPPS capital payments and Medicare inpatient capital costs using cost report data from FY 1996 through FY 2004. The results of this analysis indicated positive margins on Medicare inpatient capital costs for all hospitals, with larger, urban hospitals generally experiencing higher margins and smaller, rural hospitals experiencing lower margins. The Pacific census division averaged a 12.2 percent return between 1998 and 2002. As a result of this study, CMS is proposing a number of changes to IPPS capital payment rates.

CMS proposes that the update to the capital standard federal rate for urban hospitals for both 2008 and 2009 will be 0.0 percent. Rural hospitals will continue to receive the full update determined under CMS' usual analytical framework, which is currently estimated to be 0.8 percent for 2008. The result is separate capital rates for urban and rural hospitals. In addition, CMS proposes to discontinue the 3.0 percent additional payment that has been provided to hospitals located in large urban areas. Further, CMS is proposing to retain the estimated savings of \$147 million related to elimination of the 3.0 percent add-on rather than increasing the federal payment rate to be budget neutral.

CMS is also considering reducing or discontinuing the existing payment adjustments for teaching hospitals and DSH hospitals.

The significant reduction in capital reimbursement to compensate for capital profit margins does not take into account expected future capital expenditures, especially in California where seismic-safety retrofitting is currently mandated and, according to the RAND seismic study, is anticipated to be as high as \$110 billion, excluding financing costs which could double the impact. It also does not take into account Medicare operating margins that are not at the same levels as the capital margins, and are in fact negative, but are left unaddressed through budget neutrality adjustments. In addition, it must be recognized that the initial funding for the specific add-on for large urban hospitals was created by reducing payments to all other hospitals to maintain budget neutrality. If this add-on is eliminated it should be returned to the other hospitals through increases in payments to retain the concept of budget neutrality.

Finally, CHA is very concerned that CMS is considering the reduction in other add-on payments that are being used to supplement the high costs incurred by teaching hospitals related to the programs that they offer, or DSH hospitals that incur significant losses in treating the uninsured. Such reductions can have far-reaching implications on hospitals' ability to continue funding their teaching programs or meeting the needs of their indigent populations.

Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties for hospitals that have undertaken critical and costly capital projects based upon the Medicare program's commitment to adequately fund these projects. CHA is opposed to these inappropriate and unnecessary reductions that are essential to the ongoing maintenance and improvement of hospitals' facilities and technology. These reductions will especially impact California where hospitals are in the process of costly

retrofitting projects to ensure patient safety and meeting the needs of California Medicare beneficiaries.

Wage Index

Occupational Mix

CMS proposes to use the occupational mix survey data for the six months January 1, 2006, through June 30, 2006, as the basis for calculating the full occupational mix adjustment for the 2008 wage index. CMS said that the "purpose of the adjustment is to control for the effect of hospitals' employment choices on the AWI."

Although CHA understands why CMS has proposed to use the area's average adjustment for non-responsive hospitals and the national average adjustment for non-responsive counties for FY 2008, we are concerned that this could result in penalizing hospitals located in the same areas that do respond. If in fact the non-responding hospitals' data would have resulted in a more favorable occupational mix adjustment factor, then all hospitals in the area, including those that were compliant, will have received an artificially low rate, as their reimbursement dollars are re-distributed elsewhere. Therefore, for FY 2009 and beyond, because data from all hospitals is needed to construct an accurate national average hourly wage to avoid penalizing hospitals that do comply, full participation is critical. We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals. We also encourage CMS to establish an appeals process for hospitals with extenuating circumstances.

Wage Data

CMS expanded its collection of contract labor with cost reporting periods beginning on or after October 1, 2003, to include administrative and general (A&G), housekeeping, dietary, and management and administrative services. The FY 2008 wage index, based on FY 2004 cost report data, marks the first year CMS can determine what the impact would be if it included such costs in the wage index. CMS contends that the data are reasonable and accurate and that the vast majority of hospitals would not be affected by the change. Thus, CMS proposes to include such contract labor costs in the wage index for FY 2008.

However, we believe that the impact is greater than suggested by CMS due to an error in the calculation. We agree that lines 22.01 (Contract A&G Services), 26.01 (Contract Housekeeping Services) and 27.01 (Contract Dietary Services) are and should be included in Step 4. The purpose of Step 4 is to allocate a portion of overhead wages and wage-related costs to the excluded areas, and then to subtract a commensurate amount from wages and wage-related costs included in the wage index. However, while line 9.03 (Contract Management and Administrative) was included in the total wages in Step 2, lines 22.01, 26.01 and 27.01 were not. This results in a double negative effect. First, the contract labor for those three lines was never included. And second, a portion of those same costs are being subtracted from the wages and wage-related costs included in the wage index.

CMS should fix the calculation and then reassess the impact on hospitals.

Wage Index

In FY 2009, CMS is required by law to consider changes to the area wage index. CHA is concerned that the wage index is problematic in its current form and agrees that alternatives should be considered. CHA is also concerned over MedPAC's consideration of the use of Bureau of Labor Statistics (BLS) data rather than the hospital-reported data collected on CMS' Medicare cost reports. Although this approach may be significantly less burdensome for hospitals, it is a significant change. There are critical differences between the two data sets that need to be carefully evaluated before another major revision to the hospital reimbursement system is undertaken.

Rural Floor

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008. CMS indicates that this would result in a uniform reduction that is operationally easier and results in the same wage indices.

CHA supports this move assuming that it removes the compounding affect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998. We believe that it was an unintended error to repeatedly apply the rural floor budget-neutrality adjustment without first reversing the prior year's adjustment as is done with the outlier calculation each year. CHA also suggests that CMS remove the effects of the adjustments made from 1999 through 2006 by increasing the positive budget-neutrality adjustment proposed to the standardized amount intended to just reverse the 2007 adjustment.

Medical Education

CHA opposes the proposed rule regarding removing vacation and sick time from the total time considered to constitute a full-time equivalent (FTE) resident as operationally impracticable and unnecessary. In addition, CHA suggests that the hospital recordkeeping requirements be established well in advance of the implementation of this rule change so that both the hospitals and fiscal intermediaries have a consistent understanding of the required documentation.

The proposed rule would treat vacation and sick time differently than it would treat all other time, creating unnecessary burdens for recording keeping, especially for hospitals that share interns. Although it would be removed from both the numerator and denominator of the FTE calculation, CMS acknowledges that this would result in lower FTE counts for some hospitals and higher counts for other hospitals, solely because of this regulatory change. CHA recommends that CMS continue to count vacation and sick time, and recognize that this time is a basic part of the time interns and residents spend during their training.

In the FY 2007 final rule, CMS finalized a policy to exclude residents' time spent in non-patient care activities from the resident count for purposes of IME (in all settings) and direct graduate medical education (DGME) (in non-hospital settings) payments. Since that time, the agency has received questions about the treatment of vacation or sick leave and orientations. While recognizing that this time is neither devoted to patient care nor non-patient care, but rather a third category, the proposed rule would treat vacation and sick time differently than it would treat ori-

entation time. Orientation time would continue to be included as part of the FTE count, as it always has.

CHA appreciates CMS' efforts to clarify its policies and try not penalizing hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical since it would be necessary for hospitals to not only keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through to fairly calculate the IME and GME reimbursement. We recommend that CMS instead treat sick and vacation leave similarly to how it treats orientation time as part of the FTE count. We do not believe that it is necessary for CMS to track each hour of residents' time. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor overall impact, while having major implications at the individual hospital level.

Hospital-Acquired Conditions

CHA is strongly concerned about the breadth and timing of the proposed implementation of the reporting and coding for hospital-acquired conditions. CHA urges CMS to limit the requirements to no more than three conditions, one more than mandated by the Deficit Reduction Act (DRA), and defer implementation for an additional year to allow for education of physicians and hospital personnel on the documentation and coding requirements necessary to accurately report this information.

DRA requires CMS to identify by October 1, 2007, at least two preventable complications of care that could cause patients to be assigned to a higher DRG. Beginning in FY 2009, the DRA also requires CMS to reduce payment for cases that were assigned to a higher paying DRG in which one of the selected conditions was not present on admission. In addition, DRA also requires that hospitals submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007. Although CMS recently announced that the start date for coding what is present on admission would be delayed until January 1, 2008, due to technical difficulties in software programming to accept the new information, CHA believes that other issues should be considered when implementing these requirements.

CMS provided a list of 13 conditions it has considered, but recommended only six conditions for implementation. The six conditions are:

- Catheter-associated urinary tract infections
- Pressure ulcers
- Object left in during surgery
- Air embolism
- Blood incompatibility
- Staphylococcus aureus septicemia

CHA agrees with CMS that the other seven conditions identified in the proposed rule should not be considered at this time because of difficulties with coding or a lack of consensus on prevention guidelines. CHA believes that this policy could be implemented starting with three of the

conditions — objects left in during surgery, air embolism and blood incompatibility. These conditions are identified by discrete ICD-9 codes and they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. Hospitals in California are committed to patient safety and strive to ensure that these events do not happen.

The other three conditions will rely on correct identification and coding of conditions that are present on admission. CHA believes that implementing a present-on-admission coding indicator will be a major challenge for hospitals. CHA understands that the experiences of two states that already use present-on-admission coding show that it can be done, but that it takes several years and intense educational efforts to achieve reliable data. The two states that have undertaken the use of present-on-admission coding have reported that such educational efforts have taken 24 months or more, making it highly unlikely that CMS' plan to use present-on-admission coding for payment purposes less than a year after initiating the coding, and without any education of clinicians, would lead to the correct identification of the cases envisioned in DRA. For these reasons, CHA urges a delay in implementation to allow all hospitals the time to thoroughly educate physicians and hospital personnel on the need to identify and record present-on-admission conditions.

CHA also encourages CMS to consider the unintended consequences that might arise from implementing the hospital-acquired conditions policy. CHA believes that excessive urinalysis testing for patients entering the hospital may result from hospitals trying to accurately code for urinary tract infections that are present on admission. The necessity to complete diagnostic tests before a patient is admitted to confirm present-on-admission status could lead to delayed admissions for some patients and disrupt efficient patient flow.

CHA also requests clarification from CMS on how hospitals may appeal a decision that a particular patient falls under the hospital-acquired conditions policy and is, therefore, not eligible for a higher DRG payment.

CHA believes this policy could be implemented starting with a small number of conditions because there are significant challenges to correctly identifying cases that meet the criteria laid out by Congress. There are further difficulties ensuring appropriate accuracy in the billing data that will enable the correct identification of the relevant cases. We ask CMS to carefully consider not only the criteria for selection set forth in the DRA, but also the ability of hospitals to accurately identify and code for these conditions. Some of the proposed conditions may not be feasible at this time

Quality Data

CHA notes that CMS proposes to add six additional quality measures in FY 2008 to the existing 21 quality measures required to be reported by hospitals to be eligible for the full market basket increase. In addition, CMS proposes to add five more measures for FY 2009 — four process measures and one outcome measure — bringing the total to 32 quality measures required be included for the annual payment determination. CHA supports improvements in quality through reporting leading to the early detection of trends. However, CHA is also worried about ongoing

When amending measures, CMS and The Joint Commission should take into account the ability of hospitals, the data warehouse and data vendors to successfully and quickly implement changes in reporting measures. CMS should seek input from hospital data collection personnel as a part of the measure review process to understand the effects that reporting changes have on hospitals.

In addition to establishing a process for retiring or replacing measures, CMS should develop a policy for suspending measures when there is a change in science or an implementation issue arises during a reporting period and needs to be addressed immediately. For example, in past years, influenza vaccine shortages have precluded hospitals' ability to perform well on a measure. More recently, the National Quality Forum (NQF) endorsed as a measure the percentage of pneumonia patients receiving initial antibiotics within six hours of arrival at the hospital. This measure replaced a similar one regarding the receipt of antibiotics within four hours of arrival. The four-hour measure is no longer endorsed by NQF due to clinical concerns that, within this shorter time frame, some patients whose pneumonia diagnoses were not yet confirmed were receiving antibiotics unnecessarily. Despite the fact that the four-hour measure is no longer endorsed by NQF, it continues to be included as a measure for Medicare's pay-for-reporting program. We urge CMS to prioritize the development of a policy to address these situations.

Replaced Devices

CHA recommends that CMS reconsider implementing its proposal to reduce the amount of the Medicare IPPS payment in cases where a full or partial credit toward a replacement device is made, or the device is replaced without cost to the hospital or with full credit for the removed device.

In the calendar year 2007 outpatient PPS final rule, CMS adopted a policy that requires a reduced payment to a hospital or ambulatory surgical center when a device is provided to them at no cost. Similarly, in the proposed rule for FY 2008, CMS has stated its belief that payment of the full inpatient PPS DRG in cases in which the device was replaced for free or at a reduced cost effectively results in Medicare payment for a non-covered item. CMS proposes to apply the policy only to DRGs under the IPPS where the implantation of the device determines the base DRG assignment (22 DRGs), and situations where the hospital receives a credit equal to 20 percent or more of the cost of the device.

CMS also proposes to use new condition codes to report the use of such devices to trigger manual bill and payment processing by FIs. The hospital would be required to manually provide paper invoices or other information to the FI (or Medicare Administrative Contractor) indicating the hospital's normal cost of the device and the amount of the credit received. In cases where the device is provided without cost, CMS proposes that the normal cost of the device will be subtracted from the DRG payment. In cases where the hospital receives a full or partial credit, the amount credited will be subtracted from the DRG payment.

CMS justifies this change by noting that "in recent years, there have been several field actions and recalls with regard to failure of implantable cardiac defibrillators and pacemakers." Although CHA does not dispute this fact, we believe it ignores the underlying concept of the DRG payment system.

DRG payments are fundamentally based on averages of historical costs and charges. To reduce the payment for cases involving replacement of a medical device assumes that either these types of cases have not occurred in the past or are occurring at such a dramatic increase as to materially skew the averages used to develop the DRG weights. In fact, CMS notes that "we believe that incidental device failures that are covered by manufacturers' warranties occur routinely." This statement acknowledges that incidental device failure has occurred in the past and was likely covered by the manufacturer warranty. If so, this practice is part of the historical cost and charge data used to develop the current DRG weights for cases involving implantation. Reducing payment for certain cases involving a re-implantation would ignore the average DRG weight for those cases that already implicitly include this reduction.

Given the administrative time, effort and cost of manually processing these claims, CHA believes it is not worth the burden on hospitals and FIs if only a nominal portion of the cost of the device is at issue. In addition, IPPS payments are often less than costs. For these reasons, CHA urges CMS to reconsider implementing its proposal.

However, if CMS implements this policy, CHA recommends that estimated costs should be calculated from the charges on the claims and only reduce the DRG payment by the device cost if the payment is greater than the cost of the case less the cost of the device. CHA does agree that CMS should limit the number of DRGs to which the policy applies. In addition, we agree that insignificant credits or refunds should not trigger this policy. Therefore, CHA recommends that CMS consider raising the proposed threshold from 20 percent to greater than 50 percent or the majority of the cost of the device.

New Technology

CHA is concerned about CMS' ability to implement add-on payments for new services and technologies in the near future, and strongly recommends that the Secretary expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10).

The Department of Health and Human Services (HHS) should take the necessary steps now to avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The current ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10 were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the Medicare Modernization Act of 2003, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential re-

imbursement policies for inpatient services, including new health technology, as required under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.

To date, despite these recommendations, as well as the recommendations of several federal health care agencies and offices and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. Without a switch to ICD-10 in the near future, hospitals will experience significant coding problems that will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this problem will only impede efforts to speed the adoption of electronic health records.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) Committee meeting, many expressed the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g., musculoskeletal system, circulatory system, etc.) were available. The plan was to use codes in chapter 00 first and then begin populating chapter 17.

Category 00 is now full, and the C&M Committee is entertaining proposals for codes in category 17. At the April 2005 C&M Committee meeting, a proposal was presented that would, in effect, leave only 80 codes available in this category. In order to conserve codes, this proposal was rejected and replaced instead with three codes that did not provide information as to what part of the body the surgery was performed on. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in less than a year. CHA concurs with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10, and would support an implementation period of at least two years.

CHA believes it is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames, and urges the rulemaking process be started immediately.

Physician Ownership in Hospitals

CHA supports the implementation of a physician-ownership disclosure requirement that would mandate that all physician-owned hospitals at the beginning of an admission or outpatient visit disclose to patients that physicians have an ownership interest or investment in the hospital and offer to make a list of physician investors available on request. Such hospitals also would have to require, as a condition for medical staff privileges, that physician investors disclose to their patients that they have an ownership interest when they refer patients to the hospital for services

The beginning of an admission or outpatient visit is defined to include pre-admission testing or to require registration. We recommend that the definition be clarified to include scheduling, as well as pre-admission testing and registration. Patients should receive these disclosures at the earliest opportunity so that they have an ability to act on the information if they choose.

CHA recommends that the ownership disclosure requirement be incorporated into provider agreements rather than the conditions of participation since the conditions of participation should be focused on care delivery standards. In addition, CHA recommends that CMS clarify that the list of physician owners be provided to patients at the time the request is made. We believe providers should be able to provide the list immediately upon inquiry, so that patients would get the information in time to consider it.

In the proposed rule, CMS asked whether the definition of a "physician-owned hospital" should exclude physician ownership or investment interests based on the nature of the interest, the relative size of the investment, or the type of investment (e.g., publicly traded securities and mutual funds). CHA recommend that the only exception to the definition of a "physician-owned hospital" be when physician ownership is limited to holding publicly traded securities or mutual funds that satisfy the requirements for the exception under §411.356(a),(b). We oppose any exception based on the size of investment. It is important for patients to know whenever there is a duality of interest on the part of their physician that could cause a conflict of interest in making decisions about their care. The size of that interest is immaterial to the fact that the conflict may exist.

Patient-Safety Measures

CHA is concerned that the proposed rule requirement regarding patient safety is overly broad. The proposed rule would require a written disclosure to patients of how emergencies are handled when the hospital does not have a physician available on the premises 24 hours a day, seven days a week, and would strengthen current requirements for emergency service capabilities in hospitals both with and without emergency departments (EDs), including required staffing competencies, certain equipment availability, and required 24-hour-a-day, seven-day-a-week ED availability.

While these requirements may sound reasonable, we believe they miss the real issue to be addressed: safety concerns in physician-owned specialty hospitals.

CHA believes it makes sense to apply special requirements like these to physician-owned specialty hospitals, but not to full-service community hospitals. The safety concerns that have been raised with physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery in this country. They are freestanding facilities which are generally not part of a larger system of care, most often have no transfer agreements with other hospitals or providers of care in a community, and tend to specialize in one type of care delivery, challenging their ability to treat the unexpected event or emergency.

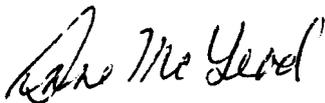
This is not the case with full-service community hospitals, which are part of a network of care in their community involving referrals from local physician practices, reliance on local trauma sup-

port networks, participation in local emergency medical transport systems, and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted and the patient's clinical information collected at one hospital goes with the patient to the next hospital. Small and rural hospitals also are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals.

CHA believes that applying additional requirements for this group of hospitals is unnecessary and costly. The broader network of care delivery, of which full-service community hospitals are a part, is the best way to ensure that care is provided to patients at the right time and in the right setting. The kinds of requirements discussed in the proposed rule can be used to assure that physician-owned facilities, in the absence of being a part of the broader care network, meet minimum standards for patient safety.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions please contact me (916) 552-7536 or amcleod@calhospital.org.

Sincerely,



Anne McLeod
Vice President, Reimbursement
and Economic Analysis

AM/AO: am

**CMS-1533-P-324 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Dr. Luana Locke

Date & Time: 06/11/2007

Organization : APIC Member

Category : Nurse

Issue Areas/Comments

**DRGs: Hospital Acquired
Conditions**

DRGs: Hospital Acquired Conditions

See Attached Letter

CMS-1533-P-324-Attach-1.DOC

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Dear Ms. Norwalk:

Thank you for the opportunity to provide additional input to the CMS proposed IPPS changes.

I serve as a member of the Association for Professionals in Infection Control and Epidemiology (APIC) an international association of 11,000 members with considerable expertise in the prevention, detection, and control of healthcare-associated infections (HAIs).

I am responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. I appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009.

I applaud the foresight of CMS in this arena, as I have a shared vision of preventing adverse events, including HAIs, in the patients I serve in our respective care settings. I understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, I understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;

2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

I support CMS in this effort to identify appropriate conditions that should not occur in hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. I reiterate my association's belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although APIC's focus is infection prevention, the association and I do **support numbers 3, 4 and 5**. That is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

APIC and I do **not support numbers 1, 2 and 6 for FY 2009; i.e.,** catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. I strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. I believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: "The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education

provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. APIC and I look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, I do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

I do not believe that each of these three conditions is always reasonably preventable. In SHEA’s previous letter to CMS³, the society noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

I offer the following specific comments on each of these conditions.

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, I propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter discontinued. Further, I would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on

admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient’s urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as *Klebsiella* or *Candida* species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

I believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians’ notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

#6 *Staphylococcus aureus* Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not

as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. I believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

Seven conditions mentioned but not recommended for consideration for FY 2009

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, I recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-acquired conditions policy in the future.⁵ Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

Of the infection-related conditions for which CMS requested comment, I will specifically address two with the most potential in the near term. I suggest two approaches that do *not* depend on POA codes, though do require coding and cross referencing. I recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although I acknowledge the comments above and agree that as stated this condition would problematic, I would suggest another approach – not dependent on POA or a special code for vascular catheters. I agree that at the moment there is no specific code for ***catheter-associated blood stream infection (CA-BSI)*** – a reasonably preventable condition. However – ***there are specific codes for insertion of catheters***. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)
- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by ***excluding*** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
 - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5
 - Code 36558 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, 5 yrs or older
 - 36560 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port , younger than 5

- 36561 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port 5 yrs or older
- 36563- Insertion of tunneled centrally inserted central venous catheter with a subcutaneous pump, younger than 5
- 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
- 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

#11 Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection)

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, I am not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although I agree with postponing consideration of surgical site infections at this time, I would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes – e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following ‘CABG without valve’ with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes
- d) Examine the record for CABG codes ‘without valve’ occurring on the same admission

In addition to our comments regarding specific conditions, I would like clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. I am committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,

Dr. Luana J. Locke, ND, CNS, CIC, MT(ASCP)

Infection Control Professional & APIC Chapter President for Colorado

LuanaLocke@centura.org

References

¹ Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies After Surgery. J. Surgical Research 2007;138:170-4.

² AHRQ POA The Case for the Present-on-Admission (POA) Indicator Report# 2006-01 Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality Access at www.hcup-us.ahrq.gov/reports/methods.jsp

³ APIC-IDSAs-SHEA letter to Mark McClellan dated June 12, 2006

⁴ National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

⁵ Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.

**CMS-1533-P-325 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. EDWARD QUINLAN

Date & Time: 06/11/2007

Organization : Hospital Association of RI

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**CMS-1533-P-326 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Loren Dyer

Date & Time: 06/11/2007

Organization : Tampa General Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See comments in attachment

CMS-1533-P-326-Attach-1.DOC



June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

**RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85),
May 3, 2007**

Dear Ms. Norwalk:

Tampa General Hospital (TGH) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule as noted above. Tampa General Hospital serves a 12-county region with a population in excess of 4 million, in West Central Florida. TGH serves as the primary teaching hospital for the University of South Florida (USF) College of Medicine. Since 1971, the College of Medicine has graduated nearly 1,700 physicians and prepared 2,000 doctors in specialty residency programs. Ranked among the nations top 100 research universities, USF and TGH are committed to developing advances in medicine through both clinical practice and research.

Tampa General comments as follows by Issue:

DRG REFORM AND PROPOSED MS-DRGS

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited-service hospitals, the Centers for Medicare & Medicaid Services (CMS) in fiscal year (FY) 2006 began significant efforts to reform the diagnosis-related groups (DRGs) and the calculation of the corresponding relative weights. While CMS adopted cost-based weights in FY 2007, it chose not to implement proposed adjustments to the DRG classification system to further recognize severity of illness.

In FY 2008, CMS proposes continuing the transition to cost-based weights and offers a refinement to the current DRG system to better account for patient severity. Tampa General supports meaningful improvements to Medicare's inpatient prospective payment system (PPS). Tampa General serves a higher proportion of severely ill patients and any system that recognizes more accurately that severity will more accurately document the services provided by Tampa General. We believe in the common goal of refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. We also believe that the system should be simple, predictable and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance.

Another core feature of the PPS is clinically cohesive and meaningful DRGs that are intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. Ultimately, the inpatient PPS should foster innovation and best practice in care delivery. We believe that these are essential characteristics of a well-functioning PPS, and it is within these policy goals that we evaluate CMS' proposal. However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral

SEVERITY OF ILLNESS

For FY 2008, CMS proposes to refine the current DRG system by implementing Medicare- Severity DRGs (MS-DRGs), increasing the number of DRGs from 538 to 745. In addition, CMS has undertaken an overhaul of today's complication and co morbidity (CC) list and created up to three tiers of payment for each DRG based on the presence of: a **major** complication or co morbidity (MCC), a **complication** or co morbidity, or **no** complication or co morbidity

Tampa General supports improvements to Medicare's inpatient PPS. MS-DRGs represent a reasonable approach to DRG refinement. CMS should commit to this system for the near future but build in the time needed to ensure that both the agency and hospitals are adequately prepared for this significant change. We urge CMS to adopt the MS-DRGs over a four-year transition period, as the implementation of the more extensive classification system, though budget neutral, would redistribute somewhere between \$800 million and \$900 million among hospitals. Specifically:

- In FY 2008, the emphasis should be on preparation for and testing of the new classification system. This provides CMS with adequate time to finalize data and a CC list, introduce and test software for case classification and payment, including the

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definitions and instructions for case classification and payment, and train its fiscal agents. It also gives hospitals adequate time to implement and test the new system and adjust operations and staffing for predicted revenues. This also will allow vendors and state agencies time to incorporate such changes into their respective software and information systems.

ARBITRARY BEHAVIORAL OFFSET

Until MS-DRGs are fully implemented, and CMS can document and demonstrate that any increase in case-mix results from changes in coding practices rather than real changes in patient severity, there should be no “behavioral offset.” The proposed rule includes a 2.4 percent cut in both FYs 2008 and 2009 to eliminate what CMS claims will be the effect of coding or classification changes that do not reflect real changes in case-mix. The 2.4 percent “behavioral offset” cut is based on assumptions made with little to no data or experience, and cannot be justified in advance of making the DRG changes.

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a *refinement* of the existing system; the underlying classification of patients and “rules of thumb” for coding would be the same. There is no evidence that an adjustment of 4.8 percent over two years is warranted when studies by RAND, cited in the preamble, looking at claims between 1986 and 1987, at the beginning of the inpatient PPS, showed only a 0.8 percent growth in case mix due to coding. Even moving from the original cost-based system to a new patient classification-based PPS did not generate the type of coding changes CMS contends will occur under the MS-DRGs.

According to an article in the magazine *Healthcare Financial Management*, the level of coding on claims suggests that the presence of a CC on a bill is not strongly influenced by financial gain. The proportion of surgical cases with a CC code is higher for cases where there is no CC split and, thus, no financial benefit, than on those cases where there is a CC split and a corresponding higher payment. Thus, coding is driven primarily by coding guidelines and what is in the medical record rather than by financial incentives.

It must be recognized that many cases simply do not have additional CCs to be coded. For many claims, additional codes are simply not warranted and not supported by the medical record. Therefore, there is no opportunity for a coding change to increase payment.

CMS should not implement a “behavioral offset” at this time. Once the MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment at this time, and should not do so without an understanding of whether there will even be coding changes in the first few years of the refined system.

REVISED CC LIST

Currently, 115 DRGs are split based on the presence or absence of a CC. For these DRGs, the presence of a CC assigns the discharge to a higher-weighted DRG. A condition was included on the revised CC list if it could be demonstrated that the presence of the condition would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). Compared with the existing CC list, the revised list requires a secondary diagnosis to have a consistently greater impact on hospital resources. The revised CC list is essentially comprised of significant acute diseases, acute exacerbation of significant chronic diseases, advanced or end-stage chronic diseases and chronic diseases associated with extensive debility.

Tampa General disagrees with the removal of many common secondary diagnoses. We do not understand why significant secondary diagnoses have been removed from the CC list. Specifically, it is unclear what threshold levels were used and at what point in the analysis the CCs were removed.

Without greater transparency, and a code-by-code explanation, we are unable to determine why significant secondary diagnoses requiring additional resources have been removed from the CC list.

- **CMS should make the final revised CC list publicly available as quickly as possible** so that hospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.
- **CMS should consider additional refinements to the revised CC list** and, in particular, address issues where the ICD-9-CM codes may need to be modified to provide the distinction between different levels of severity.
- **In situations where a new code is required, CMS should default to leaving the codes as CCs until new codes can be created.**
- **CMS should address the inconsistencies within the CC list identified by physicians and hospitals.** Where necessary, CMS should immediately obtain additional input from practicing physicians in the appropriate specialties to determine the standard of care and consequent increased hospital resource use.

RECALIBRATION OF DRG WEIGHTS

For FY 2008, CMS has not proposed any changes to the methodology adopted in FY 2007 for calculating cost-based DRG weights. The three-year transition from charge-based DRG weights to cost-based weights would continue, with two-thirds of each weight based on an estimation of costs and one-third based on charges.

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However, during the transition to cost-based weights, two significant issues surfaced:

- First, there is a mismatch between the two data sources used in establishing the cost based weights. These differing data sources, specifically the charges from the MedPAR files (an accumulation of Medicare patient claims filed by each hospital) and the cost-to-charge ratios (CCRs) from the hospital Medicare cost reports, can distort the resulting DRG weights. It is important to note that the cost report was not designed to support the estimation of costs at the DRG level.
- Second, hospitals mark-up different items and services within each cost center by different amounts. Higher-cost items often are marked up less than lower-cost items. When the same CCR is applied to charges for these items, costs can be underestimated for items with lower mark-ups and overestimated for items with higher mark-ups. This “charge compression” can lead to the distortion of DRG weights.

Tampa General supports the efforts by the American Hospital Association and the American Association of Medical Colleges to affect cost report changes. Under cost-based weights, the two sources of data that are used in establishing the DRG weights are the MedPAR files and the Medicare cost report. Charges are taken from the MedPAR files, grouped into 13 categories and reduced to cost using national CCRs calculated from the Medicare cost reports for these same 13 categories.

An examination of the cost-based weights developed for FY 2007 revealed that three problems occur by using these two different data sources together:

- First, the method used by CMS to group hospital charges for the MedPAR files differs from that used by hospitals to group Medicare charges, total charges and overall costs on the cost report.
- Second, hospitals group their Medicare charges, total charges and overall costs in different departments on their cost reports for various reasons.
- Third, hospitals across the country complete their cost reports in different ways, as allowed by CMS.

This mismatch between MedPAR charges and cost report CCRs can distort the resulting DRG weights. CMS states that it is undertaking a comprehensive review of the Medicare cost report and plans to investigate this issue during that process but does not propose any short-term changes to alleviate this problem.

CAPITAL IPPS

Under the capital inpatient PPS, capital payments are currently adjusted by the same DRGs for each case, as is done under the operating PPS. Capital PPS payments also are

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In the proposed rule, CMS seeks comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections. CMS puts forward 13 conditions it is considering, but it recommends only six conditions for implementation at this time. The six conditions are:

- Catheter-associated urinary tract infections;
- Pressure ulcers;
- Object left in during surgery;
- Air embolism;
- Blood incompatibility; and
- Staphylococcus aureus septicemia.

This policy should be implemented starting with a small number of conditions because there are significant challenges to correctly identifying cases that meet the criteria laid out by Congress. There are further difficulties ensuring appropriate accuracy in the billing data that will enable the correct identification of the relevant cases. We ask CMS to carefully consider not only the criteria for selection set forth in the DRA, but also the ability of hospitals to accurately identify and code for these conditions. Some of the proposed conditions may not be feasible at this time.

We believe that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention.

HOSPITAL QUALITY DATA

To receive a full market basket update, hospitals will have to pledge to submit data on all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

We are pleased that CMS has proposed adding only measures that have been adopted by the HQA for public reporting in FY 2009. The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality – hospitals, purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment.

IME ADJUSTMENT

Under the proposed rule, vacation and sick time would be removed from the total time considered to constitute an FTE resident. Thus, it would be removed from both the numerator and denominator of the FTE calculation. CMS acknowledges that this would result in lower FTE counts for some hospitals and higher counts for other hospitals, solely because of this regulatory change.

CMS's proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through. We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count. We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered.

The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor affects, nationally speaking, while having major implications at the individual hospital level.

REPLACED DEVICES

In the calendar year 2007 outpatient PPS final rule, CMS adopted a policy that requires a reduced payment to a hospital or ambulatory surgical center when a device is provided to them at no cost. Similarly, CMS believes that payment of the full inpatient PPS DRG in cases in which the device was replaced for free or at a reduced cost effectively results in Medicare payment for a non-covered item.

CMS proposes to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital or with full credit for the removed device. However, CMS proposes to apply the policy only to those DRGs under the inpatient PPS where the implantation of the device determines the base DRG assignment (22 DRGs), and situations where the hospital receives a credit equal to 20 percent or more of the cost of the device. CMS also proposes to use new condition codes to report the use of such devices to trigger manual processing by the FIs. The hospital would be required to provide paper invoices or other information to the FI (or Medicare Administrative Contractor) indicating the hospital's normal cost of the device and the amount of the credit received. In cases where the device is provided without cost, CMS proposes that the normal cost of the device will be subtracted from the DRG payment. In cases where the hospital receives a full or partial credit, the amount credited will be subtracted from the DRG payment.

CMS justifies this change by noting that "in recent years, there have been several field actions and recalls with regard to failure of implantable cardiac defibrillators and pacemakers." Although Tampa General does not dispute this fact, we believe it ignores the underlying concept of the DRG payment system. DRG payments are fundamentally

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based on averages of historical costs and charges. To reduce the payment for cases involving replacement of a medical device assumes that either these types of cases have not occurred in the past or are occurring at such a dramatic increase as to materially skew the averages used to develop the DRG weights.

CMS notes that “we believe that incidental device failures that are covered by manufacturers’ warranties occur routinely.” This statement acknowledges that incidental device failure has occurred in the past and was likely covered by the manufacturer warranty. If so, this practice is part of the historical cost and charge data used to develop the current DRG weights for cases involving implantation.

Tampa General asks CMS to reconsider implementing this proposal. Given the administrative burden of manually processing these claims, it is not worth the burden on the hospitals’ or FIs’ part if only a nominal portion of the cost of the device is at issue. In addition, inpatient PPS payments are often less than costs.

NEW TECHNOLOGY

We are concerned about CMS’ ability to implement add-on payments for new services and technologies in the near future. Though Tampa General is in the forefront of new technology and procedures, the degree of new technology payment is minimal due to the lack of adequate codes and means of recognizing the types of services and items actually provided. Rather, Tampa General and others bear the cost burden of providing those new technologies to Medicare patients with little support in Reimbursement.

Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

ICD-10 was developed as a replacement classification system. The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10.

Absent a switch to ICD-10 soon, hospitals will experience significant coding problems that will affect the efficiency of the current coding process, adding significant operational costs. We support the Secretary expeditiously undertaking the regulatory process to replace ICD-9-CM with ICD-10.

Sincerely,

Loren M. Dyer
Director of Revenue and Reimbursement

CMS-1533-P-327 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Victoria Fraser

Date & Time: 06/11/2007

Organization : The Society for Healthcare Epidemiology of America

Category : Health Care Professional or Association

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services for the opportunity to provide additional input to the CMS proposed IPPS changes.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology. SHEA works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. It upholds its high success rate in infection control and prevention, while applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership in all branches of medicine, public health, and healthcare epidemiology.

As an organization with considerable expertise in the prevention, detection, and control [and treatment] of healthcare-associated infections (HAIs), we are responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. We appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, we have worked collaboratively and are in essential agreement with our colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities, namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

We applaud the foresight of CMS in this arena, as we have a shared vision of preventing adverse events, including HAIs, in the patients we serve in our respective care settings. We have participated in discussions with the Centers for Disease Control and Prevention (CDC) and appreciate that the broader scope of the Deficit Reduction and Reconciliation Act (DRA) of 2005 is "Hospital-Acquired Conditions." However we will focus most of our comments on HAIs, where we believe we have the most expertise. We hope that these suggestions will help finalize decisions that must be made this year in order to implement the proposed rule scheduled for October 1, 2008 (FY 2009).

We understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, we understand hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

We support CMS in this effort to identify appropriate conditions that should not occur in our hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. We emphasize our belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

CMS-1533-P-327-Attach-1.DOC

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Introduction

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services for the opportunity to provide additional input to the CMS proposed IPPS changes.

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have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, we understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

We support CMS in this effort to identify appropriate conditions that should not occur in our hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. We emphasize our belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although our organization's focus is infection prevention, we do **support numbers 3, 4 and 5** that is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention.. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to

accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

We do not support numbers 1, 2 and 6 for FY 2009; i.e., catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. We strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. We believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. We look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, we do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

We do not believe that each of these three conditions is always reasonably preventable. In our previous letter to CMS³, we noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

We offer the following specific comments on each of these conditions

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need

long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, we propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter discontinued. Further, we would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient's urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as *Klebsiella* or *Candida* species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

We believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians' notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude

patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

#6 *Staphylococcus aureus* Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. We believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

Seven conditions mentioned but not recommended for consideration for FY 2009

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, we recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-

acquired conditions policy in the future.⁵ Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

Of the infection-related conditions for which CMS requested comment, we will specifically address two with the most potential in the near term. We suggest two approaches that do *not* depend on POA codes, though do require coding and cross referencing. We recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although we acknowledge the comments above and agree that as stated this condition would problematic, we would suggest another approach-- not dependent on POA or a special code for vascular catheters. We agree that at the moment there is no specific code for *catheter-associated blood stream infection* (CA-BSI) -- a reasonably preventable condition. However--*there are specific codes for insertion of catheters*. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)

- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by **excluding** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
 - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5
 - Code 36558 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, 5 yrs or older
 - 36560 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port , younger than 5
 - 36561 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port 5 yrs or older
 - 36563- Insertion of tunneled centrally inserted central venous catheter with a subcutaneous pump, younger than 5
 - 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
 - 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

#11 Surgical site infections are identified by ICD-9-CM code 998.59 (Other postoperative infection)

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, we are not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although we agree with postponing consideration of surgical site infections at this time, we would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes - e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes

- d) Examine the record for CABG codes ‘without valve’ occurring on the same admission

In addition to our comments regarding specific conditions, we would like clarification from CMS *on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.*

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,



Victoria J. Fraser, MD
SHEA President

References

¹ Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies after Surgery. J. Surgical Research 2007; 138:170-4.

² AHRQ POA The Case for the Present-on-Admission (POA) Indicator Report# 2006-01 Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality Access at www.hcup-us.ahrq.gov/reports/methods.jsp

³ APIC-IDSA-SHEA letter to Mark McClellan dated June 12, 2006

⁴ National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

⁵ Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.

CMS-1533-P-328 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Dorothy Seibert

Date & Time: 06/11/2007

Organization : Fauquier Hospital, Warrenton, VA

Category : Other Practitioner

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Key points from APIC letter to Leslie Norwalk, Esq, Acting Administrator, Center for Medicare & Medicaid Services

" APIC and the CMS have a shared vision of preventing any adverse event, specifically infectious complications, in patients served in their respective care settings.

" APIC supports CMS in their effort to identify appropriate conditions that should not occur in our hospitals, thereby meeting criteria defined by Congress and also ensuring accuracy in the billing data that enables the appropriate identification of cases.

" The implementation of the MS-DRG system requiring implementation of "present on admission (POA)" codes will demand enormous resources in a very short time period for training and education of clinical and coding staff

" Of the six serious preventable events identified by CMS, APIC supports the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF; are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes.

" These extremely harmful events have known methods of prevention.

" APIC does not support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. Two states currently using POA codes report a minimum of two years needed to achieve reliability—much longer than the January 1, 2008 timeframe proposed by CMS.

" APIC looks to CMS to provide the educational support needed to reliably determine POA codes.

" APIC does not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences.

" APIC recommends that CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital-acquired conditions policy in the future, since they are important causes of healthcare-associated mortality and morbidity. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.

" APIC suggests and supports two approaches that do not depend on POA codes, but instead require coding and cross referencing for vascular-associated infections (which includes infections associated with all vascular devices, implants and grants) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code.

" While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.

" While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that

are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

" APIC proposed consideration of post-operative sepsis, using a specific procedure code such as CABG (with or without valve)

" APIC requests clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

CMS-1533-P-329 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Barbara Walker

Date & Time: 06/11/2007

Organization : Greenbrier Valley Medical Center

Category : Hospital

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

I believe it to be a mistake to hold hospitals accountable for infections which are not diagnosed on admission. Many infections are incubating on admission but may not show until after the patient is hydrated and thus appear to be nosocomial when they are not, or may be present in a low level and not show fully until after diagnostic procedures done over several days, or may be secondary to other conditions. Unless total body testing is done on everyone on admission, it will be impossible to find them all. Also, reliance on coding for surveillance is misleading; specific investigation regarding "where & when" an infection occurred is not accurate when done by numeric codes entered by non-medical personnel. Of the first 6 conditions being considered by CMS for initial implementation, I believe that #'s 1 & 6 are particularly open to mis-interpretation. I also believe that there has not been sufficient investigation into these, basically feeling that they are not always preventable, and in addition, much more clarification of the conditions is needed if CMS is going ahead with this.

I have seen the letter from APIC to Leslie Norwalk, and agree with the key points made; I urge CMS to re-consider.

Thank you,

Barbara Walker RN, BSN, CIC
Infection Control Coordinator
Greenbrier Valley Medical Center
Ronceverte, WV

CMS-1533-P-330 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Marj Mancuso

Date & Time: 06/11/2007

Organization : Marj Mancuso

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the sister of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Marj Mancuso

CMS-1533-P-331 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Sylvia Garcia-Houchins

Date & Time: 06/11/2007

Organization : Ms. Sylvia Garcia-Houchins

Category : Individual

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

The determination of Hospital acquired infection is complicated. It should be done by application of standardized definitions, such as those developed by CDC and used by Infection Control Programs accros the country not purely by ICD-9 coding. I would suggest that the Association for Infection Professionals work with CMS to develop a system that allows for review of medical records by a trained infection control profesional determination of whether a helthcare associated infection has occurred, documenting in the reviewed records and then coding yes: healthcare associated infection: type or no healthcare associated infection.

CMS-1533-P-332 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Daniel Myers

Date & Time: 06/11/2007

Organization : Florida Hospital

Category : Individual

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

I oppose this capital cut to the important source of funding for ongoing improvement of facilities and purchase of new technology. The reduction of this increase has the potential to limit beneficiary option to quality care in certain locations

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

As cited in the proposed rule, this methodology has some merit, compared to other systems. However, CMS should not rush to implement this system without giving the provider community ample time to prepare. Providers have been using other methods of severity-adjusted systems for years, and are more familiar with them. Furthermore, the analysis by RAND will not be completed until September 1st! CMS should wait for the Rand analysis, and then sometime in the 2nd half of 2007, issue a notice for Oct 1, 2008, giving providers, vendors, and all other parties ample time to prepare and modify coding and billing systems

GENERAL

GENERAL

See Attachment

Operating Payment Rate

Operating Payment Rate

CMS has not provided adequate documentation how this number was calculated. In effect the number is somewhat derived from a guess, and has the potential to be overstated or understated. I recommend that until CMS has better information, this behavioral offset not be implemented. It could be evaluated after people have had 1 or 2 years of experience under the new system. At that point CMS would understand the changes in practice that have occurred, and could adjust the DRG weights accordingly

Replaced Devices

Replaced Devices

Since the DRG system is loosely based on the average costs and charges associated with each DRG, there is no need to

further reduce payments. The average costs and charges have already been reduced when providers received free replacement product in the past. Now requiring a payment reduction on current cases is double-dipping by CMS by setting the DRG weight lower than it would have been if the original free devices had been excluded and now reducing payments again. In addition, it creates a tremendous amount of burden on hospital operations and billing. There is likelihood that hospitals would experience compliance problems by not always recognizing and reporting a device as below the 20% threshold. It may require additional staff at some hospitals to consistently catch and report this information.

CMS-1533-P-333 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Elise Roberts

Date & Time: 06/11/2007

Organization : St. Joseph Hospital, Orange

Category : Nurse

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

To: Leslie Norwalk, Esq, Acting Administrator, Center for Medicare and Medicaid Service
Re: Preventable Hospital Conditions CMS-1533-P

I am a Registered Nurse who has practiced nursing for over 30 years in hospitals in California. My experience includes critical care bedside nursing, nursing management, hospital administration and, currently, infection control. While I laud efforts to prevent adverse events and outcomes for the patients we serve, certain aspects of the proposed regulation changes will hamper hospitals' efforts to provide patient care through unfair withholding of reimbursement.

Specifically, 3 of the serious preventable events dealing with hospital-acquired conditions (catheter associated urinary tract infections, pressure ulcers and Staphylococcus aureus septicemia) identified by CMS should not be included in these regulation changes. The practice of Medicine or Nursing is not an exact science. The recipients of our ministrations are complex entities with individual risk factors (prior illness/addictions, poor nutritional status, poor personal hygiene, variable abilities to follow directions, to name only a few) and qualities that make for variations outside our control. In many instances, infections/conditions, such as the three listed above, occur despite our best efforts and processes to prevent them. What will come of penalizing hospitals that treat these patients? Cherry picking only the healthiest patients to treat? Denial of care to the poor or the elderly who are most at risk of these complications of care? Closure of hospitals? I am sure that these negative consequences are not the intent of these regulation changes but I fear that they are the outcome.

Therefore, I urge you to abandon the inclusion of these three conditions. Further, I urge collaboration and cooperation with APIC, the Association for Professionals in Infection Control, in establishing measurable, easily retrievable indicators of quality care. We share the same goals...prevent adverse outcomes in a cost effective patient centered manner... so collaboration can only be positive for the patients and taxpayers of the State of California.

Sincerely,
Elise Roberts, RN, BSN, MBA
Infection Control Practitioner, St Joseph Hospital, Orange
Member APIC, Orange County Chapter
20322 Randall St.
Orange, CA 92869
714 878-3701

**CMS-1533-P-334 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mrs. Rhonda Martin

Date & Time: 06/11/2007

Organization : NorthBay Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-334-Attach-1.DOC

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Dear Ms. Norwalk:

Thank you for the opportunity to provide additional input to the CMS proposed IPPS changes.

I serve as a member of the Association for Professionals in Infection Control and Epidemiology (APIC) an international association of 11,000 members with considerable expertise in the prevention, detection, and control of healthcare-associated infections (HAIs).

I am responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. I appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, I have worked collaboratively and am in essential agreement with my colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities, namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

I applaud the foresight of CMS in this arena, as I have a shared vision of preventing adverse events, including HAIs, in the patients I serve in our respective care settings. I understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, I understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

I support CMS in this effort to identify appropriate conditions that should not occur in hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. I reiterate my society's belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although SHEA's focus is infection prevention, the society and I do **support numbers 3, 4 and 5**. That is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

SHEA and I **do not support numbers 1, 2 and 6 for FY 2009; i.e.,** catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. I strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. I believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. SHEA and I look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, I do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

I do not believe that each of these three conditions is always reasonably preventable. In SHEA’s previous letter to CMS³, the society noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

I offer the following specific comments on each of these conditions.

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, I propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter

discontinued. Further, I would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient’s urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as Klebsiella or Candida species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

I believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians’ notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

#6 Staphylococcus aureus Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. I believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

Seven conditions mentioned but not recommended for consideration for FY 2009

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, I recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-acquired conditions policy in the future.⁵ Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

Of the infection-related conditions for which CMS requested comment, I will specifically address two with the most potential in the near term. I suggest two approaches that do *not*

depend on POA codes, though do require coding and cross referencing. I recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although I acknowledge the comments above and agree that as stated this condition would be problematic, I would suggest another approach – not dependent on POA or a special code for vascular catheters. I agree that at the moment there is no specific code for **catheter-associated blood stream infection** (CA-BSI) – a reasonably preventable condition. However – **there are specific codes for insertion of catheters**. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)
- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by **excluding** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
 - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5

- Code 36558 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, 5 yrs or older
- 36560 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port , younger than 5
- 36561 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port 5 yrs or older
- 36563- Insertion of tunneled centrally inserted central venous catheter with a subcutaneous pump, younger than 5
- 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
- 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

#11 Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection)

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, I am not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although I agree with postponing consideration of surgical site infections at this time, I would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes – e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes
- d) Examine the record for CABG codes 'without valve' occurring on the same admission

In addition to our comments regarding specific conditions, I would like clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. I am committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,

Rhonda Martin, RN, BHA, CPHQ
Director, Infection Prevention and Control
NorthBay Healthcare Hospitals

References

¹ Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies After Surgery. J. Surgical Research 2007;138:170-4.

² AHRQ POA The Case for the Present-on-Admission (POA) Indicator Report# 2006-01 Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality Access at www.hcup-us.ahrq.gov/reports/methods.jsp

³ APIC-IDSA-SHEA letter to Mark McClellan dated June 12, 2006

⁴ National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

⁵ Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.

**CMS-1533-P-335 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Mike Myers

Date & Time: 06/11/2007

Organization : Southeast Alabama Medical Center

Category : Hospital

Issue Areas/Comments

RRCs

RRCs

Re: RRCs

CMS-1533-P-335-Attach-1.DOC

June 11, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Acting Administrator Norwalk:

Re: RRCs

In response to the "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates" (file code CMS-1533-P), we submit the following comments regarding Rural Referral Centers (RRCs) for your consideration.

We appreciate the Centers for Medicare and Medicaid's (CMS) recognition that RRCs play a significant role in treating rural Medicare beneficiaries, regardless of whether they are physically located in a rural area or an urban area. Therefore, we are concerned that the Fiscal Year (FY) 2008 Inpatient Prospective Payment System (IPPS) proposed rule would prohibit urban hospitals that acquire rural status from maintaining their RRC designation if they are subsequently reclassified as urban through the Medicare Geographic Classification Review Board (MGCRB) process, unless the hospital was designated as an RRC in FY 1991 or they lost their RRC status as a result of an Office of Budget and Management redesignation of the area from rural to urban. This proposal is clearly in conflict with congressional intent.

In an effort to provide needed flexibility to urban hospitals that serve predominately rural Medicare beneficiaries, the Balanced Budget Refinement Act of 1999 (P.L. 106-113, Section 401) created a mechanism, separate and apart from the MGCRB, to permit certain urban hospitals to acquire rural status. P.L. 106-113 defines "certain urban hospitals" as subsection (d) hospitals that are located in urban areas (as defined in paragraph (2)(D) of the Social Security Act) and that satisfy any of the following criteria:

- I. The hospital is located in a rural census tract of a metropolitan statistical area.
- II. The hospital is located in an area designated by any law or regulation of such State as a rural area.
- III. The hospital would qualify as a rural, regional, or national referral center or a sole community hospital if the hospital were located in a rural area.
- IV. The hospital meets such other criteria as the Secretary may specify.

Hospitals qualifying under this provision are eligible for all categories and designations available to rural hospitals, including sole community hospitals (SCHs), Medicare-dependent, critical access, and RRCs. Additionally, qualifying hospitals are eligible to apply to the MGCRB for geographic reclassification to an urban area and are entitled to the exceptions extended to RRCs and SCHs, if such hospitals are so designated.

In light of the congressional intent surrounding Public Law 106-113, we do not believe the CMS proposal to remove RRC status once a hospital has terminated its acquired rural designation and/or to increase the minimum duration of acquired rural status under § 412.103 to be appropriate. In addition, CMS contends that the proposed rule is consistent with CMS's policy that a hospital cannot continue to be an RRC once it cancels acquired rural status under § 412.103. However, the historical facts point to just the opposite as summarized below:

- 1) In an August 1, 2000, Federal Register notice (65 FR 47089), CMS indicated its agreement "that Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(8)(E) of the Social Security Act in order to become RRCs so that the hospital would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area." CMS further stated, "**...we believe that the intent underlying this language (a description of the House bill) was to allow certain urban hospitals to become RRCs (upon reclassifying from urban to rural under section 1886(d)(8)(E) of the Act) and then reclassify under the MGCRB process (as RRCs, the hospitals would be exempt from the MGCRB's proximity requirements.**" [Emphasis added].
- 2) The phrase "certain urban hospitals" is specifically defined at section 1886(d)(8)(E) of the Social Security Act to include urban hospitals that would qualify as RRCs if located in a rural area.
- 3) CMS expressed concern regarding the potential interface between rural reclassifications under section 401 and section 407(b)(2) of Public Law 106-113, which authorized a 30-percent expansion in a rural hospital's resident full-time equivalent count for purposes of Medicare payment for the indirect costs of medical education (IME) under section 1886(d)(5)(B) of the Social Security Act. Under the regulatory provisions at the time, an urban hospital could have potentially reclassified as rural under section 1886(d)(8)(E) of the Social Security Act for purposes of receiving the IME benefit while also reclassifying under the MGCRB process for purposes of a higher wage index. To prevent this situation from occurring, CMS revised the regulations governing MGCRB reclassifications by adding paragraph (a)(5)(iv) to section 412.230 stating that: "An urban hospital that has been granted redesignation as rural under Sec. 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status as long as such redesignation is in effect."
- 4) However, to address the congressional intent expressed in P.L. 106-113, CMS decided to revisit their policy decision on section 4202(b) of Public Law 105-33. Specifically, in the August 1, 2000, Federal Register (65 FR 47089), CMS stated its revised policy decision as follows: "**Accordingly, in light of section 1886(d)(8)(E) of the Act and the language in the Conference Report, we have decided to revisit our policy decision on section 4202(b) of Public Law 105-33. Effective as of October 1, 2000, hospitals located in what is now an urban area, if they were ever an RRC, will be reinstated to RRC status under section 4202(b) of Public Law 105-33.**" [Emphasis added]. CMS goes on to explain how this policy revision will allow OMB redesignated hospitals to regain their former RRC status; however, nowhere in the policy statement does CMS indicate that urban hospitals who were once RRCs under section 1886(d)(8)(E) of the Act are exempt from the revised policy. In

fact, as indicated in the above quotation, CMS references section 1886(d)(8)(E) of the Act in the introduction to their revised policy decision.

- 5) In addition, we note the subsequent revision of the RRC regulations at section 412.96. In the August 12, 2005, Federal Register (70 FR 47485), CMS amended the regulation to eliminate all references to subsequent review of RRC status. This amendment validates the intent of the revised policy decision on section 4202(b) of Public Law 105-33 to allow all hospitals (regardless of their subsequent ability to meet any of the RRC criteria at § 412.96) to retain RRC status indefinitely once initially obtained under § 412.96. The CMS Central Office further clarified this policy in an email from Ms. Linda McKenna on January 27, 2005, which stated: "...an RRC cannot lose its status because of the failed triennial review, MGCRB reclass, or urban designation. I know of no other circumstances where an RRC could lose its designation (voluntarily withdraws perhaps)." [See attached copy].

Taken together these facts, at a minimum, imply the following allowances from CMS:

- 1) Certain urban hospitals (as defined by section 1886(d)(8)(E) of the Social Security Act) are allowed to reclassify as rural under § 412.103 and obtain RRC status under § 412.96.
- 2) Rural hospitals under § 412.103 are allowed to reclassify under the MGCRB only if they first terminate their acquired rural designation.
- 3) Effective October 1, 2000, any hospital located in an urban area, if they were ever an RRC, will be allowed to maintain its RRC status.

These allowances permit an urban hospital meeting the applicable criteria to obtain RRC status through rural designation under § 412.103, to subsequently terminate its acquired rural designation while still maintaining its RRC status, and to reclassify under the MGCRB process through a waiver to the proximity requirements. We believe this to be the only logical conclusion given the above occurrences took place during a time when the only benefit for an urban hospital to obtain RRC status was the waiver to the MGCRB proximity requirements. Any other conclusion would put CMS policy in direct violation with its understanding of congressional intent.

As a final comment, we note the number of urban hospitals pursuing the above mechanism to be extremely small for the following reasons:

- The urban hospital must be able to meet all remaining RRC criteria.
- The urban hospital's wage index would need to be at or very near the level of the State rural wage index to avoid a significant loss in reimbursement while designated rural under §412.103.
- The urban hospital's DSH payment percentage would need to be at or below 12%. Any higher and the hospital could lose significant reimbursement during the time between the effective date of rural designation and the effective date of RRC status (given the CMS

Regional Office has 60 days to review the rural designation request, hospitals would likely file the request at least 60 days prior to the start of their next cost reporting period to ensure RRC status for the following fiscal year).

- The urban hospital must be situated in an area where it is beneficial to reclassify to the closest urban area.
- The urban hospital must meet the 82% test under § 412.230(d)(3)(ii) of the MGCRB process.

Taking these factors into consideration, there are very few hospitals that would qualify for or benefit financially from the process. Market research indicates approximately 18 hospitals nationwide in which this mechanism would make sense from a financial feasibility perspective. These hospitals fit the profile of other existing urban RRCs. If it is CMS's desire to treat all RRCs on an equal basis, then these hospital's should not be prevented from maintaining their urban RRC status and successfully reclassifying under the MGCRB process.

Like their counterparts, these hospitals play a significant role in treating Medicare beneficiaries from surrounding rural areas, and this proposal would place them and the rural beneficiaries they serve, at a significant disadvantage to their urban RRC counterparts. We respectfully request CMS reconsider its proposed changes governing acquired rural status and RRCs.

Sincerely,

Mike Myers,
Division Director Finance
Southeast Alabama Medical Center

CMS-1533-P-336 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Ryan Eula

Date & Time: 06/11/2007

Organization : Mr. Ryan Eula

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

To Whom it May Concern,

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a family member of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases

involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter.

Respectfully,
Ryan Eula

CMS-1533-P-337 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter :

Date & Time: 06/11/2007

Organization : Intermountain Healthcare

Category : Hospital

Issue Areas/Comments

CC Exclusion List

CC Exclusion List

The American Hospital Association has responded in great detail to the CC exclusion list and we urge CMS to consider their recommendation regarding those conditions and retain them as CC conditions as they greatly impact the resources in the treatment of patients with those conditions.

Capital IPPS

Capital IPPS

In the proposed rule, CMS states that capital margins for urban hospitals are too high. As a result, CMS proposes to use a 0% capital inflation update for FY 2008 and FY 2009 and to either reduce or eliminate the capital disproportionate share hospital and capital indirect medical education adjustments in the future.

However, CMS does not recognize that total Medicare reimbursement for urban facilities is below costs. To single out one component of reimbursement without considering the hospital's reimbursement in total is inappropriate. Thus, we would recommend that CMS give urban hospitals an inflation update and not eliminate the capital disproportionate share hospital and capital indirect medical education adjustments.

DRG Reform and Proposed

MS- DRGs

DRG Reform and Proposed MS-DRGs

We oppose CMS's proposal to significantly expand the list of DRGs subject to the postacute transfer policy. In order to identify patients meeting the home health criteria, manual processes have to take place. Hospitals either have to contact patients to determine if they have received home health services within three days after discharge or wait for the FI to let the hospital know that a patient received home care that was not planned at the time of discharge which requires coders to review and correct the disposition and for the Business Office to resubmit the claim. A major expansion in the number of DRGs included in this policy, without any changes to the home health criteria, will place a tremendous administrative burden on hospitals because of the increased number of patients subject to this cumbersome process.

DRGs: Hospital Acquired

Conditions

DRGs: Hospital Acquired Conditions

We urge CMS to consider the following regarding conditions that will be classified as present on admission (POA).

? Catheter-associated urinary tract infections: Many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and prevention guidelines are still debated by clinicians.

? Pressure ulcers: It is difficult to detect stage I pressure ulcers on admission, as the skin is not yet broken, even though the tissue is damaged. The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. We also are concerned that the present-on-admission coding of pressure ulcers will rely solely on physicians' notes and diagnoses, per Medicare coding rules, and cannot make use of additional notes from nurses and other practitioners; in those cases the physician would need to be queried prior to code assignment which would delay the billing process and have added pressure on coders and physicians. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. There also is evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers because, in these cases, the condition may not be reasonably prevented.

? Staphylococcus aureus septicemia: Accurately diagnosing staphylococcus aureus septicemia on admission will be a challenge. Patients may be admitted to the hospital with a staphylococcus aureus infection of a limited location, such as pneumonia or a urinary tract infection. Subsequent development of staphylococcus aureus septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the proliferation of changes in coding guidelines for sepsis in recent years presents further challenges to hospital coding personnel to accurately capture present-on admission status. Finally, there is still some debate among clinicians regarding the prevention guidelines for staphylococcus aureus septicemia.

In addition, we believe the category of staphylococcus aureus septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have been reasonably prevented.

With regard to the seven conditions that CMS mentions in the proposed rule but does not recommend for implementation, we agree that these conditions cannot be implemented at this time because of difficulties with coding or a lack of consensus on prevention guidelines.

Please also consider the unintended consequences that might arise from implementing the hospital-acquired conditions policy. Trying to accurately code for urinary tract infections that are present on admission may lead to excessive urinalysis testing for patients entering the hospital. The necessity to complete diagnostic tests before a patient is admitted to confirm present-on-admission status could lead to delayed admissions for some patients and disrupt efficient patient flow. This would also increase utilization and costs for laboratory services that may not be necessary.

DRGs: Spinal Procedures

DRGs: Spinal Procedures

? Multiple level spinal fusion: For the proposed new DRG for non-cervical spinal fusions with a principal diagnosis of curvature of the spine or malignancy, codes 737.40-737.43 are included in the list of applicable principal diagnoses. However, these codes are manifestation codes, and, according to ICD-9-CM conventions, can never be sequenced as the principal diagnosis. The underlying etiology would be sequenced as the principal diagnosis. Therefore, these codes should not be included in the list of principal diagnoses for proposed DRG 546.

IME Adjustment

IME Adjustment

CMS says that approved vacation time and sick leave are not appropriately categorized as patient care activities, or as didactic, research, or other non-patient care activities. As a result, CMS proposes to create a distinct third category of time that would be removed both the numerator and the denominator of the resident FTE calculations.

The rule is not clear as to whether the change relates to only vacation and sick leave taken vs. vacation allowed and eligible sick leave. Moreover, the change would significantly increase the administrative burden associated with determining resident counts by adding another layer of complexity to the count without any corresponding benefit. The change also creates an inconsistency between allowable Medicare costs in PRM ?2102.1 and ?2102.2 vs. allowed resident costs. Finally, Medicare's IRIS software doesn't even give hospitals the capability of changing the denominator for each resident.

Given the above issues regarding CMS's proposed change in policy to create a third category of time for resident FTE calculation, we would recommend that the proposal not be implemented.

Medicare Code Editor

Medicare Code Editor

? Newborn age edit: As long as CMS has an age edit in the MCE, it should be accurate, up-to-date, and not include codes that could appropriately be assigned to older children or adults. If there are errors in this edit, an adult Medicare claim could be rejected due to inappropriate triggering of the newborn age edit. The introduction for Chapter 15 in ICD-9-CM states that the chapter includes conditions, which have their origin in the perinatal period even though death or morbidity occurs later. Some of those conditions in this chapter may potentially persist into adulthood. CMS should utilize the necessary expertise to develop and maintain pediatric edits on an up-to-date basis, or consider deleting this edit from the MCE.

CMS-1533-P-338 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. George Shrodo

Date & Time: 06/11/2007

Organization : Mr. George Shrodo

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a family member of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

George Shrodo

CMS-1533-P-339

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Gina Briscoe

Date & Time: 06/11/2007

Organization : Decatur General

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

" These comments are in reference to the Hospital Quality Data section beginning on page 161.

1. Concerning the question listed on page 471: Which of the measures or measure sets should be included in the FY 2009 RHQDAPU program or in subsequent years?
2. The Intensive Care Measures are appropriate measures of quality, and would have a significant impact of not only quality care but efficient cost saving care for hospitals.
3. While the readmission measures purposes are to determine if hospitals are sending patients home too sick, or meeting their needs, CMS and other payers are setting up systems that penalize Hospitals that keep patients too long. Hospitals are forced to streamline every aspect of care and "hurry" the patients out in order to just break even. Patients do not understand the system and lay blame on the hospital. Then you add the aspect of HCAHPS into the mix. All of this during a time where there is a nursing shortage. Readmission measures are not recommended.
4. The Nursing Sensitive Condition Set appears to be difficult to measure, difficult to pinpoint who exactly is responsible for ensuring these measures are met, and have so many uncontrollable factors.
5. The Cancer measures appear to be clinically sound and very straightforward to measure.
6. The Leapfrog measures listed on page 472 (number 16-18) would require hospitals to spend money they do not have and are not going to get from CMS. Perhaps if you are requiring Hospitals to invest in expensive equipment, rather than holding money back, CMS should give more money for compliance with such measures.

" Concerning the question: What challenges for data collection and reporting are posed by the identified measures and measure sets? What improvements could be made to data collection or reporting that might offset or otherwise address those challenges? With the addition of more quality measures, and the ever increasing data collection requirements, Hospitals are struggling with having competent staff to collect the information (and paying them). To collect valid data, coordinate rapid cycle improvement in most healthcare systems where the Quality departments have little if any control over Nurses and Doctors, has proven very difficult. This effort has contributed to the nursing shortage by pulling Nurses from taking care of patients to pushing paper to "prove" their worth or collecting data. With all the extra work of collecting the data, then the only incentive is to give back the 2%- which was originally Hospitals to begin with rather than giving Hospitals more seems to be a no win situation. It is recommended that the Government and CMS provide funding to match the requirements to enhance care. Hospitals also need computer programs which interface with their current programs to enhance data collection and promote patient safety as well.

" Concerning Electronic Medical Records, Page 484: Again, if CMS expects hospitals to create or purchase electronic programs- they should provide the programs or the funds for the Hospitals to purchase the programs.

" Concerning Value Based Purchasing Plan, page 486: Adequate time is needed in order for Hospitals to provide information/education to their Hospital Boards, Administrative Staff and all staff on the proposed plan. The phased in option of initiating the effort is advised where the

payment will not be fully based on performance until 2011. Additionally, more support in the manner of suggested approaches, processes, site visits, and training should be required of the States QIOs to ensure Hospitals have the tools to meet the measures.

CMS-1533-P-340 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Kyle Kennedy

Date & Time: 06/11/2007

Organization : Freeman Health Systems

Category : Physician

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,800 employees, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed behavioral offset cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGS

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 — \$24 billion over five years — to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they

own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS's interim report on the strategic plan required by the Deficit Reduction Act of 2005.

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If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

DRG Reclassifications

DRG Reclassifications

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

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**DRG Reform and Proposed
MS- DRGs**

DRG Reform and Proposed MS-DRGs

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DRGs: Hospital Acquired Conditions

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DRGs: Relative Weight Calculations

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June 11, 2007

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While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

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CMS-1533-P-341 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Gary Duncan

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Health Care Professional or Association

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,800 employees, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

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CMS-1533-P-342 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. James Foley

Date & Time: 06/11/2007

Organization : Shore Memorial Hospital

Category : Hospital

Issue Areas/Comments

Impact--Overall Conclusion

Impact--Overall Conclusion

Dear Sirs/Madams:

I am the Chief Finacial Officer of Shore Memorial Hospital, a Medicare provider located in Somers Point, New Jersey. I am writing to express my disappointment with the proposed changes to the Inpatient Prospective Payment System and Fiscal Year 2008 rates. Simply put, the proposal puts this and many other New Jersey institutions at severe financial risk. While we appreciate the full market basket, it seems that the DRG changes will result in a significant reduction in reimbursement.

Based on our modelling, the DRG changes will result in a reduction of \$1.4 million in reimbursement. This is 3.2% of our Medicare reimbursement, effectively taking back the 3.3% market basket adjustment. Effectively, we see no budget neutrality in this issue, only a net rate reduction. This and other New Jersey hospitals, already reeling with threatened take-backs of five year's of disproportionate share funds, can not abide further rate reductions.

I hereby petition for immediate rate relief, a recomputation of the proposed inpatient DRG payment structure and a return to real budget neutrality that maintains the market basket and wage index provisions.

Thank you.

Sincerely,

James T. Foley, CPA, MBA, FACHE
Chief Financial Officer

CMS-1533-P-343**Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates****Submitter : Donna Glenn****Date & Time: 06/11/2007****Organization : Donna Glenn****Category : Nurse****Issue Areas/Comments****DRGs: Hospital Acquired Conditions**

DRGs: Hospital Acquired Conditions

I am a member of APIC and I know, along with my fellow Infection Control Practitioners, we have a shared vision of preventing any adverse event, specifically infectious complications, in patients served in our respective care settings. I also know CMS shares this sentiment. The concept of wanting to identify appropriate conditions that should not occur in our hospitals and ensuring accuracy in the billing data that enables the appropriate identification of cases is not arguable by any. However, there are some concerns related to these proposed changes:

? Of the six serious preventable events identified by CMS, I support the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF; are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes. These events are supportable because they have known methods of prevention.

? I do not support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes.

? I do not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences.

Because of the potential for misinterpretation and error, CMS should provide clarification on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

Conceptually, I find no fault, however, the proposed changes leave too much opportunity for error for me to be supportive. Please, please, please consider the vast numbers of experts out there before making a final decision.

CMS-1533-P-344 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Meghan Carney

Date & Time: 06/11/2007

Organization : Central New Jersey Brain Tumor Support Group

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the wife and caregiver of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

**CMS-1533-P-345 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Glenn Hackbarth

Date & Time: 06/11/2007

Organization : Medicare Payment Advisory Commission

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-345-Attach-1.PDF

#345

MEDPAC Medicare Payment Advisory Commission

601 New Jersey Avenue, N.W. • Suite 9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 11, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1533-P
Box 8011
Baltimore, Maryland 21244-1850

Re: file Code CMS-1533-P

Dear Ms Norwalk:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled *Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates*, Federal Register Vol. 72, No. 85, pages 24680-25135 (May 3, 2007). We appreciate your staff's ongoing efforts to administer and improve the payment system for acute inpatient services, particularly considering the agency's competing demands.

In this letter, we comment on changes to the DRG classification system and relative weights, hospital-acquired conditions, hospital wage index, reporting of hospital quality data and value-based purchasing, disclosure of physician ownership in hospitals and patient safety measures, and payment for capital-related costs.

DRG reclassification

As we indicated in our letters in response to last year's proposed rule (dated April 19 and June 12, 2006), we are pleased that CMS has been actively considering three of the four payment refinements to the PPS that MedPAC recommended in our March 2005 report to Congress on physician-owned specialty hospitals. The CMS-funded development of Medicare severity DRGs (MS-DRGs) by 3M Health Information Systems and studies by RAND, Inc. and RTI International, Inc. have identified important short- and long-term steps that CMS can take to improve payment accuracy in the PPS. Further opportunities for improvement may become apparent after the RAND study is completed later this year. The one change that CMS has not yet considered (outlier financing) would require new legislation.

As we discuss further below, we have several specific comments and suggestions that are based on our extensive analysis of the MS-DRGs, methods for calculating cost-based

weights, and other issues discussed in the proposed rule. For fiscal year 2008, we recommend that you:

- Adopt MS-DRGs, as proposed;
- Make two refinements to your proposed methods for estimating cost-based weights for MS-DRGs:
 - As a short-term step to ameliorate the effects of charge compression on the weights, adopt the RTI-recommended methods for calculating national revenue center cost to charge ratios (CCRs), for drugs, supplies, radiology, emergency room, and blood products. This would increase the number of revenue centers—groups of hospital departments in which hospitals charge patients for services—from 13 to 19;
 - Standardize the Medicare charges and costs used in calculating national revenue center CCRs to adjust for differences in local wage levels and the extent of hospitals' teaching activity and service to low-income patients. This change would be consistent with your use of national standardized charges by revenue center for each MS-DRG in the other half of the cost-weight calculation;
- Terminate the transition to cost-based weights—adopting 100 percent cost-based weights, or adopt a two-year transition period for MS-DRGs that coincides with the remainder of the current transition period for implementing cost-based weights. These actions would help to balance the payment impacts of implementing severity refinements and cost-based weights; and,
- Adopt an adjustment that is between -1.6 and -1.8 percent per year (for at least the two years following adoption of MS-DRGs) to the standardized amounts to offset the expected impact of improvements in documentation and reporting of diagnoses.

Some alternative ways of implementing the last two items are discussed below. These actions are needed to improve payment accuracy, smooth the payment impacts associated with the adoption of major payment refinements, and prevent unwarranted overpayments to hospitals that otherwise would occur due to improvements in case-mix reporting.

Although adoption of MS-DRGs and our recommended refinements to the cost weights are important steps toward achieving higher levels of payment accuracy, CMS should continue to pursue further payment refinements. Our analyses show that substantial differences in relative profitability would remain, on average, for cases grouped in many MS-DRGs, even if payments were based on the refined cost-based weights described above. Many of these differences in profitability might be reduced by selectively adopting some of the grouping logic refinements found in all-patient refined DRGs (APR-DRGs) that take into account interactions among secondary diagnoses and between combinations of secondary diagnoses and certain principal diagnoses. Our findings also suggest that adopting cost-based, hospital-specific relative value (HSRV) weights would result in substantial further improvements in payment accuracy.

In addition, CMS needs to make a sustained effort to improve the quality and specificity of the information that hospitals submit on their annual cost reports. To meet this goal, CMS

will have to change the cost reporting form and instructions, and step up efforts to inform providers and monitor the information they furnish. We are pleased that you are undertaking a comprehensive review of the cost report, including the schedule for collecting data on uncompensated care. This effort will provide an opportunity to develop longer-term solutions to important problems raised in the RTI report, such as charge compression, as well as other long-standing issues. We will be pleased to assist you in this effort and you also can take advantage of significant opportunities for cooperation with the hospital industry. These longer-term improvements are needed to reduce the extent to which Medicare encourages community hospitals to allocate capital to profitable services, such as cardiology, and stimulates the formation of specialty hospitals that often focus on providing profitable services and tend to care for low-severity patients.

MS-DRGs and cost-based weights

We commend CMS for its commitment to improve the accuracy of Medicare payments for hospital acute inpatient services. The CMS staff has made significant progress toward achieving this goal with the development of MS-DRGs coupled with cost-based weights. Our analyses show that using MS-DRGs will result in a substantial improvement in payment accuracy. We also find that adoption of the refinements developed in the RTI study that reduce the effects of charge compression on CMS's cost-based weights would yield additional gains in payment accuracy, especially for certain MS-DRGs. (Charge compression results from hospitals' use of lower markups for high cost items or services and higher markups for low cost items or services within a single hospital department, such as central supply or radiology. Under these circumstances, when CMS applies a national cost to charge ratio for the department to all related charges to estimate costs for the department's services used in each MS-DRG, costs for MS-DRGs that use the high cost items are understated, while costs for MS-DRGs that use low-cost items are overstated.)

We have taken several steps to evaluate the proposed MS-DRGs. First, we examined their face validity. An effective patient classification system—in the context of a payment system—should group together clinically similar cases that have similar costs. In addition, relative weights calculated for the classification groups (MS-DRGs) generally should exhibit a consistent hierarchy of values across levels of severity of illness for different conditions. So one issue is how much costs vary around the mean cost per case for cases grouped within MS-DRGs. Another issue is whether relative weights for different severity levels show the expected hierarchy across most clinical conditions. For comparison, we also looked at cost variation and relationships among relative weights for cases grouped in the current DRGs and in the severity categories of the all-patient refined DRGs (APR-DRGs).

We also examined how the MS-DRGs would affect payment accuracy in the PPS, measured by how closely payments would track costs for different types of cases. Again, we compared payment accuracy under the MS-DRGs with the results under the current DRGs and the severity categories of the APR-DRGs.

In addition, we wanted to examine alternative methods for constructing relative weights. Although CMS did not propose any substantial changes to the current method for calculating cost-based weights, it did ask for comments on the refinements that RTI

developed to address charge compression. We also wanted to see how cost-based weights calculated by the proposed CMS method, with and without the RTI refinements, would compare with HSRV weights calculated by the more detailed methods that we recommended in our March 2005 report to Congress on physician-owned specialty hospitals.

Data set and methods—To provide the data needed for these comparisons, we developed an updated data set like the one we used in our report on physician-owned specialty hospitals. We started with the latest annual Medicare cost report for each PPS hospital that was available in January 2007. For each cost report, we then matched all Medicare inpatient claims from the fiscal year 2003-2005 standard analytic files (SAF) that had discharge dates within the hospital's cost reporting period. After editing—using edits similar to those used by CMS—the data set included 3,336 IPPS hospitals with 11.2 million claims falling mostly in fiscal years 2004 and 2005.

To estimate the cost of each service reported on a claim, we took the charges for each detailed revenue code and multiplied them by the cost to charge ratio (CCR) for the corresponding revenue center from the hospital's cost report. Then we summed the costs of all services on the claim to get the total cost for the patient's hospital stay. To put the data for claims from different fiscal years on a common footing, we inflated the costs and charges for all claims to correspond to the mid-point of fiscal year 2005.

In making these calculations, we used CCRs for most revenue centers that were based on the corresponding costs and charges hospitals reported in their cost reports. To improve the accuracy of our cost estimates, we incorporated the refinements to reduce charge compression developed in the RTI study for drugs, supplies, and radiology. For each of these target revenue centers, we estimated hospital-specific CCRs for two or more component groups of services using the regression coefficients from the RTI study along with the appropriate version of each hospital's overall CCR for all ancillary services (calculated from our data set). We then applied the CCRs to the charges for the corresponding detailed revenue codes to estimate the costs for the component services on each claim.

The RTI regression estimates, which were based on a similar data set, demonstrate that hospitals tend to use significantly different markups for certain services within the drugs, supplies, and radiology revenue centers. For example, hospitals tend to use higher markups for IV solutions than for other drugs charged to patients. Similarly, hospitals tend to use lower markups for devices and implants than for other supplies. Consequently, using the average CCRs calculated from each hospital's cost report for each of these revenue centers would result in a substantial overstatement of costs for IV solutions and understatement of costs for other drugs. Costs would be substantially understated for devices and implants, but overstated for all other supplies. Costs for CAT scans and MRI procedures also would be overstated, while costs for other radiology procedures would be understated. These errors would bias estimated costs upward or downward for different types of patients, depending on the mix of services that they typically use.

We used the inflated charges and cost estimates from the claims and the charges and costs from the hospitals' cost reports to calculate several different sets of cost-based relative weights. We developed cost-based relative weights for DRGs using the same methods that CMS currently uses (FY 2007), but incorporating the minor changes CMS proposed for FY 2008. We estimated three sets of cost-based weights for MS-DRGs. For clarity, we call them:

- **MedPAC refined**—a version of MedPAC's recommended cost-based HSRV weights updated to incorporate the RTI-recommended refinements to reduce charge compression for drugs, supplies, and radiology,
- **CMS proposed**—the cost-based weights that CMS developed using 13 revenue centers as proposed for fiscal year 2008, and
- **CMS refined**—a version of the CMS proposed method that incorporates the RTI-recommended refinements that split drugs (2 centers), supplies (2 centers), and radiology (3 centers); refinements also include breaking out ER and blood and blood processing from "other services", for a total of 19 revenue centers. These weights also differ from the CMS proposed weights in that the refined version uses national CCRs for the 19 revenue centers that are based on national sums of standardized Medicare charges and costs. In contrast, the national CCRs in the CMS proposed weights are based on Medicare charges and costs that have not been standardized to remove the effects of local differences in wage levels, each hospital's teaching activity, and the extent to which it serves low-income patients.

We also calculated cost-based HSRV weights for the severity classes of APR-DRGs, using our detailed case-level cost estimates that incorporate the RTI refinements.

We used these weights and corresponding case-mix indexes along with MedPAC's PPS payment model with FY 2008 payment policies to calculate what payments would have been under current policy and alternative combinations of MS-DRGs and the different sets of weights. As described below, we used the resulting payments and the estimated cost for each case to calculate measures of payment accuracy. We also used hospital-level payments in examining the payment impact of adopting MS-DRGs and 100 percent cost-based weights, with and without the RTI refinements.

Grouping claims by MS-DRG—A central objective of the DRG patient classification system is to group cases with similar clinical attributes and similar resource use into a common DRG. We used MedPAC's case-level cost estimates for cases from 2003 to 2005 to calculate the amount of variation in costs among cases within the DRGs. We then recalculated the amount of cost variation among cases within MS-DRGs (and within the severity classes of APR-DRGs) for comparison.

To measure the amount of cost variation, we first standardized our case-level cost estimates to remove the effects of local differences in wage levels, teaching activity, and service to low-income patients. Then we calculated the difference between the standardized cost for each case and the average standardized cost for all cases in the same category (DRG, MS-

DRG, APR-DRG). We converted these differences to absolute values and calculated the average of the absolute differences.

The average absolute difference for MS-DRGs was 4.8 percent lower than the average absolute difference for the current DRGs. In other words, the MS-DRGs did a better job of grouping cases with similar costs into the same category. This was expected because the MS-DRGs break out high severity (and high cost) cases with major comorbidities or complications (MCCs) into separate DRGs. For comparison, we also calculated the amount of variation in costs among cases within the severity classes of APR-DRGs (version 23). The average absolute difference for the APR-DRGs, in turn, was 7.4 percent lower than the value for DRGs. This suggests that at least some opportunities are available for further refinement of the MS-DRGs. Although the MS-DRGs are not perfect, and may need to be further refined over time (as discussed below), they represent a significant improvement over the current DRGs.

Refining current methods for calculating cost-based weights—How do the CMS proposed weights and the CMS refined weights compare to the MedPAC refined weights? Neither alternative set of weights will exactly match the MedPAC refined weights. The MedPAC refined weights are based on more detailed cost estimates derived using each hospital’s own CCRs and the weights are calculated by the HSRV method (discussed more fully later). Both the CMS proposed and CMS refined weights are based on national sums of standardized charges for each of the revenue center groupings within each MS-DRG and national average revenue center CCRs.

To see how the two CMS alternatives differ from the MedPAC refined weights, we calculated the percentage differences between each set of CMS weights and the MedPAC refined weights (separately for all MS-DRGs). Then, we converted the percentage differences to absolute values and calculated the weighted average of the absolute values over all MS-DRGs, weighting by the volume of cases in each category. The resulting weighted average absolute differences in Table 1 summarize the extent of the differences in the weights (smaller is better), comparing the CMS proposed and CMS refined weights with the MedPAC refined weights for MS-DRGs.

Table 1. Weighted average absolute difference from MedPAC refined weights

<u>Method:</u>	<u>MS-DRGs</u>
CMS proposed	2.8%
CMS refined	2.5

Source: MedPAC analysis of Medicare hospital inpatient claims and cost reports from CMS, fiscal years 2003-2005.

The weights based on the CMS refined method more closely matched the MedPAC refined weights than did the weights based on CMS’s proposed method. The gain from adding the RTI refinements and standardizing the costs and charges used in calculating national CCRs may appear to be very small. But the effects of these refinements are focused primarily on the weights for a relatively small number of MS-DRGs, with comparatively minor effects on the weights for most other categories.

Combined impact of MS-DRGs and CMS refined weights—The CMS refined method discussed above would bring the MS-DRG weights closer to the weights computed using the MedPAC refined methodology. Table 2 illustrates differences between 100 percent cost-based weights calculated by the current method (for DRGs), the MedPAC refined method, the CMS proposed method, and the CMS refined method for six sets of MS-

Table 2: Comparison of methods for computing cost-based weights

MS-DRG (CC level)	Current 2007 Policy (DRGs: no MCC differentiation)	MedPAC Refined (HSRV, hospital CCRs w/ RTI)	CMS proposed method (13 cost centers)	CMS refined method (19 cost centers w/ RTI)
Coronary bypass with cardiac cath				
MS-DRG 233 (with major cc)	5.68	6.87	7.25	7.10
MS-DRG 234 (without major cc)	5.15	4.35	4.58	4.43
Cardiac pacemaker implantation w/o AMI				
MS-DRG 242 (with major cc)	2.83	3.96	3.87	4.07
MS-DRG 243 (with cc)	2.59	2.82	2.69	2.88
MS-DRG 244 (without cc/mcc)	2.31	2.22	2.06	2.23
Cardiac defibrillator implant w/o cardiac cath				
MS-DRG 226 (with major cc)	5.35	7.59	7.16	7.76
MS-DRG 227 (without major cc)	5.35	5.68	5.12	5.73
Major joint replacement or reattachment				
MS-DRG 469 (with major cc)	2.06	3.26	3.24	3.26
MS-DRG 470 (without major cc)	2.06	2.07	2.01	2.04
Diabetes				
MS-DRG 637 (with major cc)	0.81	1.47	1.49	1.49
MS-DRG 638 (with cc)	0.81	0.84	0.84	0.84
MS-DRG 639 (without cc/mcc)	0.81	0.58	0.57	0.57
Pneumonia				
MS-DRG 193 (with major cc)	1.05	1.56	1.53	1.52
MS-DRG 194 (with cc)	1.04	1.07	1.03	1.03
MS-DRG 195 (without cc/mcc)	0.96	0.82	0.77	0.76

Source: MedPAC analysis of Medicare hospital inpatient claims and cost report data from CMS, fiscal year 2003-2005.

Note: Current policy weights may differ among MS-DRG severity classes due to each severity class having cases drawn from a different mix of DRGs (e.g., DRGs with or DRGs without complications). Because all weights were computed using 2003-2005 claims, the CMS proposed weights will differ from the weights that CMS published in the 2008 proposed rule. In the CMS proposed method, only the charges for the 13 cost centers within each MS-DRG are standardized for factors such as the wage index and teaching status. In a refinement of the CMS method, we suggest that the charges and costs used in calculating the national CCRs in 19 cost centers also should be standardized.

DRGs. For MS-DRG 233 (Coronary bypass with cardiac cath), the MedPAC refined method generated a payment weight of 6.87. The CMS proposed method produced a weight of 7.25, while the CMS refined method produced a weight of 7.10. As is true for most (but not all) MS-DRGs, the CMS refined weight is closer to the MedPAC refined weight than the CMS proposed weight.

The MS-DRGs for implantation of cardiac pacemakers (MS-DRGs 242-244) and cardiac defibrillators (MS-DRGs 226 and 227) also illustrate the effect that the RTI refinements have on the weights for cases involving costly devices. The CMS refined weights are all higher than the CMS proposed weights, which primarily reflects the effect of reducing charge compression for costly devices within the supplies revenue center.

Note, however, that the differences between the CMS refined and the CMS proposed weights are much smaller for the major joint replacement groups (MS-DRGs 469 and 470). Although costly devices are used in these DRGs, the smaller differences may reflect offsetting effects from reduced charge compression in the radiology and drugs revenue centers for services that are also used by these patients, such as MRI procedures or IV solutions.

Improvement in payment accuracy—As shown in Figure 1 below, we also used our claim-level estimates of costs and payments to compare payment accuracy (how closely payments track relative costs) for cases grouped in the MS-DRGs under three scenarios in which payments are based on:

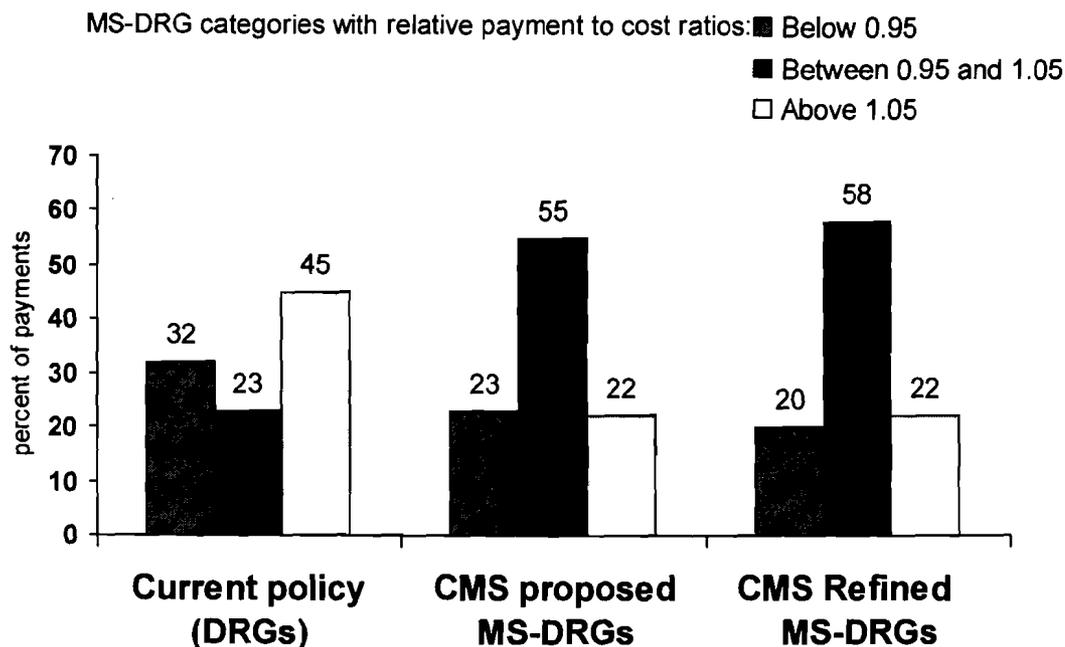
- 2007 DRGs with 100 percent cost-based weights based on CMS's current methods (13 revenue centers);
- Proposed MS-DRGs with cost-based weights based on CMS's current methods; and
- MS-DRGs with CMS refined cost-based weights that incorporate the RTI refinements discussed above (19 revenue centers) and use standardized Medicare charges and costs in the calculation of national average revenue center CCRs.

Payment accuracy increased substantially when moving from the current (DRG-based) payment policy to one based on the MS-DRGs. There was a further small improvement in payment accuracy by moving from the current to the refined method of calculating cost weights. The RTI refinements to the cost weights use more detailed charge data on supplies, drugs, and radiology services, which improves the accuracy of payments for MS-DRGs with significant charges in those revenue centers. Standardizing the Medicare charges and costs used to calculate the national revenue center CCRs also affects the CCRs, especially for routine and intensive care, which improves payment accuracy for MS-DRGs that have a high share of charges for these services.

Under the DRG system, only 23 percent of total payments fall in MS-DRG categories that have payment to cost ratios that are within 5 percent of the national average payment to cost ratio. In the case of proposed MS-DRGs, 55 percent of payments fall in MS-DRGs with payment to cost ratios that are within 5 percent of the national target. If CMS adopted the refined version of the cost-based weights, 58 percent of payments would meet the target for payment accuracy. Accuracy would improve even further if the Congress were to

change the way outlier payments are financed as the commission has recommended. The outlier issue is discussed further in the section on future refinements.

Figure 1. MS-DRGs improve payment accuracy



Note: DRG (diagnosis-related group). The distribution labeled "Current policy" compares the average cost-based payments that would have been made in 2005 based on 100 percent cost-based weights (calculated for DRGs using 13 revenue centers) to their costs. The "CMS proposed" compares payments that would have been made in 2005 if CMS had used 13 revenue centers to estimate costs for the MS-DRGs (this is the method CMS has proposed for 2008). The distribution labeled "CMS refined" compares the payments that would have been made using CMS refined cost-based weights, which incorporate the RTI recommended refinements (19 revenue centers) and standardized national CCRs, applied to MS-DRGs to estimate relative costs of each MS-DRG category. MS-DRG (Medicare severity diagnosis-related group).

Source: MedPAC analysis of Medicare hospital inpatient claims and cost reports from CMS, fiscal years 2003–2005

Balancing the effects of severity refinements and the transition to cost-based weights

As we have argued previously, the payment impacts of adopting significant severity refinements to the DRGs and cost-based weights tend to offset each other to some extent—although if both policies were implemented together, some hospitals would experience substantial changes in payments. It made sense to adopt cost-based weights last year with a transition period because the adoption of major severity refinements was postponed. The transition period helped to reduce swings in payment that would have occurred if cost weights had been fully implemented in 2007 followed by full implementation of severity refinements in 2008.

Now that CMS is proposing to adopt MS-DRGs in 2008, continuation of the transition period for cost-based weights would produce payment swings between 2008 and 2009. Many of the hospitals that benefit from cost-based weights (including small urban and rural hospitals) will see their payments decline under the MS-DRGs. Therefore, some hospitals that saw an increase in their DRG weights and payments in 2007 due to the phase-in of cost-based weights will see a decrease in their weights and payments in 2008, and then a slight increase in 2009 when cost weights are fully phased in. Conversely, many of the hospitals that saw a decrease in weights and payments due to the phase-in of cost-based weights will see their payments increase under MS-DRGs in 2008 and then decline again as the cost-weight transition ends in 2009.

One approach to reduce continued fluctuations in payments would be to move ahead immediately to adopt the MS-DRGs and at the same time end the transition period by adopting 100 percent cost-based weights for fiscal year 2008. Others have argued that adoption of MS-DRGs should be deferred until 2009 and then implemented with a long transition because \$800 to \$900 million in total payments would be redistributed among PPS hospitals. (\$900 million is about 0.9 percent of total PPS payments to hospitals.)

We do not see sufficient cause to delay the proposed adoption of MS-DRGs beyond fiscal year 2008. However, if MS-DRGs were fully implemented in fiscal year 2008, the resulting changes in payments would likely exceed 5 percent up or down for a few hundred hospitals. To smooth the impact, CMS could decide to implement MS-DRGs in 2008 with a transition period. If you choose this path, we think that the transition should coincide with the transition to cost-based weights—that is, implement MS-DRGs over a two-year period beginning in 2008.

A two-year transition could be managed in several ways. One approach that is fairly simple would be to group cases using the MS-DRG grouper beginning in 2008, but then use a blended weight for each category. The blended weight for an MS-DRG would reflect partly the weight that would have been assigned to the cases under prior policies and partly the weight that would be assigned under an MS-DRG system with fully implemented (100 percent) cost-based weights. Thus the weight for each MS-DRG in 2008 would be a blend of two parts:

- 50 percent of the average DRG weight that would have been attached to cases in the MS-DRG from the 2006 MedPAR file under a policy of 1/3 charge-based weights and 2/3 cost-based weights. These are the DRG weights that would have applied to the same cases under fiscal year 2008 policy if CMS simply continued the transition to cost-based weights without changing the DRG definitions; and
- 50 percent of the CMS refined weight for the MS-DRG for fiscal year 2008.

In fiscal year 2009, cases would be grouped in the MS-DRGs and the weight for each MS-DRG would be a 100 percent cost-based weight calculated using fiscal year 2007 MedPAR claims and the CMS refined method.

Correcting for anticipated improvements in hospitals' coding

To maintain budget neutrality while adopting MS-DRGs, CMS has proposed reducing payments by -2.4 percent for two years or -4.8 percent in total. The -4.8 percent reduction is designed to offset increases in total payments that are expected to occur as hospitals improve documentation and coding of comorbidities and complications (secondary diagnoses). The Commission is on record as supporting the need for an adjustment.

Historical experience—The historical experience under Medicare is clear:

- Hospitals have consistently improved documentation and coding when they have had a financial incentive to do so.
- Past prospective adjustments to reduce payments for the effects of expected coding improvements have been consistently lower than the increases in payments that actually occurred as a result of improved case-mix reporting.
- Consequently, hospitals have received higher payments resulting from increases in reported case mix that were not accompanied by increases in their costs of furnishing care.

CMS applied prospective adjustments to the payment rates to offset the effect of improved case-mix reporting when the original PPS system was implemented in fiscal year 1984. Payments were reduced by -3.38 percent for fiscal year 1984.¹ Based on early claims data from the first year of the PPS, payments were reduced an additional -1.05 percent for 1985.² However, later analysis found that these adjustments were substantially smaller than the actual change in case mix, which increased more than 7 percent from the pre-PPS period to the first full year of the PPS system (Steinwald and Dummit, 1989).³ RAND examined changes in case mix during the third year of the PPS system and found that coding improvements continued to lead to increases in case mix and payment over an extended period of time (RAND, 1990).⁴ The Prospective Payment Assessment Commission (a predecessor of MedPAC) considered case-mix change in developing its annual update recommendations to the Congress and made offsetting adjustments for continuing coding improvements for 10 consecutive years from 1986 to 1995. More recently, CMS has had similar experiences with the introduction of prospective payment systems for inpatient rehabilitation facilities (IRF) and long-term care hospitals (LTCH).

¹ See Federal Register, Vol. 48, No. 171, September 1, 1983, p. 39889 and Federal Register, Vol. 49, No. 171, August 31, 1984, p. 34770.

² Federal Register, Vol. 49, No. 171, August 31, 1984, pp. 34770-34775.

³ Steinwald B. and L. Dummit. 1989. "Hospital Case-mix change: Sicker patients or DRG Creep? *Health Affairs*. Summer 1989.

⁴ Rand. 1990. "Methodology for Measuring Case-Mix Change: How much Change in the Case Mix Index is DRG Creep? Report E-90-5 April.

The case-mix increase this time—We have every reason to expect that hospitals will respond to the adoption of MS-DRGs in much the same way as they have responded to similar events in the past. They will improve their documentation and coding of diagnoses and procedures, and this change in behavior will lead to increases in reported case mix. The reason to make offsetting adjustments is also the same. Although hospitals' efforts to improve the specificity and accuracy of documentation and coding are perfectly legitimate, the increases in payments that result are not warranted because the increase in measured case-mix does not reflect any real change in illness severity or the cost of care for the patients being treated. Therefore, offsetting adjustments to the PPS payment rates are needed to protect the Medicare program and those who support it through taxes and premiums from unwarranted increases in spending.

The question is not whether documentation and coding will improve, resulting in higher case mix and payments. The question is how much will coding change when the incentives to code particular secondary diagnoses change with the adoption of MS-DRGs, and how long will these changes continue until hospitals reach a new steady state of reporting accuracy.

The case-mix reporting changes that occurred in Maryland—when that state adopted APR-DRGs in its all payer rate-setting system—provide one of the few recent benchmarks for comparison outside of Medicare's historical experience. The Health Services Cost Review Commission in Maryland began the transition to APR-DRGs in 2000 for major teaching hospitals; this change was not adopted for other hospitals in Maryland until 2005 (although hospitals received training in the new system and began coding for the change in 2004). CMS bases its expected 4.8 percent increase on a comparison of case-mix changes for Maryland hospitals and for all hospitals outside of Maryland during the 2004–2006 period.

No one can definitively predict whether the switch from DRGs to MS-DRGs will lead to case-mix change equal to the change that occurred in Maryland. On the one hand, the APR-DRG system relies on interactions among secondary diagnoses, perhaps making more complete reporting of all secondary diagnoses more important than it may be for the MS-DRG system. Thus, case mix might increase less than the 4.8 percent estimate that CMS derived from Maryland's experience. On the other hand, past experience indicates that it takes several years for hospitals to reach a new steady state of documentation and coding after a new DRG system is implemented. Consequently, over several years, the increase in reported case mix in response to the MS-DRGs might turn out to be more than 4.8 percent.

MedPAC estimates—To examine this issue more thoroughly, we used claims from the MedPAR files for fiscal years 2004–2006 to estimate changes in case mix separately for hospitals in Maryland and in the rest of the nation. For each group, we looked at overall case-mix change for all hospitals and separately for major teaching and all other hospitals. We also examined case-mix change for these groups calculated based on DRGs, MS-DRGs, and APR-DRGs. For each of these systems, we used the weights (described earlier) that we developed to evaluate the MS-DRGs and the alternative methods for calculating cost-based weights.

The resulting estimates of the difference between case-mix growth in Maryland (where hospitals had incentives to improve documentation and coding) and in the rest of the nation

(where hospitals had few incentives to change their practices) vary widely depending on the DRG classification system used. We think that the most important estimates, however, are those based on the MS-DRGs because that is the classification system that CMS is proposing to adopt.

Our estimate based on MS-DRGs is 2.0 percent (over two years). This estimate may not capture the full effect of changes in case-mix reporting, however, for two reasons. One reason, as we mentioned earlier, is that many hospitals do not respond quickly to improve reporting after major changes in the DRG definitions. Consequently, the full effect of reporting improvements may not be felt until three or four years after the adoption of MS-DRGs. The second reason is that the estimated change in case mix for hospitals in the rest of the nation may reflect some improvements in documentation and coding in response to changes in the DRG definitions that were adopted in 2006. These include changes in the definitions of important cardiac care DRGs, among others. To the extent that coding improvements are part of the reported change in case mix for the rest of the nation, the actual difference between case-mix growth in Maryland and growth in the rest of the nation would be larger than the estimate.

So we have two estimates of the effect of changes in case-mix reporting and both are subject to uncertainty. Although our estimate may be too low at 2.0 percent, the CMS estimates may be too high. We think that CMS should adopt an adjustment that lies somewhere in the middle between these two values. A middle point in the range of 1.6 to 1.8 percent per year would put both Medicare and the hospital industry at some risk that the actual value will turn out to be higher or lower than the adjustment that is applied. If the actual increase due to improvements in case-mix reporting turns out to be higher, then the Medicare program will have paid more than it should have. If the actual increase is lower, then the hospitals will have been paid less than they should have received.

Either way, you have already stated your willingness to correct for any forecast error when data become available to estimate the actual effect of improvements in documentation and coding on case mix and payments. Data to make such estimates will first become available in the MedPAR file for fiscal year 2008, which CMS will use in 2009 as it prepares the proposed rule for fiscal year 2010. With this fundamental protection in mind, we recommend that CMS adopt a prospective adjustment in the range of -1.6 to -1.8 percent per year and we suggest that CMS plan on taking coding adjustments for longer than two years. CMS may want to adopt a series of adjustments that takes somewhat higher adjustments in the first few years of the MS-DRG changes, on the assumption that history has shown that previous coding adjustments have underestimated the impact of the changes.

Future refinements to computing DRG payment rates

As we indicated earlier, our analyses suggest several opportunities for additional refinements that we believe should be pursued.

Financing outlier payment—As we stated in our March 2005 report to Congress on physician-owned specialty hospitals, there is a need to reform the financing of outlier

payments. Currently, variation in the prevalence of high-cost outlier cases contributes to disparities in relative profitability across and within DRGs. These disparities can penalize hospitals (usually small urban and rural) that treat patients in DRGs with a low prevalence of outliers. To level the playing field, Congress should amend the law to give the Secretary authority to adjust the DRG relative weights to account for differences by DRG in the prevalence of high-cost outlier cases.

Further refinements to the method of calculating cost weights—In addition, the current method of calculating cost-based weights still results in some distortions that arise from two sources. One source is the practice of standardizing charges. Other distortions result from problems with the specificity and accuracy of the cost data that hospitals submit on their cost reports. Adjusting hospitals' charges by their revenue centers' CCRs removes most of the distortions in relative costliness across types of discharges that occur because hospitals use different markups across services (and have different overall markup levels). Distortions in relative costliness remain, however, because certain types of cases tend to be treated predominately in high- or low-cost hospitals. This results in relative weights that are too high for some types of cases and too low for others.

CMS deals with this problem by standardizing the charges for geographic differences in wage levels (the wage index), differences in teaching activity (the indirect medical education adjustment) and in the extent to which the hospital serves a disproportionate share of low-income patients (the DSH adjustment) before the charges are summed to the national level within each revenue center and MS-DRG. Standardizing by these factors, however, only accounts for part of the variation in the level of costs across hospitals.

In contrast, the HSRV method removes all of the differences in the level of costs across hospitals, regardless of their sources. In this method, we first compare the costs of different types of discharges (MS-DRGs) within each hospital to its average cost per discharge for all Medicare claims to create hospital-specific relative values. We then apply the HSRV method to the relative values to calculate a set of national relative weights for the MS-DRGs (or any other classification system). Converting all costs to relative values first prevents the weight for any case type from being raised or lowered because of where patients in that category happen to be treated.

We find that weights calculated by the HSRV method improve payment accuracy compared with either the current or refined versions of the method now used by CMS. The standardization method now used by CMS is less desirable because it is incomplete and introduces avoidable errors into the computation of payment weights.

Longer-term improvements in the quality of cost data—As indicated in the RTI study report, several other problems need to be addressed to improve the quality of the cost data used to set relative weights under the PPS. One problem is ongoing charge compression. Another problem is substantial mismatches between the charges recorded on the claims by revenue code and the charges reported for the corresponding revenue centers on hospitals' cost reports.

Charge compression exists under the old charge-based weights now being phased out and will continue to persist under the system of cost-based weights. From MedPAC's studies of charging practices, we have learned that hospitals tend to have higher percentage markups on lower cost items and lower percentage markups on higher cost items. As RTI has shown, these systematic differences in markups within a department lead to compressed estimates of the cost of drugs, supplies and devices, and radiology procedures. It is important to note that charge compression results from hospitals' mark-up practices. If each hospital would use a single markup for all items and services included within a revenue center—or better yet, all items and services in all revenue centers—this problem would disappear. Improvements in price transparency may encourage hospitals to move toward more uniform markups, but as long as they continue their historical charging practices, the use of a single departmental cost-to-charge ratio will result in inaccurate cost estimates, understating the costs of high cost items and overstating costs for low cost items.

The RTI regression estimates provide a practical short-term approach to address charge compression in the drugs, supplies, and radiology revenue centers. However, this method does not capture all of the charge compression that occurs at each hospital for the three target revenue centers. Moreover, substantial charge compression (that is undetectable with current data) also may be occurring in other revenue centers, such as cardiology, or in the routine and intensive care revenue centers where nursing costs per day are currently treated as if they were uniform across patient categories.

The RTI report offers a number of recommendations regarding changes to the cost report (such as requiring separate cost centers for devices and implants, MRIs, CTs, IV solutions) and to the MedPAR file that we think would go a long way to improve the quality of the cost data available to CMS. These changes would help improve the accuracy of the relative weights and payments under the PPS. As RTI also indicated, however, better forms and instructions to providers are only part of the solution. CMS also needs to put more emphasis—backed up by more audit resources—on ensuring that hospitals properly fill out their cost reports. This action is needed to substantially reduce the current disparities between the allocation of charges among revenue codes on the claims and their allocation among revenue centers on the cost reports.

Refining the MS-DRGs—CMS will also need to continually refine the MS-DRG categories (as it has DRGs) to reflect changes in technology and practice patterns. In addition, as we mentioned earlier, opportunities exist to selectively refine MS-DRGs to better account for the effects of interactions among secondary diagnoses on the cost of care. Review of the APR-DRGs may reveal instances where some further distinctions within MS-DRGs may reduce variation in costs among cases and improve payment accuracy.

MS-LTC-DRGs

CMS proposes revising the long-term care diagnosis-related groups (LTC-DRGs) to mirror the proposed MS-DRGs for the acute care hospital PPS. We commend CMS for its commitment to improving the accuracy of Medicare payments for long-term care hospital (LTCH) services and believe that the new MS-LTC-DRGs will go a long way toward achieving this goal.

To maintain budget neutrality in adopting MS-LTC-DRGs, CMS has proposed reducing payments by 4.8 percent (-2.4 percent for two years), the same reduction in payments it proposes for acute care hospitals. The reduction is designed to offset increases in total payments expected to occur as hospitals improve documentation and coding of comorbidities and complications under the new classification system. For the acute care hospital PPS, CMS proposes reducing the standardized payment amounts. However, because the LTCH standardized payment amounts have already been set through a different rulemaking process and are effective beginning July 1, 2007, CMS proposes applying the reduction in LTCH payments, beginning October 1, 2007, to the MS-LTC-DRG relative weights rather than to the LTCH standardized payment amounts.

As noted above, the Commission believes that CMS is justified in making some prospective adjustment to payments in anticipation of improved documentation and coding. Reducing the MS-LTC-DRG relative weights is an acceptable method of making this adjustment. We have not made separate estimates of recent case-mix change in LTCHs and so have no direct information to evaluate the appropriateness of your proposed -4.8 percent adjustment. For the reasons described above, however, this estimate may be as much too large for LTCHs as it is for acute care hospitals. Given the level of uncertainty, we think that it would be prudent for you to adopt an adjustment similar to the -1.6 to -1.8 percent adjustment per year that we recommend for the first two years following the adoption of MS-DRGs in the acute care PPS.

CMS has stated its willingness to correct for any forecast error when data become available to estimate the actual effect of improvements in documentation and coding on case mix and payments. Since LTCHs may differ in the extent to which they can make such improvements, CMS should analyze the effects of coding and documentation improvements on LTCH case mix and payments separately from those of acute care hospitals. Data to conduct such analyses will first become available in the MedPAR file for fiscal year 2008.

Hospital-acquired complications

The Deficit Reduction Act of 2005 requires CMS to select at least two hospital-acquired conditions for which hospitals will not receive additional DRG payments for cases when one of the selected conditions applies but was not present on admission. We commend CMS for carrying out a comprehensive review process in consultation with the Centers for Disease Control to identify six conditions proposed for reduced payment in FY 2009 and nine conditions that will be considered for reduced payment in the future.

Method for implementing payment reductions

The six conditions to be used in 2009 include three so-called “never events” (object left in surgery, air embolism, and blood incompatibility), pressure ulcers, and two types of infections. Each of the six conditions is coded as a secondary diagnosis, and under CMS’s proposed MS DRG system can be a complication or co-morbidity (CC) that moves the patient to a higher-weighted DRG. CMS interprets the DRA provision as requiring that “the case will be paid as though the secondary diagnosis was not present.” This means that

if another CC applies, then the patient will still move to the higher-weighted DRG. Although CMS was unable to determine how often its six proposed conditions provide the sole CC, we suspect that it is infrequent. Consequently, payment will be reduced for only a limited proportion of cases with these six conditions.

For the three never events, CMS should adopt a policy that the presence of the identified complication will bar assignment to the higher-weighted MS-DRG regardless of any other CCs that apply. Although this could result in a significant reduction in payment linked in part to unrelated complications, the never events are so grievous and easily preventable that a penalty is always warranted. For the other three conditions, however, an automatic penalty would be inappropriate. Because even the highest quality hospitals will experience at least some potentially preventable complications, a penalty should not be triggered whenever a patient acquires one of the identified conditions. Further, the risk of infection or other potentially preventable condition depends on the complexity and severity of the patients involved. If every patient exhibiting the condition triggered a penalty, hospitals with high case-mix index values under the MS-DRG system would likely suffer greater average losses, which would not be equitable.

For the conditions CMS has identified other than never events—as well as others it will develop in the future—CMS should consider adding an occurrence rate measured with a year's data to the list of measures to be included in its pay-for-performance program. With this approach, hospitals' performance can be risk adjusted to reflect their case mix and payment rewards or penalties will be based on each hospital's performance relative to its peers.

Reporting secondary diagnoses present at admission

CMS states that hospitals will be required to begin coding secondary diagnoses present at admission effective October 1, 2007, as DRA requires. CMS does not, however, detail how this coding process will work or commit to requiring hospitals to code *all* secondary diagnoses present at admission. Ideally, we would like to see hospitals code all secondary diagnoses and whether or not each was present at admission, to support the development of new complication rate measures and other quality indicators in the future. But this goal is constrained by the fact that the hospital claim form accommodates only 8 secondary diagnoses. Therefore, CMS can only require that for every secondary diagnosis the hospital enters as present at discharge, it must also indicate whether the diagnosis was present at admission.

This raises a larger issue. To avoid the possibility of hospitals failing to code secondary diagnosis codes for conditions that could result in lower payments, CMS should require that hospitals code all secondary diagnoses that are part of the logic defining the specified hospital-acquired conditions. This requirement should apply to conditions present at discharge as well as the corresponding code for whether the conditions were present at admission. CMS might also wish to expand the requirement to include the secondary diagnoses required by all quality measures in its pay-for-reporting system.

It is important that the claim form accommodate the secondary diagnoses needed to support MS-DRG assignment, reporting of hospital-acquired conditions, and required quality

measures. Our sense is that the 8 secondary diagnosis positions on the current claim form will be sufficient. But as experience is gained, CMS should monitor the reporting of secondary diagnoses and consider expanding the claim form to accept more than 8 secondary diagnoses if needed.

Data to evaluate potential conditions for reduced payment

In evaluating whether potential hospital-acquired conditions were “high cost” as mandated by the DRA, CMS calculated the average charges of patients who had the condition. For example, you reported that patients with pressure ulcer as a secondary diagnosis had average charges for their hospital stay of \$40,381. But it would be helpful if you provided a reference value for comparison; for example, you could publish the average charges of patients with and without the complication. The accuracy of the comparison might also be helped by controlling for DRG assignment (since the patients with the identified complications will likely be distributed among a number of DRGs) as well as for differences among hospitals in other factors such as teaching intensity and local wage levels.

Hospital wage index

We are proposing a new approach to the hospital wage index in our June report as mandated by Congress in the TRA. As you point out in the proposed rule, the same law requires CMS to consider our recommendation in the FY2009 proposed rule. Our recommendations will simplify the current wage index by automatically adjusting for occupational mix and eliminating exceptions to the calculated wage index—two areas you ask for comment about in this proposed rule. We look forward to working with CMS on wage index reform over the next year.

Reporting of hospital quality data and value-based purchasing

The Commission continues to support CMS’s work toward refining and expanding the set of quality indicators for inpatient acute care. CMS’s proposal to expand the surgical infection set, add a 30-day mortality measure, and add patient experience (HCAHPS) are consistent with priorities the Commission suggested for the hospital measure set in our March 2005 report to the Congress.

Selection of quality measures

The Secretary asked for input on an additional 26 measures that he will consider for “pay for reporting” in FY 2009 and beyond. We encourage the development and application of measures of resource use, such as the 30-day readmission rates that are included in the proposed measure set. Reducing potentially avoidable readmissions should be a part of efforts to increase the value of healthcare because it reduces unnecessary spending for the Medicare program and enhances the quality of care for beneficiaries.

We have some concerns, however, about the choice of length of stay as a resource use measure because it does not necessarily align with improving transitions from the inpatient

The disclosure requirement should include CAHs because there is no clear distinction between the services offered by physician-owned specialty hospitals and CAHs. Most CAHs are non-profit hospitals that provide a range of services to their small rural communities. However, some CAHs are for-profit hospitals, and some offer specialty surgical services. For example, we are aware of one CAH with a hand surgery focus and another with a cardiac catheterization lab. Because CAHs are not restricted in the services they offer, they should have the same disclosure requirements as other hospitals.

Physician ownership in hospitals

CMS plans to adopt a disclosure regulation that requires hospitals to disclose to patients whether they are physician-owned, and if so, the names of physician owners. CMS is seeking comment on whether this should be addressed in the conditions of participation applicable to PPS and critical access hospitals.

All patients at physician-owned hospitals should be informed that the hospital is physician-owned and be provided a list of all physician owners. Physicians should be deemed owners if they directly or indirectly have a beneficial interest in the hospital. For example, if a partnership or a trust owns an interest in the hospital and physicians own interest in the partnership or trust, their ownership should be disclosed. Because small financial interests are thought to affect physician behavior (that is why they are recruited to be investors), even small investments should be reported.

Because there is no clear distinction between the financial incentives associated with operating a for-profit specialty hospital, for-profit traditional hospital, or for-profit critical access hospital, this disclosure requirement should apply to all privately held hospitals. The requirement should be waived for hospitals that are fully owned by publicly traded companies.

Payment for capital-related costs

The proposed rule includes proposals for the update to capital payment rates and elimination of the payment adjustment for hospitals in large urban areas. It requests comments on whether the indirect medical education (IME) and disproportionate share hospital (DSH) adjustments to capital payment rates should be reduced or eliminated.

Elimination of the large urban adjustment

The large urban adjustment increases the capital payment rate for hospitals in large urban areas by 3 percent. The Commission supports the Secretary's proposal to eliminate this adjustment starting in 2008. The Congress equalized the operating base rates of urban and rural hospitals in the MMA, and eliminating the 3 percent add-on for large urban hospitals will similarly equalize the capital base rates. Urban and rural hospitals' overall Medicare margins, reflecting both operating and capital inpatient payments along with payments for outpatient and hospital-based post-acute services, are roughly equal.

CMS-1533-P-346 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Doris Lyons

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Other Health Care Professional

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,800 employees, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGS

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 -- \$24 billion over five years -- to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even

with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS's interim report on the strategic plan required by the Deficit Reduction Act of 2005.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that the change redistributes between \$800 million and \$900 million among hospitals.

CAPITAL PAYMENT UPDATE

The proposed rule would eliminate the capital payment update for all urban hospitals (a 0.8 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). These changes would result in a payment cut of \$880 million over five years to urban hospitals.

We are opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

CMS has gone well beyond its charge by recommending arbitrary and unnecessary cuts in this proposed rule. These backdoor budget cuts will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging.

If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

Sincerely,

Doris Lyons

CMS-1533-P-347 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Victor Vilela

Date & Time: 06/11/2007

Organization : Central New Jersey Brain Tumor Support Group

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

**CMS-1533-P-348 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Wendy Johnson

Date & Time: 06/11/2007

Organization : APIC

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

see attachment

#348

file:///T:/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1533-P-349 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Richard L. Gentile

Date & Time: 06/11/2007

Organization : Mr. Richard L. Gentile

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

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Thank you for your consideration of this important matter!

Richard L. Gentile, PE

CMS-1533-P-350 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Doris Lyons

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Other Health Care Professional

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,800 employees, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed behavioral offset cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGS

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 \$24 billion over five years to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they

own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS's interim report on the strategic plan required by the Deficit Reduction Act of 2005.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that the change redistributes between \$800 million and \$900 million among hospitals.

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We are opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

CMS has gone well beyond its charge by recommending arbitrary and unnecessary cuts in this proposed rule. These backdoor budget cuts will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging.

If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

Sincerely,

Doris Lyons

CMS-1533-P-351 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. dorothy willcoxon

Date & Time: 06/11/2007

Organization : freeman health system

Category : Other Health Care Provider

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

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Our detailed comments are attached. If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

Sincerely,

Dorothy B. Willcoxon
Member of the Board of Directors

CMS-1533-P-352 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Deborah Chiodo

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

Sincerely,
Deborah Chiodo
Director of Human Resources
Freeman Health System
1102 West 32nd St
Joplin MO 64804

dechiodo@freemanhealth.com

**CMS-1533-P-353 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mrs. Joan Gentile

Date & Time: 06/11/2007

Organization : Mrs. Joan Gentile

Category : Individual

Issue Areas/Comments

**DRG Reform and Proposed
MS- DRGs**

DRG Reform and Proposed MS-DRGs

DRG Reform and Proposed MS-DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24 I am a caregiver to a brain tumor patient, who has had two (2) brain tumor surgeries and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23. You propose the following titles for these MS-DRGs: MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC I would like to suggest that the DRGs be restructured so that their titles are the following: MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors. When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!) The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC. Thank you for your consideration of this important matter! Joan Gentile -----

CMS-1533-P-354 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Maryellen Sullivan

Date & Time: 06/11/2007

Organization : Mrs. Maryellen Sullivan

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am both a brain tumor patient and a family member of a patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Sincerely,
Maryellen Sullivan
Dx 2/23/98 Anaplastic Mixed Oligo-Astrocytoma

Submitter : Mrs. Leza Cummins

Date & Time: 06/11/2007

Organization : Written Communications Specialties

Category : Other Health Care Professional

Issue Areas/Comments

**DRG Reform and Proposed
MS- DRGs**

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification of MS-DRG 23 and MS-DRG 24

I am a brain tumor patient who had a craniotomy in November of 2005 that changed my life and the way I am able to live my life forever. I am fighting to increase funding for brain tumor research and all brain tumor related issues so that we can eventually eradicate brain tumors of all kinds that completely change lives to the detriment of those affected by them. I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs,

we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-356 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. William Walters

Date & Time: 06/11/2007

Organization : Acute Long Term Hospital Association

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1533-P-356-Attach-1.PDF



ALPHA, INC.
625 SLATERS LANE
SUITE 302
ALEXANDRIA, VA 22314

PHONE: 703.518.9900
FAX: 703.518.9980
WEBSITE: ALTHA.ORG
INFO@ALTHA.ORG

June 12, 2007

Hon. Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: 42 CFR Parts 411, 412, 413, and 489
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment
Systems and Fiscal Year 2008 Rates

Dear Ms. Norwalk,

This letter presents comments and recommendations of the Acute Long Term Hospital Association (ALTHA) to certain aspects of the proposed transition to Medicare Severity-adjusted Long-Term Care Diagnosis Related Groups (MS-LTC-DRGs), annual relative weight updates, and other policy changes under the prospective payment system for inpatient hospitals (IPPS) for fiscal year (FY) 2008, which were published by the Centers for Medicare & Medicaid Services ("CMS") on May 1, 2007.

ALTHA represents over three hundred long-term acute care hospitals (LTACHs) across the United States. ALTHA member hospitals provide highly specialized care for critically ill patients with multiple, medically complex problems. We are pleased to submit these comments on the proposed regulation.

CMS proposes that the current LTC-DRG system be replaced with a Medicare severity-adjusted long-term care diagnosis-related group (MS-LTC-DRG) system for FY 2008. Under this proposed rule, CMS would impose significant changes in the DRG system to further recognize severity of illness and resource usage by adopting MS-LTC-DRGs. ALTHA supports the adoption of a patient classification system which recognizes differences in patient acuity, however we request CMS consider some modifications to the MS-LTC-DRG as currently proposed. ALTHA offers comments concerning the proposed MS-LTC-DRG system in four areas: (1) the basis for the proposed system; (2) the proposed 2.4 percent downward adjustment associated with adapting to the proposed system; (3) the implementation timeframe for the MS-LTC-DRG system; and (4) the interaction between MS-LTC-DRGs and other aspects of the LTACH PPS which are updated on a rate year (RY) basis. ALTHA is troubled by the speculative nature of the support CMS has set forth in the proposed rule for the 2.4 percent behavioral offset. Our membership believes there are better methods to address CMS' concerns about

how LTACHs will adapt to the new system including (a) a transition period over three years to minimize the impact of any behavioral changes in coding on payment followed by (b) an analysis of the data from that transition period that will provide CMS with concrete evidence of possible coding changes and the magnitude of any adjustment that may need to be imposed prospectively under the system to ensure budget neutrality.

In addition to the submission of this comment letter, ALTHA supports the comments made by the Federation of American Hospitals on the proposed regulation.

General Description of MS-LTC-DRGs

CMS is proposing that, for fiscal year 2008, the current DRG categories will be replaced with MS-LTC-DRGs. CMS states that the new MS-LTC-DRG system will more accurately capture resource utilization by splitting a large number of the current Medicare DRGs into as many as three different DRGs based on the presence or absence of diagnoses categorized as either "major complications or comorbidities" (MCCs), "complications or comorbidities" (CC), or "without MCC/CC (Non-CC)." As a result, CMS is proposing to increase the total number of DRGs from 538 to 745. Within each base DRG there will be one, two, or three severity levels denoted by individual MS-LTC-DRGs. The most severe level has at least one code that has a major complicating condition ("with MCC"). The second severity level contains cases with at least one complicating condition ("with CC"), and the third severity level contains cases without complicating conditions ("without CC/MCC"). Where there does not appear to be a need for three severity levels, the base DRG will be divided into two subdivisions (either "With CC/MCC" and "Without CC/MCC", or "With MCC" and "Without MCC"). LTACH cases will be classified into the appropriate MS-LTC-DRG using version 25.0 of the LTACH GROUPER. As with the current LTC-DRGs, MS-LTC-DRG weights will be applied to the base rate to determine the amount Medicare pays for a case.

Analysis of Proposal to Adopt MS-LTC-DRGs

Under this proposed rule, CMS would impose significant changes in the DRG system to further recognize severity of illness and resource usage by adopting MS-LTC-DRGs. ALTHA supports the intent of the proposal, but asks CMS to consider the following comments concerning the proposed MS-LTC-DRG system prior to finalizing the system: (1) the basis for the proposed system; (2) the proposed adjustment associated with anticipated LTACH coding changes under the proposed system; (3) the implementation timeframe of an MS-LTC-DRG system; and (4) the interaction between MS-LTC-DRGs and other parts of the LTACH PPS usually updated on an LTACH rate year basis. ALTHA does not support the prospective 2.4 percent downward adjustment to the MS-LTC-DRG weights that CMS proposes. Our membership believes there are better methods to address CMS' concerns about the impact of coding under the new system including (a) a transition period over three years to minimize the impact of any behavioral changes in coding on payment followed by (b) an analysis of the data from that transition period that will provide CMS with concrete evidence of such coding changes and the magnitude of any adjustment that may need to be imposed prospectively under the system to ensure budget neutrality once the transition to the new system has been completed.

(1) Basis for Proposed System

(a) At present a lack of available tools to analyze the MS-LTC-DRG system will limit meaningful comments by ALTHA

ALTHA finds the adoption of any aspect of MS-LTC-DRGs during FY 2008 to be problematic due to the lack of access to the necessary tools to fully evaluate the impact of the proposed system on ALTHA's member hospitals. Since the publication of the proposed regulation, no MS-LTC-DRG grouper or MS-LTC-DRG definition manual have been made available to the public. The availability of the grouper or a definition manual would provide valuable information as to the formation and details of the proposed system. CMS has advised ALTHA that the grouper and definition manual is in draft format and will not be available until this fall, well after the deadline for submission of comments.

Without a grouper or a definition manual, ALTHA member hospitals are unable to *fully* understand, evaluate, or analyze the specifics related to the assignment of their cases to MS-LTC-DRGs and evaluate the aggregate changes to Medicare revenues. For example, the primary purpose of a definition manual is to provide a description of patient attributes, including a complete listing of all the ICD-9-CM diagnosis or procedure codes that define each DRG. When additional patient characteristics are used within the DRG assignment such as discharge status, this should be clearly delineated within the definition manual. An available grouper would allow LTACHs to analyze cases individually as well as at the DRG level. Using CMS administrative data, such as MedPAR, to assess the impact of the proposed system can only provide a close approximation of the actual results; MedPAR cannot replace a grouper, especially given the limitations of the available number of diagnoses codes in MedPAR. ALTHA finds that the unavailability of the grouper and the definition manual has prevented its members from thoroughly and completely evaluating the proposed system and providing meaningful comments. We provide comments in section 3 on an implementation timeframe which would provide sufficient time for ALTHA members to analyze the impact of the MS-LTC-DRG system once the grouper and manual become available.

In its FY 2007 Inpatient Prospective Payment System Proposed rule, CMS proposed the consolidated severity-adjusted (CSA) DRG System developed by 3M Corporation. As in this rulemaking, none of the underlying support for that system was available to the public because it was still in draft form. ALTHA commented last year that it was inappropriate to propose a system that was not sufficiently developed for meaningful public comment. ALTHA commends CMS for its decision last year not to go forward with the CSA DRG system absent concrete information that would allow industry testing of the new system.

(b) ALTHA does not support the use of MS-LTC-DRGs as a transition system.

We commend CMS' efforts to analyze several different severity-adjusted systems in order to create a LTC-DRG system that will better recognize severity of illness in this population. However, as CMS notes in the proposed rule, these studies are not yet finished. RAND has not completed its evaluation of alternative severity-adjusted DRG systems, and CMS states in the proposed rule that even though CMS proposes to adopt the MS-LTC-DRG system for FY2008, such decision would not preclude CMS from adopting any of the systems being evaluated by RAND for FY2009.

The potential that an alternative system could be recommended for FY2009 is alarming to ALTHA. Implementing a newly refined DRG system is a change of major proportions. ALTHA views the possibility that this could occur twice within a year to create unnecessary burdens on the operations and information systems of its members, who are already dealing with significant regulatory changes such as the adoption of the 25 percent rule for all LTACHs, the payment cut for certain short-stay outlier cases, and the large increase in the fixed loss amount for high-cost outliers. From an operations and resource efficiency perspective, there does not seem to be grounds for CMS to require the adoption of a system envisioned to exist for a single year. ALTHA strongly recommends the completion of the RAND study, including the analysis of the MS-LTC-DRG system, prior to any CMS recommendation being made so that *one and only one* transition will be made to a severity adjusted DRG classification system. Because of this concern ALTHA proposes an alternative timeframe for implementation, set forth below, with a delayed implementation of a final system commencing with FY 2009.

Given that the proposed MS-LTC-DRG system is under study by RAND, and similarly lacking in public disclosure of the underlying system support, ALTHA renews its comment from last year that it is premature to implement a system that cannot be fully analyzed by LTACHs in advance of becoming final.

(2) Prospective 2.4 percent Downward Adjustment to MS-LTC-DRGs

(a) ALTHA does not support the use of prospective adjustment to MS-LTC-DRG weights to account for coding changes in advance of the implementation of the new system.

CMS proposes to reduce the MS-LTC-DRG weights by 2.4 percent in each of FYs 2008 and 2009 for coding changes CMS predicts will happen with the implementation of its proposed MS-LTC-DRG system. CMS bases this proposal to reduce payments on data that were insufficiently explained in the proposed rule to support a conclusion that LTACHs would or could change their coding practices in response to the CMS proposal to modify existing DRGs to account for severity of illness by 2.4 percent each year. The underlying system of classifying patients and the rules for coding are quite extensive and do not necessarily vary depending on the patient classification system used. Thus, it is not a foregone conclusion that LTACHs will perceptively change classification and coding practices.

ALTHA is concerned that CMS is acting too hastily in moving forward with this system and has not completed its analysis or provided sufficient justification to impose, in advance of the implementation, \$70 million in LTACH payment cuts in the first year alone. These cuts, referred to as "behavioral offsets", are imposed without CMS making public the data to support their assumptions regarding anticipated coding practice changes. Without sufficient data presented in the proposed rule, it is challenging to respond to this estimate with meaningful comments.

ALTHA recommends that CMS delay the implementation of any adjustment to account for coding changes until after the transition to the proposed system has occurred, and to base all adjustments on actual coding change experience.

(b) ALTHA finds that the 2.4 percent downward adjustment for expected coding changes is inapplicable to certain MS-LTC-DRGs.

In this rule, CMS proposes to apply the 2.4 percent reduction factor to every MS-LTC-DRG weight, even in instances where the agency is not making changes to patient classifications. However, this proposal appears to not take into consideration the fact that certain MS-LTC-DRGs were changed during last year's rulemaking and no new changes are proposed this year. As a result, ALTHA believes CMS's assumption that LTACHs will make coding changes in response to this year's proposed changes for those DRGs – and therefore should experience a 2.4 percent payment reduction – is not supported.

In constructing the proposed MS-LTC-DRG system, CMS created additional categories of patient classification for certain kinds of patients. In some instances, within a single base MS-LTC-DRG, there are three separate MS-LTC-DRGs – for patients without any complications, for patients with complications, and for patients with major complications.

However, for many MS-LTC-DRGs there are the same number of subclassifications under the proposed system as exist under the current system. For example, there are currently two LTC-DRGs for patients on ventilators, LTC-DRGs 565 and 566. Under the proposed MS-LTC-DRG system, there are also two groups to which ventilator patients may be assigned. In this example, there is no new patient classification group that ventilator patients could be classified into because changes to LTC-DRGs were made last year and no new changes are proposed in this proposed rule. For ventilator patients, the classification groups laid out in this rule do not represent a change from past classification groups and would therefore not be expected to lead to a change in the overall distribution of patients across both ventilator groups. Therefore, there does not seem to be any basis for applying a 2.4 percent adjustment to the weight for these DRGs. This logic is applicable to other conditions where currently there is the same number of classification groups as are proposed under the MS-LTC-DRG system. In the rule, CMS is proposing to reduce payments by 2.4 percent for these patients when the MS-LTC-DRGs groups are not set up to so that one would expect a change in the distribution of patients into different (higher) classification groups. In essence, CMS would be imposing a payment penalty for these cases.

ALTHA asks CMS to not apply an adjustment to any MS-LTC-DRGs where the number of patient classification groups is unchanged relative to the current LTC-DRG system, because there is no real expectation that the distribution of cases would change across those groups. In addition, ALTHA recommends that any adjustment for coding changes reflects actual experience, rather than the 2.4 percent proxy amount and that such adjustment be applied only after the full transition.

(c) ALTHA finds that the application of the 2.4 percent coding adjustment to MS-LTC-DRGs which have experienced a reduction in relative weight is illogical

In the rule, CMS proposes to apply the 2.4 percent coding adjustment to MS-LTC-DRG weights that decrease. The application of a behavior offset to MS-LTC-DRG weights that have lower reimbursements under the proposed system versus the current system makes no sense, as the coding adjustment is designed to address an expectation of overall higher payments to LTACHs. For example, for DRG 88, Chronic Obstructive Pulmonary Disease, the weights would decline under the proposal for a majority of cases, according to tables released in the rule (cases that code into MS-LTC-DRGs 191

and 192). However, CMS proposes to reduce payment for these cases because of the agency's expectation that otherwise payments to LTACHs would increase under the new system. In fact every instance of a patient being classified into those MS-LTC-DRGs represents would lead to a reduction in payments by Medicare versus the current system. Therefore, ALTHA cannot support the application of a 2.4 percent downward adjustment to those DRG weights.

This example highlights the uncertainty of what effect the transition to the MS-LTC-DRG system might have on patient distribution across the MS-LTC-DRGs and on overall payments to LTACHs. It further supports ALTHA's recommendation that CMS delay any adjustment to the relative weights, and that such adjustment be based on actual experience, not conjecture.

(d) The recalibration of the relative weights to include the downward 2.4 percent adjustment leads to large payment swings within DRGs.

Furthermore, the prospective 2.4 percent coding adjustment exacerbates large payment cuts for some DRGS brought about by the new weights assigned to the MS-LTC-DRGs. Analysis of potential changes in payment under the new system (performed by modeling the new MS-DRG system using MedPAR 2005 and the information CMS provided in the proposed rule) reveals several dramatic changes in Medicare payments for cases in 2008 in comparison to similar payments made for those cases in 2007. For the ten base MS-LTC-DRGs with the most cases in 2006 (see Table 1), the change in payments range from over a quarter reduction in some cases to a 30 percent increase in others. For example, in 2006 Skin Ulcers (Base MS-DRG 592) was the second most common diagnosis in LTACHs. With the breakdown into the new MS-LTC-DRGs, CMS proposes to cut payments for seven percent of cases in this group by 22 percent and nearly half of cases by 11 percent, while increasing payments for the remaining cases by 11 percent. Similarly large payment changes are found throughout the new system, with 50 percentage point payment changes not uncommon.

Table 1: Typical Reimbursement Changes for the 10 Most Common LTC-DRGs¹

2007 LTC-DRG	2007 DRG Description	Base MS-LTC-DRG	MS-LTC-DRG	MS-LTC-DRG Description	2007 Reimbursement	2008 Reimbursement	% Change 2007 - 2008
565	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT 96+ HOURS	207	207	RESPIRATORY SYSTEM DIAGNOSIS W VENTILATOR SUPPORT 96+ HOURS	\$776,957,567	\$755,926,804	-2.7%
271	SKIN ULCERS	592	592	SKIN ULCERS W MCC	\$90,610,801	\$100,769,138	11.2%
271	SKIN ULCERS	592	593	SKIN ULCERS W CC	\$23,400,422	\$20,811,994	-11.1%
271	SKIN ULCERS	592	594	SKIN ULCERS W/O CC/MCC	\$36,169,616	\$28,161,974	-22.1%
87	PULMONARY EDEMA & RESPIRATORY FAILURE	189	189	PULMONARY EDEMA & RESPIRATORY FAILURE	\$142,227,600	\$132,546,488	-6.8%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	177	177	RESPIRATORY INFECTIONS & INFLAMMATIONS W MCC	\$120,347,384	\$126,718,332	5.3%

¹ Table I results derived from published tables at www.cms.hhs.gov and from MedPAR 2005 data. Analysis compares expected payments to LTACHs by DRG under the current system vs. the proposed system.

79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	177	178	RESPIRATORY INFECTIONS & INFLAMMATIONS W CC	\$1,179,573	\$1,050,190	-11.0%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	177	179	RESPIRATORY INFECTIONS & INFLAMMATIONS W/O CC/MCC	\$15,699,398	\$11,610,371	-26.0%
80	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	177	177	RESPIRATORY INFECTIONS & INFLAMMATIONS W MCC	\$1,177,324	\$1,531,777	30.1%
80	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	177	178	RESPIRATORY INFECTIONS & INFLAMMATIONS W CC	\$83,004	\$92,846	11.9%
80	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	177	179	RESPIRATORY INFECTIONS & INFLAMMATIONS W/O CC/MCC	\$266,346	\$248,868	-6.6%
576	SEPTICEMIA W/O MV 96+ HOURS AGE >17	871	871	SEPTICEMIA W/O MV 96+ HOURS W MCC	\$46,791,604	\$49,516,797	5.8%
576	SEPTICEMIA W/O MV 96+ HOURS AGE >17	871	872	SEPTICEMIA W/O MV 96+ HOURS W/O MCC	\$57,310,419	\$47,781,986	-16.6%

ALTHA feels that, given the expected cuts to high volume DRGs, LTACH providers will experience a general decline in payments and that these changes will be an extreme hardship on LTACH providers, thereby compromising providers' ability to deliver high quality care to Medicare beneficiaries.

Significant year-to-year changes in payments, whether the result of weight adjustments or other payment policy changes, can make it difficult for Medicare providers to plan for the future. This is particularly true for rural and other low-volume LTACHs. In this uncertain environment, it can be challenging for providers to effectively operate their facilities and maintain the highest quality of care for their Medicare patients. For many providers, the adoption of the MS-LTC-DRG system will result in an expected reduction in Medicare payments (see Table 2 below). ALTHA recommends delaying any adjustment to the relative weights for coding changes until after the full three-year transition (as described below) as a means for smoothing out the payment changes LTACHs will experience.

Table 2: Expected Reduction in Medicare Payments by Revenue Level and Number of Cases²

Revenues		Expected Reduction in Payments
	LTACHs with Revenues <\$10 million	-2.3%
	LTACHs with Revenues >\$10 million	-1.6%
Cases		Expected Reduction in Payments
	<200 Cases	-2.4%
	>200	-1.9%
	<500	-2.1%
	>500	-2.0%
	<1000	-2.1%
	>1000	-1.7%

² Data on LTACH number of cases and annual revenue from MedPAR 2005; expected reimbursement levels derived from tables at www.cms.hhs.gov. Analysis compares annual revenues by LTACH characteristic under the current patient classification system versus the proposed system.

ALTHA asks CMS to consider the effect of the downward coding adjustment on LTACHs and recommends the agency apply only an adjustment necessary to maintain budget neutrality after the full transition to the MS-LTC-DRG system.

(d) The CMS proposal would penalize LTACHs twice for the same case-mix changes.

CMS recently finalized a reduced market basket update for LTACHs for RY 2008 of 0.71 percent. The stated rationale for this policy was that there has not been an "actual" increase in case-mix for LTACH patients, but instead CMS asserts that there has been an "apparent" increase in case-mix due to changes in coding practices. Accordingly, CMS claims that LTACHs have not experienced cost increases that would justify paying LTACHs a full market basket to account for the increase in the cost of inputs purchased by health care providers. ALTHA is very concerned that this rationale for finalizing the policy for a reduced market basket for LTACHs is the exact same rationale that the non-budget neutral DRG re-weighting is designed to address. Specifically, individual DRG weights go down under CMS' methodology if costs in that particular DRG do not increase commensurate with the payment weight. If, as CMS asserts, actual case-mix does not increase, then DRG weights will be adjusted accordingly. As a result, CMS has made two payment adjustments for LTACHs in the same rate year for the same purpose.

CMS maintains that the adjustment to the market basket update is for retrospective adjustments to past case-mix changes, while the update to the annual weights (now done in a budget neutral manner) is to adjust prospective payments for the following fiscal year. In fact, the reduction in the market basket update has a prospective effect, in that it prospectively reduces the base rate. This prospective effect is permanent in nature, reducing payments to LTACHs not only in the next rate year, but in all subsequent years. Thus the effect of the CMI adjustment to the market basket of 2.49 percent is applicable to payments in RY 2008 and each rate year thereafter. For CMS to apply an additional coding adjustment factor of 2.4 percent, or any actual adjustment that is born out by retrospective analyses after the full transition, to payments to LTACHs in future years is redundant.

Recommendation

Lacking clear and convincing evidence that MS-LTC-DRGs and the new CC and MCC lists will lead to the coding changes CMS suggests may occur the more prudent course would be to wait until the system is in place and an empirical analysis can be conducted using actual claims experience. Allowing the new system to transition to full implementation over a three-year period, as suggested in more detail below, with a ramped blending of the current and proposed systems would protect CMS in the event of some level of changed coding behavior under the new system, while providing CMS with a perfect benchmark on coding behavior as it can compare for each claim coding under the current and proposed systems. Appropriate payment adjustments can then be made on the basis of experience rather than conjecture.

In addition, ALTHA recommends that CMS conduct an analysis of the proposed implementation of the MS-LTC-DRG system, and in particular of the proposed coding adjustment, on LTACH payment adequacy. In the past 12 months, CMS has lowered payment rates to LTACHs on multiple occasions, creating revenue instability for these providers. Specifically, LTACHs have experienced:

Description of Regulatory Change	Expected Impact on Revenues
Policy Changes for RY 2007	-3.7%
Inflation Not Compensated for by Market Basket Update for RY 2007	-3.4%
Non Budget Neutral LTC-DRG Reweighting for FY 2007	-1.3%
Policy Changes for RY 2008	-3.8%
Inflation Not Compensated for by Market Basket Update for RY 2007	-3.2%
Total Changes Within Past 12 Months	-15.4%

ALTHA has conducted preliminary analyses which suggest that the combined impacts of these recent CMS payment changes will be significantly reduced LTACH payments below costs. Since we believe that overall Medicare payment adequacy is necessary to ensuring Medicare beneficiaries access to high-quality care, we respectfully recommend that CMS delay implementing the coding change adjustment to the MS-LTC-DRG weights until the agency has assessed the combined effects of the proposed reweighting with other recent payment policy changes on the overall adequacy of Medicare payments to LTACHs. CMS should account for any effect of the reductions in market basket for RY 2007 and RY 2008 in calculating the behavioral offset amount to be applied after the transition period to the new DRG system, since both of those adjustments were for the same case-mix changes.

If CMS chooses to implement a coding adjustment to the MS-LTC-DRG relative weights, CMS should make such an adjustment only after the transition to the MS-LTC-DRG system has taken place, and the agency has actual data on what coding changes have occurred.

ALTHA and its membership lauds CMS initiatives to develop a system in the public domain that increases the payment efficiency of the acute care PPS system. We believe with some work, the MS-LTC-DRG system contained within the proposed rule will be such a system. However, ALTHA strongly urges that implementation of such a system be delayed until FY 2009, assuming the problems addressed herein can be resolved by early in FY 2008 for the reasons set forth above and in summary below.

(3) Alternative Implementation Timeframe

In the proposed rule, CMS laid out a timeframe for implementation of the MS-LTC-DRG system with an immediate transition beginning in FY 2008 for all LTACH providers.

Recommendation

ALTHA recommends that CMS use the following schedule, as it would lead to an orderly transition to as MS-LTC-DRG system by FY 2009.

- a. September – October 2007

Once RAND completes its work the RAND Report should be made available to the public, along with a grouper and definition manual. As soon as these materials are available, CMS should issue an Interim Final Rule for the MS-LTC-DRG system with an October 1, 2008 effective date. The Interim Final Rule should contain a comment period of 90 days to allow a full and complete interchange of relevant

information

b. March 2008

CMS should issue a response to comments and a final rule with any relevant changes responsive to public comments. This would give the industry six full months to put systems in place and train personnel to properly code under the new system for claims that will begin to be submitted shortly after October 1, 2008.

Second, the MS-LTC-DRG system should be transitioned over a three-year period, with a blend of 1/3 MS-LTC-DRG weights and 2/3 current DRG weights in FY 2009, and 2/3 MS-LTC-DRG weights and 1/3 current DRG weights in FY 2010, before the system is 100 percent MS-LTC-DRG in FY 2011.

Our analysis indicates that the MS-LTC-DRG system would negatively impact 7 percent of LTACHs who would experience more than a 5 percent payment reduction next year. Many of these LTACHs are low-volume with little ability to recoup these losses in other areas. That is too large a reduction for most LTACHs to absorb with short notice, especially when considering this policy change in light of the numerous payment reductions in recent years, as described above. In Table 3 below, we demonstrate the typical effect of an immediate transition to the MS-LTC-DRG, and ask CMS to consider providing LTACHs with a three year transition to the new system beginning in FY 2009 to give LTACHs time to adjust to the new system and mitigate the first year effect.

Table 3: Typical 1-Year Reductions for LTACHs under the MS-LTC-DRG system³

Hospital	2007 Reimbursement	2008 Reimbursement	% Change 07-08
A	\$7,108,118	\$7,042,956	-0.9%
B	\$6,333,921	\$6,317,671	-0.3%
C	\$7,377,946	\$7,143,044	-3.2%
D	\$11,298,136	\$10,920,264	-3.3%
E	\$6,722,833	\$6,689,858	-0.5%
F	\$152,423	\$144,267	-5.4%
G	\$5,203,173	\$5,084,413	-2.3%
H	\$1,385,034	\$1,262,557	-8.8%
I	\$16,322,209	\$16,520,844	1.2%
J	\$9,286,437	\$9,014,511	-2.9%

Third, such a transition would allow CMS to monitor coding behavior under the two systems concurrently to determine whether an adjustment is necessary to maintain budget neutrality and the direction and magnitude of any such adjustment. Thus, CMS should consider delaying implementation of a behavioral adjustment until FY 2011, when it has at least two years of data on actual coding behavior under the new system. The magnitude of the adjustment proposed by CMS in the current rule is simply too large to be based on guesswork.

³ Data on the effect of the proposed system on individual LTACHs comes from tables at www.cms.hhs.gov applied to data from MedPAR 2005.

The effect of such reductions would be widespread and will disrupt hospitals' ability to meet long-term financial obligations associated with capital expenditures. Hospital capital investments occur in cycles – some as long as 15-20 years. The payment system was designed to permit variation in capital costs by funding at a level that allows hospitals to establish funds in anticipation of future capital expenditures. As a result, capital payments would exceed costs in some years, and would be below costs in other years.

Hospitals rely on Medicare capital payments as a stable source of income to finance current or future capital investments. We believe that the CMS justification for the cuts, based on analysis of hospital margins for the period 1996-2004, is not relevant for adjusting capital payments in FY 2008, as proposed.

Further, we are very concerned about the effects of significant capital payment reductions on adoption and use of technology advances. We note that the proposed cuts are targeted at large urban and teaching hospitals where much of technology innovation, early adoption and research take place. Moreover, at a time when Congress and the Administration are encouraging the adoption of health information technology, the proposed cuts present seemingly opposite financial incentives for the building of health information infrastructure to support such initiatives.

Value-based Purchasing and Quality Initiatives

As we have stated in previous comments, **GEHC fully supports CMS efforts to incorporate value-based purchasing (VBP) measures into its reimbursement processes.** We continue to believe that any VBP system should be evidence based, deploying clinical data captured by electronic medical record systems. Further, we believe that interoperable health information technology will play an important role in these initiatives.

In the proposed rule, CMS proposes the addition of five new quality measures to the Hospital Quality Alliance (HQA) public reporting initiative. To receive the full market basket update, hospitals would be required to submit data for all HQA measures beginning on January 1, 2008. GEHC supports the adoption of these additional measures. Further, we urge CMS to provide a mechanism for hospitals (and their software vendors) to resubmit quality measure data in the event that they become aware of an error in reporting. In this way, CMS can be assured of accurate reporting for the agency as well as the public.

Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,



Michael S. Becker
General Manager, Global Reimbursement

**CMS-1533-P-357 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Michael Becker

Date & Time: 06/11/2007

Organization : GE Healthcare

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-357-Attach-1.PDF



GE Healthcare

Michael S. Becker
General Manager, Reimbursement

3000 N. Grandview Blvd., W-400
Waukesha, WI 53188

T 262-548-2088
F 262-544-3573
michael.becker@med.ge.com

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1533-P

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Payment Rates; Proposed Rule

Dear Ms. Norwalk:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare hospital inpatient prospective payment system for fiscal year (FY) 2008 (*Federal Register*, Vol. 72, No. 85, May 3, 2007). Our comments focus on the following issues:

- Proposed MS-DRGs
- Recalibration of DRG Weights
- Behavioral Offset Reduction to the Payment Rates
- Capital Payment Update
- Value-based Purchasing and Quality Initiatives

GE Healthcare is a \$17 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery and biopharmaceuticals manufacturing technologies. GE Healthcare's broad range of products and services enable healthcare providers to better diagnose and treat cancer, heart disease, neurological diseases and other conditions earlier. Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

Our detailed comments follow.

Proposed MS-DRGs

For FY 2008, CMS proposes to refine the existing DRG system to implement Medicare Severity DRGs (MS-DRGs), thereby increasing the number of DRGs from 538 to 745. Included are significant modifications to the current complication and comorbidity (CC) list. **GEHC believes that the MS-DRGs are an effective approach for incorporating greater refinement to reflect variation in patient severity and its associated costs.** We encourage CMS to pursue implementation of MS-DRGs.

We urge CMS to take the necessary measures to ensure that the agency and hospitals are adequately prepared for this significant reform. **Specifically, GEHC recommends that CMS adopt the MS-DRGs over a pre-determined transition period, with the first year dedicated to adequate preparation and system testing.** This approach recognizes the potential disruptive nature of changes in the DRG classification system – a change that will redistribute \$800-900 million in payments among hospitals. Moreover, the shift to MS-DRGs will occur at a time when hospitals are adjusting to other major changes including implementation of additional quality measures and potential coding system reforms. A transition plan will also allow software vendors, such as GEHC, the time needed to incorporate, test and implement case classification and payment changes into hospital information systems. Following this one-year preparation, we recommend that CMS begin phase-in of the new system over a two- to three-year period.

Recognizing the significant resources that are required to implement a new system, as outlined above, **GEHC does not support an approach wherein CMS would adopt one severity system for FY 2008, and then change to another severity system in FY 2009.** Should the RAND analysis of alternative classification systems yield useful information, we urge CMS to consider its findings in the context of future refinements to the MS-DRG system.

GEHC also appreciates measures taken by CMS to provide for the MS-DRG classification system in the public domain and to not adopt a proprietary severity-adjusted DRG system. As we have commented previously, we believe that creating a system that is transparent and non-proprietary is critical to successful implementation and long-term sustainability. We urge CMS to continue to preserve this priority as it implements changes to the DRG system.

Recalibration of DRG Weights

In FY 2007, CMS began a three-year transition to DRG weights based on hospital cost data. The purpose of this change was to more accurately reflect differences in relative resource use across DRGs. During this transition, two key issues have arisen however. First, use of two different data sources used to establish the cost-based weights (MedPAR files and MCR files) could distort the weights. Second, differences in hospital mark-up practices can also result in distortion, often referred to as “charge compression”.

To address the charge compression issue, CMS contracted with Research Triangle Institute International (RTI) to examine hospital cost and charge data and to identify methods for improving the data used to develop cost-based DRG weights. Among the RTI recommendations was expansion of the cost center groupings from 13 to 19, as well as a temporary or permanent regression-based adjustment to address underlying concerns with the cost report data.

GEHC strongly recommends that CMS refrain from applying any regression-based or other adjustments to the DRG weights for radiology services in FY 2008. Hospital practices vary in the ways in which they categorize charges and costs into departments on the cost reports. Moreover, methods for allocating costs, including fixed plant and equipment costs vary considerably from hospital to hospital. We are concerned about the RTI study findings and any resulting adjustments involving radiology services given the complex nature of accounting for these capital-intensive costs and charges. Further analysis and refinement of the RTI findings, as well as improvements in use of the two data sources, are needed before moving forward.

Behavioral Offset Reduction to the Payment Rates

The proposed rule includes a 2.4 percent reduction in FY 2008 and 2009 payments to offset the anticipated effect of coding and classification changes that are not associated with real changes in case mix, but rather are the result of reporting practices by hospitals in response to the MS-DRG system. **GEHC opposes the proposed 2.4 percent reduction in payments in FY 2008 and 2009 as an adjustment for anticipated changes in hospital coding practices.**

It is important to note that the proposed MS-DRG system represents a refinement to a system that has been in operation since the mid 1980s. CMS has not presented evidence sufficient to justify a downward adjustment of 4.8 percent over the next two years. In fact, even upon the implementation of the inpatient DRG system more than 20 years ago, studies indicated that only 0.8 percent growth in case mix was due to coding during that time. Moreover, we believe that the experience with the Maryland system reflects a significantly different payment transition and does not justify the proposed adjustment.

Once the MS-DRGs are fully implemented, CMS can evaluate the underlying causes of case-mix change and determine the degree to which coding, rather than patient severity contributed to increases in case mix. CMS has full discretion to adjust payments at a later date to account for coding influences, once sufficient evidence is available to justify such an adjustment.

Capital Payment Update

CMS proposes to eliminate the 0.8 percent capital payment update for all urban hospitals, as well as the large urban hospital add-on payment. These reductions would amount to a decrease in capital payments of \$880 million over the next five years for these facilities. **GEHC opposes reductions in the capital payment levels for urban hospitals, as proposed by CMS.**

The effect of such reductions would be widespread and will disrupt hospitals' ability to meet long-term financial obligations associated with capital expenditures. Hospital capital investments occur in cycles – some as long as 15-20 years. The payment system was designed to permit variation in capital costs by funding at a level that allows hospitals to establish funds in anticipation of future capital expenditures. As a result, capital payments would exceed costs in some years, and would be below costs in other years.

Hospitals rely on Medicare capital payments as a stable source of income to finance current or future capital investments. We believe that the CMS justification for the cuts, based on analysis of hospital margins for the period 1996-2004, is not relevant for adjusting capital payments in FY 2008, as proposed.

Further, we are very concerned about the effects of significant capital payment reductions on adoption and use of technology advances. We note that the proposed cuts are targeted at large urban and teaching hospitals where much of technology innovation, early adoption and research take place. Moreover, at a time when Congress and the Administration are encouraging the adoption of health information technology, the proposed cuts present seemingly opposite financial incentives for the building of health information infrastructure to support such initiatives.

Value-based Purchasing and Quality Initiatives

As we have stated in previous comments, **GEHC fully supports CMS efforts to incorporate value-based purchasing (VBP) measures into its reimbursement processes.** We continue to believe that any VBP system should be evidence based, deploying clinical data captured by electronic medical record systems. Further, we believe that interoperable health information technology will play an important role in these initiatives.

In the proposed rule, CMS proposes the addition of five new quality measures to the Hospital Quality Alliance (HQA) public reporting initiative. To receive the full market basket update, hospitals would be required to submit data for all HQA measures beginning on January 1, 2008. GEHC supports the adoption of these additional measures. Further, we urge CMS to provide a mechanism for hospitals (and their software vendors) to resubmit quality measure data in the event that they become aware of an error in reporting. In this way, CMS can be assured of accurate reporting for the agency as well as the public.

Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,



Michael S. Becker
General Manager, Global Reimbursement

**CMS-1533-P-358 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Fred Kagarise

Date & Time: 06/11/2007

Organization : MidMichigan Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1533-P-358-Attach-1.DOC

MidMichigan Health

June 11, 2007

Centers for Medicare and Medicaid Services
Leslie Norwalk, Acting Administrator
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-1850

**RE: FY 2008 Medicare Inpatient Prospective Payment System Proposed Rule
CMS-1533-P**

On behalf of MidMichigan Health and MidMichigan Medical Center – Midland, MidMichigan Medical Center – Gladwin, MidMichigan Medical Center – Clare, and Gratiot Medical Center, providers of inpatient hospital services to Medicare Beneficiaries, I am submitting these comments on the proposed rule.

Addendum, II D (2)(a) Calculation of Hospital-Specific Rate & DRG Weighting Changes

Nowhere in the Proposed Rule addresses the impact of the DRG grouping and weighting changes on the Hospital-Specific rates. These Rates were established under the prior framework of DRG weighting logic. The actual Medicare cost was matched to the Case Mix specific to an individual hospital's patients. This Proposal disconnects this matching by not allowing the Hospital-Specific DRG Rate to float against the new Case Mix that would be created. The analysis for the change in grouping logic and weighting as cited shows rural hospitals will have reduced case mixes from this process. The revisions to the grouping and weighting has no impact on the underlying costs of an MDH or SCP. So, as part of the change to a new grouping and weighting, the Hospital-Specific DRG Rates should be held-harmless for the changes. If a hospital's average case mix decreases as a result of the new weighting and grouping, the Hospital-Specific DRG Rate should be adjusted up to compensate. This adjustment is justified because of the entire revision in the grouping and resulting weighting for DRGs from the one used to establish these Hospital-Specific rates. This adjustment should be prospectively set using the old and new grouping and weights.

The Hospital-Specific DRG Rates for MDH and SCP should be adjusted for the reduction in average case mix that results from the change in the grouping and weighting logic from that used to establish those rates.

FY 2008 Medicare Inpatient Prospective Payment System Proposed Rule, CMS-1533-P

6/12/2007

Page 2

Proposed Changes to DRG Classifications and Relative Weights, 6, Changes to Case-Mix Index from the Proposed MS-DRG

The proposed effective date of this dramatic a change is way too short. The final rule will not be available in enough time to make all the necessary changes to staffing or software. There is no need to rush this out and leave all PPS hospitals to struggle to comply. This is not just an issue of we were paid X before and now we'll be paid Y. There are many changes that will be required of hospitals. Our Medical Record computer programs will need to be revised. Billing programs will need changed. Training will need to take place. And there is a 2.4% penalty if you are not ready October 1. We are left to ponder how this will effect our Medicaid inpatient payments as well. Each year we are required to bill the new ICD-9 codes as of October 1 with the Medicare change, but because the Grouper software is not available in time, the State continues to pay using the prior Grouper version. The Medical Records software has not caught up with having to code under the latest ICD-9 codes and the DRG Grouper using an older version. It would be helpful if this grouping and weighting change would be available in time to make the changes necessary, for hospitals as well as other Programs that base payment on DRGs.

The effective date is too soon after a final rule would be published to make the needed changes to computer software and has an inherent payment penalty for not being ready on day one. The effective date should be delayed until software vendors can catch up and we all can be ready at the start.

Proposed Changes to DRG Classifications and Relative Weights, 6 Changes to Case-Mix Index from the Proposed MS-DRG, Coding Improvement Adjustment

While we can see it is reasonable to assume there will be some increase in the average case mix from improvements in coding, we are not convinced the Maryland experience is determinative of how much it will be. How much room for improvement was there in Maryland as compared to MedPAR data? If the national claims data already reflects a higher level of CCs and MCCs on claims than in Maryland, there is likely less room for improvement gain. As you state, the experience of the nation was only a 1.6% per year improvement at the three year start-up of PPS. Using a 2.4% reduction over two years seems to be jumping the gun. If anything, a lower adjustment over a longer time period seems to fit the PPS experience better, rather than assuming Maryland is just like the nation. It is in no one's interest to over-play the change. The danger is in making the payment adjustment and then nothing happens or does not happen as fast as October 1. The coding improvement is not going to happen October 1. It will take time for any improvement to occur. We are not now coding any and every thing that applies under the new logic and we don't know which items we are missing are important. Under the Proposal, our coding staff will have to spend more time researching and documenting than is currently needed. We have trouble keeping up now. In rural areas it is difficult to find coders,

FY 2008 Medicare Inpatient Prospective Payment System Proposed Rule, CMS-1533-P
6/12/2007

Page 3

so openings go unfilled for long periods of time. It will cost us more as we have to compete for the few people that are available. The expansion in coding will need software improvements. These are not going to happen by October 1.

The adjustment to the DRG Rates for anticipated improved coding as a result of the new incentives is too high for the first year and should be spread over a longer time period that two years.

Time Spent by Residents on Vacation or Sick Leave and Orientation

We can agree with the proposed removal of vacation and sick time from both the numerator and denominator in the FTE calculation. The Proposal does not go far enough it should also include any benefit time such as holidays as well. A policy statement should also be made to eliminate an over-zealous reading of the rules as of FY2007 eliminating vacation or holiday or sick time out of the FTE count in the numerator only as a whole day spent not in patient care. This proposal should be retroactive to the clarification of policy made in the FY2007 rule.

The elimination of all benefit paid time off should be removed from both numerator and denominator of the Resident FTE Count effective with the FY2007 rule clarifications so as to not leaving a gap open to interpretation for FY 2007 counts.

Submitted on behalf of MidMichigan Health,

Fred Kagarise

Fred Kagarise
Manager of Corporate Reimbursement

**CMS-1533-P-359 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Bonita Allen

Date & Time: 06/11/2007

Organization : Henrico Doctor's Hospital - Parham

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#359

file:///T:/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1533-P-360 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Aline Holmes

Date & Time: 06/11/2007

Organization : New Jersey Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

The DRA requires CMS to identify at least two preventable complications of care that could cause patients to be assigned to a CC DRG. The conditions must be either high cost or high volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonable preventable through the application of evidence-based guidelines. CMS is recommending six conditions for implementation at this time: catheter-associated urinary tract infections; pressure ulcers; object left in surgery; air embolism; blood incompatibility; and staphylococcus aureus septicemia.

The New Jersey Hospital Association believes that three of these (object left in during surgery, air embolism and blood incompatibility) are appropriate conditions to include for FY 2009. We have serious concerns with the possible inclusion of the other three, based on a lot of work done in our Quality Institute. We are currently involved in a statewide initiative in cooperation with our Department of Health and Senior Services to reduce the incidence of CAUTI, and one of our early issues was consensus among all clinicians on the definition and diagnosis of CAUTI. We have reviewed all the medical literature and information from CDC and NQF, and there is not yet consensus on these issues. There are no currently evidence-based best prevention practices, supported in the literature, so we have just had our organizations (hospitals, nursing homes, home health agencies) focus on appropriate insertion technique and removing the indwelling catheters as soon as possible.

Septicemia has some of the same problems, esp. with universally accepted definition and criteria for diagnosis. Again, there are no consistent evidence-based prevention practices that have been identified in the literature as being closely correlated to the prevention of this condition. With both of these infections we have concerns re. how physicians are documenting whether or not these infections are present on admission. NJHA envisions a return to the era when urine specimens were routinely sent for U/A and C&S at the time of insertion of the indwelling catheter, with an unintended consequence of increased cost.

NJHA also have concerns over the proposed inclusion of pressure ulcers. It appears that CMS has made the assumption that pressure ulcers are totally preventable. CMS uses the terminology 'avoidable' and 'unavoidable' in the long term care setting, and many of the pressure ulcers seen in acute care hospitals also fall into those categories. We have worked for two years with a total of 145 organizations to reduce the incidence of pressure ulcers, and there is no good evidence-based practice that if you ensure it gets done consistently will result in no pressure ulcers. We have focused on comprehensive skin and risk assessments and implementation of prevention strategies in 'at risk' patients, and have seen a 19% reduction (so far) in incidence across all settings, but there are still significant issues with specific patient populations, ie. trauma patients, elderly patients undergoing long operative procedures, patients in ICUs and end-of-life care/palliative care patients.

NJHA would be happy to share the work we have done with our hospitals to implement best practices in the reduction of incidence of VAP and CRBSI. Despite the fact that we have hospitals who are now experiencing a year or more of no VAP or CRBSI, we have not been able to solve the

issue that not all hospitals use the same methodology to diagnose/identify these conditions, so while we had them reporting infection rates, we also had them reporting on process measures related to these infections.

If you have any further questions, please contact Aline Holmes, Senior Vice President, Clinical Affairs at aholmes@njha.com. Thank you for considering our comments.

CMS-1533-P-361 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Kim Gillilan

Date & Time: 06/11/2007

Organization : Ms. Kim Gillilan

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a caregiver of a brain tumor patient, who has the Gliadel Wafer and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Kim Gillilan

**CMS-1533-P-362 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Sue Annesser

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-362-Attach-1.DOC

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,800 employees, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGs

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also **includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 – \$24 billion over five years** – to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of

physician-owned, limited-service hospitals and consider our comments on CMS' interim report on the strategic plan required by the *Deficit Reduction Act of 2005*.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that the change redistributes between \$800 million and \$900 million among hospitals.

CAPITAL PAYMENT UPDATE

The proposed rule would eliminate the capital payment update for all urban hospitals (a 0.8 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). **These changes would result in a payment cut of \$880 million over five years to urban hospitals.**

We are opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

CMS has gone well beyond its charge by recommending arbitrary and unnecessary cuts in this proposed rule. These backdoor budget cuts will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging.

If you have any questions, please feel free to contact Gary Duncan, President and CEO, at 417/347-6601 or gdduncan@freemanhealth.com.

Sincerely,

Sue Annesser
Freeman Health System
Director, Information Technology

CMS-1533-P-363

**Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Steven P. Johnson

Date & Time: 06/11/2007

Organization : The Williamsport Hospital

Category : Hospital

Issue Areas/Comments

508 Reclassifications

508 Reclassifications

Please see attached comment letter from The Williamsport Hospital & Medical Center, regarding the Hospital Inpatient PPS and FY2008 Rates - Section 508 Reclassifications. The attachment is in MSWord format.
If at all possible, please confirm that the attached submission was received. Thank you.

Steven P. Johnson, President & CEO
The Williamsport Hospital & Medical Center
777 Rural Ave.
Williamsport, PA 17701
Phone:570-321-3170
Fax:570-321-3199

CMS-1533-P-363-Attach-1.DOC

#363



The art of caring. The science of healing.
Divine Providence Hospital Muncy Valley Hospital The Williamsport Hospital & Medical Center

June 12, 2007

Electronically Filed

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates
Published in the Federal Register on May 3, 2007

508 Reclassifications

I am writing on behalf of The Williamsport Hospital & Medical Center ("TWH&MC") relating to the section on "508 Reclassifications" in the FY 2008 proposed rule for Medicare's Inpatient Prospective Payment System (IPPS). In the 2007 Final IPPS Rule, the Centers for Medicare & Medicaid Services (CMS) invoked the Secretary's special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Social Security Act to give TWH&MC the same wage index as the nearby 508 hospitals until the expiration of the 508 provision. This provision, subsequently extended by the Tax Relief and Health Care Act of 2006, is currently scheduled to expire on September 30, 2007. We are requesting that you again invoke your special exceptions and adjustment authority to remedy a "consequential problem" resulting from the application of the Medicare area wage index. We are asking that you extend the special exception that you previously granted in the FY2007 IPPS Final Rule. You stated in that Rule that "we believe it is appropriate in these circumstances to give the hospital in the single hospital urban area the same wage index as the nearby 508 hospitals until the expiration of the provision on March 31, 2007." As noted above, the section 508 provision was subsequently extended until September 30, 2007. We believe that TWH&MC deserves equitable treatment relative to the 508 hospitals with which it closely competes. As of the end of 2007, the section 508 hospitals will have received three and a half years of increased labor payments while TWH&MC will have only received one year of comparably increased payments.

Permitting improved employee compensation was an important justification for the section 508 wage index increases, and TWH&MC has conformed to this expectation. TWH&MC has directed 100 percent of its increased Medicare payments to additional payments to employees. Faced with severe competition for nurses and other clinical and support staff from surrounding hospitals, TWH&MC increased salaries and improved funding for employee retirement.

Congressional sponsors of the section 508 intended TWH&MC to be included under this provision along with other hospitals in its vicinity. However, a technical insufficiency in the

drafting of the provision precluded TWH&MC from being treated as its peers and resulted in an inequitable outcome. The lack of a wage index increase has placed TWH&MC at a serious competitive disadvantage relative to other hospitals in its area. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. (See Attachment A for a comparison of services.)

As we argued to you last year in connection with the development of the FY 2007 IPPS rule, the almost unique situation of TWH&MC presents immense challenges. We believe that TWH&MC is in one of only two areas in the country that have an individual urban hospital¹ that is the sole hospital in the urban area and that is surrounded by rural hospitals that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because CMS considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals. Because these operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indices.

The following bullets provide more detail about the competitive situation affecting TWH&MC.

- TWH&MC's two major competitors, Geisinger Medical Center and Evangelical Community Hospital, along with neighboring 508 hospitals, have been able to reclassify to MSAs with much higher area wage indexes (Harrisburg – Carlisle, and Allentown, Bethlehem- Easton), even though these competitors are closer to the Williamsport MSA.
- Comparing core service areas and populations from Williamsport and surrounding areas from the 2000 census, it is clear that TWH&MC is serving an urban market while having to compete with rural hospitals that receive a higher wage index. This is critical because there are more Medicare beneficiaries in Lycoming County than the entire population of Geisinger's home base of Montour County.

Hospital	County Population	City Population	Medicare Population
Williamsport Hospital	120,044	30,706	19,251
Geisinger	18,236	4,897	3,120
Evangelical	41,624	5,620	5,584

¹ Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.

- 31 percent of the Medicare discharges within a 35-mile radius of TWH&MC were treated by the hospital yet the hospital is reimbursed at a much lower rate than its competitors. The majority of the remaining Medicare discharges (52 percent) within the 35-mile radius of the hospital were treated at competing facilities that have reclassified due to special exceptions and receive increased Medicare reimbursement. (Data gathered from the FY 2005 Healthcare Cost Report Information System (HCRIS)).
- TWH&MC has attained very high operating efficiency as a result of a joint operating agreement with two other hospitals in the Susquehanna Health System "(SHS)", whereby licensed beds in the SHS have been reduced from 607 to 325. Savings of over \$105 million in five years were recorded in an audit conducted by the Pennsylvania Attorney General's office. Despite this record, TWH&MC had an operating margin in 2005 of only 1.29 percent; while Evangelical's was 2.41 percent and Geisinger's was 6.65 percent.
- In the interest of caring for beneficiaries, TWH&MC must update its facilities. The last major construction project at TWH&MC was completed in the late 1980's. The emergency room, laboratory, radiology department and operating rooms are more than 30 years old and should have been replaced at least 10 years ago.
- During this period, the Evangelical Community Hospital built a new ambulatory surgery center, a new power plant, a new fitness and rehabilitation center, a new radiology imaging center and a new emergency room.
- Also during this time, Geisinger built a new ambulatory surgery center, a brand new heart hospital and a 33,000 square foot outpatient facility, and purchased a 195-bed hospital. It has both a sports medicine center and a 63,000 square-foot rural health center under construction. In addition, they announced plans to develop a new 50-acre Centre County property to provide advanced technology, comprehensive diagnostics and therapeutic cancer treatment and other outpatient treatment services in direct competition with the local community hospital.
- Geisinger has purchased four helicopters to transport trauma cases to its facility – one is stationed in Williamsport. It is now using this fleet to transport high margin, non-trauma cases directly from local community emergency rooms to its facilities. A failure to "level the playing field" means not only will TWH&MC be unable to afford helicopters if deemed necessary, but we may also be required to significantly decrease or eliminate our county paramedic program and city ambulance service.
- With 50,766 Emergency Room visits a year, TWH&MC provides the most single site ER services of any hospital in our nine-county region. Compare this to 30,351 visits to Evangelical's ER and 38,054 visits to Geisinger's. The ER volume at Williamsport is far more comparable to the volumes seen in Harrisburg hospitals.

Centers for Medicare & Medicaid Services
Department of Health & Human Services
June 12, 2007
Page 4

To address this situation and remedy the inequity described above, we request that CMS continue the special exception granted TWH&MC in FY 2007 for one additional year so that the hospital can continue to increase employee compensation and benefits to levels comparable to those of competing hospitals in the area.

When last year's special exception was implemented, CMS was able to apply the same wage index to all of TWH&MC's PPS reimbursement that was subject to wage index adjustment - not just the inpatient reimbursement and capital add-on. We request that a further extension for TWH&MC apply to outpatient services as in FY 2007.

We thank you for the opportunity to comment on the FY 2008 Inpatient Prospective Payment System Proposed Rule and appreciate your consideration of the issues we raised. As always, we would welcome the opportunity to discuss with you in more detail the special circumstances facing isolated hospitals in single-hospital MSA's and our recommendation to address TWH&MC's challenging situation.

Sincerely,

s/Steven P. Johnson

Steven P. Johnson, President/CEO
The Williamsport Hospital & Medical Center

attachment

cc: Senator Arlen Specter
Senator Robert P. Casey
Congressman Christopher P. Carney
Congressman John E. Peterson

SERVICE CONTRAST CHART – ATTACHMENT A

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Regional Rural Health Partnership Initiative	Yes	Yes	No	No	No	No
Trauma Center and Emergency Department	Level III Eligible	Yes	No	No	No	No
Infectious Disease Center	Yes	Yes	No	No	No	No
Regional IT Infrastructure and Connectivity Among Hospital Facilities and Health System Physicians	Yes	Yes	No	No	No	No
Comprehensive Electronic Medical Record/Lifetime Clinical Record	Yes	Yes	No	No	No	No
Regional Pharmacy Center Supporting 5 Hospitals	Yes	No	No	No	No	No
Comprehensive Community Cancer Center (Accredited)	Yes	Yes	No	No	No	No
Comprehensive Wellness & Health Promotion Center LifeCenter	Yes	No	No	No	No	No
Comprehensive Physical Medicine and Rehabilitation Services (CARF Accredited)	Yes	Yes	No	No	No	No
Comprehensive Stroke Center	Yes	Yes	No	No	No	No
Inpatient Dialysis Center	Yes	Yes	No	No	No	No
Cardiac Surgery	Yes	Yes	No	No	No	Yes
Cardiac Catheterizations	Yes	Yes	No	No	Yes	Yes
Cardiac Angioplasty	Yes	Yes	No	No	No	Yes

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Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Comprehensive Neuroscience Center ◦ Neurosurgery Services	Yes	Yes	No	No	No	Yes
Family Center for Reproductive Health ◦ Family Planning Center	Yes (including a Family Planning Center)	Yes (without a Family Planning Center)	No	No	Yes	No
Thoracic Surgery	Yes	Yes	No	No	Yes	Yes
Vascular Surgery	Yes	Yes	Yes	No	Yes	Yes
Palliative Care Program	Yes	Yes	Yes	No	No	No
Comprehensive Pain Management Center	Yes	Yes	No	No	No	No
Certified Pastoral Education	Yes	Yes	No	No	No	No
PET Scanning/PET CT Fusion	Yes	Yes	Yes	No	No	No
Emergency Ambulance Services	Yes	Yes	Yes	No	No	No
JCAHO Accreditation	Yes	Yes	No	No	Yes	Yes
Comprehensive Referral Laboratory Services	Yes	Yes	No	No	No	No
Comprehensive CME Program	Yes	Yes	No	No	No	Yes
County Forensics Center	Yes	No	No	No	No	No
Diabetes Resource Center	Yes	Yes	No	No	No	Yes
Hyperbaric Chamber Care	Yes	No	No	No	No	No
Helicopter Services	No	Yes	No	No	No	No

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June 12, 2007
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Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
NICU	No	Yes	No	No	No	No
Family Practice Residency Training Program	Yes	No	No	No	No	No
Other Physician Residency Training Programs	No	Yes	No	No	No	No
Transplant Services	No	Yes	No	No	No	No

CMS-1533-P-364 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Mary Pagliuca

Date & Time: 06/11/2007

Organization : Ms. Mary Pagliuca

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS DRG 24

I am a caregiver for a brain tumor patient and would like to request a change to the structure of proposed MS-DRGs 23 and all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-C code 00.10) would be assigned to MS-DRG 23.

I strongly suggest that the DRGs be restructured so that their titles are the follow:

MS-DRG 23: craniotomy with acute complex CNS PDX with MCC or major device implants.

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC.

Please do not ignore this request. Patient with brain tumors are in need of receiving all possible treatments available. You simply need to change the structure of the new MS-DRGs to allow the involving the implantation of devices to be assigned to MS-DRG.

Thank you.
Mary Pagliuca BSMT
Research Scientist
Maplewood, NJ 07040

CMS-1533-P-365

**Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Gary McLaughlin

Date & Time: 06/11/2007

Organization : Overlake Hospital Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-365-Attach-1.DOC

#365



1035 116th Avenue NE
Bellevue, WA 98004
425.688.5000
www.overlakehospital.org

June 8, 2007

Department of Health and Human Services
Attention: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20510

Dear Ms. Norwalk

The mission of Overlake Hospital Medical Center is to provide exceptional patient care and medical excellence every day. Medical excellence is an ongoing process that requires us to invest in our facility, staff, supplies, information technology and pharmaceuticals in order to maintain our mission. Excellence involves us meeting the needs of our patients, the technology requests of our physicians and the quality improvements required by Washington State, CMS and the commercial payers in our service area. All of the patients that are treated at our facility, including those with Medicare, Medicaid and commercial insurance, benefit from these improvements. However, it is the commercial payers that are increasingly paying for both the full cost of providing service to their members, as well as the shortfall from Medicare and Medicaid.

In a report prepared by Milliman Consultants and Actuaries, on behalf of Premera Blue Cross, this issue of cost shifting by Medicare and Medicaid cost was reviewed in detail. Milliman identified the overall margins for all Washington State hospitals to be a loss of more than 15% in 2004, or \$430 million to Washington State on all of the Hospital Medicare business. Since 1997, all Washington State hospitals have fared progressively worse under the Medicare program, dropping from a 3% margin on Medicare business in 1997, to a 15.4% loss in 2004. This ongoing drop in hospital margins is not due to unique growth in the Washington State area, but due to annual increases in Medicare

rates falling *below* Market Basket, as tracked by CMS. The adjustments made each year have either intentionally been set below medical cost inflation by mandate, or are based on future projection estimates that end up being well below the actual rate of medical inflation. Compounded, the impact is that inpatient PPS rates have increased by only 22% since 1997, while Hospital Cost inflation has risen more than 40% for the same period. This continued decline in reimbursement, adjusted to medical inflation, forces hospitals to reduce the services they are able to provide and/or offset losses from Medicare and Medicaid with higher commercial rates. We recommend that CMS reconcile the difference in the previous FY Market Basket estimate and the actual change in Market Basket for the same period, adding this amount to the Market Basket estimate for the next Fiscal Year.

Coding Behavioral Offset

Now on top of the mounting losses Washington hospitals are already facing from Medicare, CMS is recommending a further reduction of \$42.7 million in payments to hospitals in our state. \$40.3 million of this amount is from the "behavior offset" reduction, \$37.4 million loss in operating revenue, and \$2.9 million in capital revenue, with an additional \$43 million planned for FY 2009. Although we support the implementation of a severity based DRG system (MS-DRGs), it is impossible for us to support such a system which also requires such a severe reduction in payments. This reduction amounts to nothing more than an unlegislated cut in hospital reimbursement. As the CMS Secretary has the authority to make adjustments to the standard rates in future fiscal years, based on DRG coding changes, we recommend that the Secretary refrain from making adjustments to the standard rate in FY 2008. Once MS-DRGs are implemented, CMS can review claims paid under the MS-DRG system and determine if a nationwide increase in case weights has occurred due to coding changes, and make adjustments based on actual claims data. This would provide a more accurate assessment of coding improvements, rather than extrapolating results from coding changes that occurred in Maryland under 3M's APR-DRG severity classification system, a vastly different payment system.

Capital Large Urban Add-On

The additional \$2.4 million loss to Washington hospitals in FY 2008 is from the reduction in Large Urban add-on and reduction in the base capital rate. Capital payments have increased slowly under the Medicare program, and cuts to capital are unjustified. Our hospital faces ever increasing demands for capital to improve existing facilities, increase capacity, purchase additional medical equipment, and implement critical information technology systems. Information technology systems are critical to providing the highest quality, safest care that is demanded by patients in the 21st century. Our organization already is struggling with the capital required to implement Computerized Physician Order Entry, electronic medical records, and other technology to enhance patient safety and improve quality measures. Cuts to our capital payments would hinder the development and implementation of these and other critical programs. At a time when Medicare enrollment continues to grow, and Medicare quality standards

and reporting continue to rise, cuts to capital payment would inhibit our hospital's ability to respond to these ongoing changes. In short, we recommend that capital payments not be cut, the large urban add-on payment remain in place, and the base rate be increased by the Market Basket amount.

IME and DSH Payments

In addition we recommend that CMS review the allocation and distribution of IME and DSH payments. Hospitals, like ours, whose core mission is to provide direct patient care, are at a severe financial disadvantage to teaching hospitals. Per the MedPAC report, the IME amount paid under Inpatient PPS, is higher than the "empirical level" and "more than \$3 billion in extra payments to teaching hospitals." Returning these extra funds to the base rate would greatly improve reimbursement to the non-teaching hospitals under the Medicare program. In addition, the DSH payments are also above the "empirical level" and per the MedPAC report "about three-quarters of DSH payments were not empirically justified, accounting for about \$5.5 billion in Medicare spending." Again returning these additional funds to the base rate would improve reimbursement to non-teaching hospitals. These add-on payments cause these facilities to be misidentified as efficient providers. They have positive Medicare margins because of these payments, and not because of substantial lower cost. Per the MedPAC report, the gap in major teaching and non-teaching hospitals would be reduced from 12% to only 3.4% if the DSH and IME payments were reduced to the "empirical level". We recommend CMS phase out these additional payments under DSH and IME and return this money to the base rate, which would improve the overall sustainability of the Medicare program.

Medicare Advantage and PFFS Plans

It is surprising that CMS is recommending reductions in reimbursement and capital to hospitals, while at the same time protecting the overpayments to Medicare Advantage plans. The CBO testimony on 3/21/2007 indicates that these plans cost 12% more than it would cost to cover the same individuals under the Medicare FFS plan. Even worse is private fee for service (PFFS) plans which are not required to build a network and provide no management of benefits to restrain cost, and yet they cost 19% more than Medicare FFS. PFFS plans provide the *same network* and *services* as Medicare FFS, but cost *19% more*. These payments are nothing more than a subsidy to insurance companies, while providing no additional funding to the providers of service. CMS stated that cutting these overpayments would reduce funding to the states and impact members, but these funds are not being used for patient care. These funds are consumed by the insurance companies to cover high overhead cost and profit margins. Reducing these payments would have almost no impact on Medicare providers. As CMS is unable to regulate these plans, and unable to determine if the benefit packages are indeed an improvement in services, it is impossible to tell if the enrollees benefit at *all* from enrollment in a Medicare Advantage or PFFS plan. If CMS is really concerned about the impact of removing the \$8 billion in overpayment to Medicare Advantage plans and the impact on providers and members, it should re-direct these funds to reduce out of pocket expenses in FFS, Part B premiums, or improve payments to providers.

**CMS-1533-P-366 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Vicky Mieseler

Date & Time: 06/11/2007

Organization : Freeman Health System

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1533-P-366-Attach-1.DOC

366

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-1533-P, Medicare Program, Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of Freeman Health System and our 3,000 employees, we appreciate the opportunity to comment on the Center's for Medicare and Medicaid Services (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While Freeman Health System supports many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 - \$24 billion over five years - to eliminate what you claim will be the effect of classification changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS' interim report on the strategic plan required by the "Deficit Reduction Act of 2005".

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that the change redistributes between \$800 million and \$900 million among hospitals.

The proposed rule for capital payment update would eliminate the capital payment update for all urban hospitals (a .08 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). These changes would result in a payment cut of \$880 million over five years to urban hospitals.

We are opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

CMS has gone well beyond its charge by recommending arbitrary and unnecessary cuts in this proposed rule. These backdoor budget cuts will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging.

Sincerely,

Vicky L. Mieseler, MS
Licensed Psychologist
Ozark Center and Freeman Health System

**CMS-1533-P-367 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mrs. Nancy Church

Date & Time: 06/11/2007

Organization : APIC

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1533-P-367-Attach-1.TXT

CMS-1533-P-367-Attach-2.DOC

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Dear Ms. Norwalk:

Thank you for the opportunity to provide additional input to the CMS proposed IPPS changes.

I serve as a member of the Association for Professionals in Infection Control and Epidemiology (APIC) an international association of 11,000 members with considerable expertise in the prevention, detection, and control of healthcare-associated infections (HAIs).

I am responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. I appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, I have worked collaboratively and am in essential agreement with my colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities, namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

I applaud the foresight of CMS in this arena, as I have a shared vision of preventing adverse events, including HAIs, in the patients I serve in our respective care settings. I understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, I understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

I support CMS in this effort to identify appropriate conditions that should not occur in hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. I reiterate my society's belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although SHEA's focus is infection prevention, the society and I do **support numbers 3, 4 and 5**. That is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

SHEA and I **do not support numbers 1, 2 and 6 for FY 2009; i.e.,** catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. I strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. I believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. SHEA and I look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, I do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

I do not believe that each of these three conditions is always reasonably preventable. In SHEA’s previous letter to CMS³, the society noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

I offer the following specific comments on each of these conditions.

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, I propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter

discontinued. Further, I would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient’s urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as Klebsiella or Candida species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

I believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians’ notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

#6 Staphylococcus aureus Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. I believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

Seven conditions mentioned but not recommended for consideration for FY 2009

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, I recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-acquired conditions policy in the future.⁵ Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

Of the infection-related conditions for which CMS requested comment, I will specifically address two with the most potential in the near term. I suggest two approaches that do *not*

depend on POA codes, though do require coding and cross referencing. I recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although I acknowledge the comments above and agree that as stated this condition would problematic, I would suggest another approach – not dependent on POA or a special code for vascular catheters. I agree that at the moment there is no specific code for **catheter-associated blood stream infection (CA-BSI)** – a reasonably preventable condition. However – **there are specific codes for insertion of catheters**. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)
- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by **excluding** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
 - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5

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- 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
- 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

#11 Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection)

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, I am not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although I agree with postponing consideration of surgical site infections at this time, I would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes – e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following ‘CABG without valve’ with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes
- d) Examine the record for CABG codes ‘without valve’ occurring on the same admission

In addition to our comments regarding specific conditions, I would like clarification from CMS *on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.*

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. I am committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,
Nancy B. Church, RN, BSN, MT, CIC
Chair, Practice Guidance Council
Association for Practitioners in Infection Control

References

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³ APIC-IDSAs-SHEA letter to Mark McClellan dated June 12, 2006

⁴ National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

⁵ Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Dear Ms. Norwalk:

Thank you for the opportunity to provide additional input to the CMS proposed IPPS changes.

I serve as a member of the Association for Professionals in Infection Control and Epidemiology (APIC) an international association of 11,000 members with considerable expertise in the prevention, detection, and control of healthcare-associated infections (HAIs).

I am responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. I appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, I have worked collaboratively and am in essential agreement with my colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities, namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

I applaud the foresight of CMS in this arena, as I have a shared vision of preventing adverse events, including HAIs, in the patients I serve in our respective care settings. I understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." For discharges occurring on or after October 1, 2008, I understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

I support CMS in this effort to identify appropriate conditions that should not occur in hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. I reiterate my society's belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although SHEA's focus is infection prevention, the society and I do **support numbers 3, 4 and 5**. That is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

SHEA and I **do not support numbers 1, 2 and 6 for FY 2009; i.e.,** catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. I strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. I believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. SHEA and I look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, I do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

I do not believe that each of these three conditions is always reasonably preventable. In SHEA’s previous letter to CMS³, the society noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

I offer the following specific comments on each of these conditions.

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, I propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter

discontinued. Further, I would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient’s urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as *Klebsiella* or *Candida* species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

I believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians’ notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

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CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. I believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

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It is possible to:

- a) Screen for bloodstream infection codes (996.62)
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#11 Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection)

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- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes
- d) Examine the record for CABG codes ‘without valve’ occurring on the same admission

In addition to our comments regarding specific conditions, I would like clarification from CMS *on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.*

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. I am committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,
Nancy B. Church, RN, BSN, MT, CIC
Chair, Practice Guidance Council
Association for Practitioners in Infection Control

References

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CMS-1533-P-368 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Jane Mault

Date & Time: 06/11/2007

Organization : Ms. Jane Mault

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the mother of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-369 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Diane Bier

Date & Time: 06/11/2007

Organization : Mrs. Diane Bier

Category : Individual

Issue Areas/Comments

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MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Diane Bier

CMS-1533-P-370 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Monica Fontes

Date & Time: 06/11/2007

Organization : Infection Control Practitioner

Category : Health Care Professional or Association

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

I support CMS in their effort to identify appropriate conditions that should not occur in our hospitals, thereby meeting criteria defined by Congress and also ensuring accuracy in the billing data that enables the appropriate identification of cases. I only support 3 extremely harmful events with known methods of prevention: object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF. These are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes. I do not support the following three events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. I do not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences. I suggest and support two approaches that do not depend on POA codes, but instead require coding and cross referencing for vascular-associated infections (which includes infections associated with all vascular devices, implants and grafts) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code. While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.

CMS-1533-P-371 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter :

Date & Time: 06/11/2007

Organization :

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a friend of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-372 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Cynthia Smith

Date & Time: 06/11/2007

Organization : Sisters of Charity of Leavenworth Health System

Category : Health Care Provider/Association

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

The Sisters of Charity of Leavenworth Health System (SCLHS) is a Catholic not-for-profit health system, composed of nine hospitals and four safety-net clinics in California, Colorado, Kansas and Montana. SCLHS is a high technology health care system sponsored by the Sisters of Charity of Leavenworth, with nearly 11,000 employees and 2,200 staffed beds.

We appreciate the opportunity to comment on the proposed rule for FY 2008 Hospital Inpatient Prospective Payment System (IPPS), published by the Centers for Medicare and Medicaid Service in the May 3, 2007, Federal Register.

There are many issues raised in the proposed rulemaking which cause our health system concern. Thorough comments have been submitted by our national organizations, including the Catholic Health Association, American Hospitals Association, and our state hospital associations. We are writing to reiterate their comments and to communicate in particular our alarm about the proposed 2.4 percent "behavioral offset."

CMS proposes to reduce IPPS standardized amounts by 2.4 percent each year for FY 2008 and FY 2009. CMS will then determine if there are increases in case-mix due to coding once actual data is available, and make further adjustments to account for any difference between CMS projections and actual data.

It is unreasonable and unfair for CMS to assume that the new MS-DRGs will result in a case mix that creates a windfall for all hospitals. It is purely speculative to assume that a 2.4 percent downward adjustment is warranted to apply uniformly to all hospitals as a "behavioral offset." It is estimated that this cut in reimbursements under Medicare will amount to a loss of approximately \$5.6 million to our hospitals in 2008 alone, which will have a significant impact on our ability to serve our communities and accomplish our mission.

We also dispute the assertion that changes in coding will not increase resource demands. We expect to expend significant additional resources on retraining and retooling all our hospitals to be able to code

correctly and transition to MS-DRGs, as well as to assure that doctors document certain information in the record of admission.

CMS should not implement a "behavioral offset" at this time. Once the MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding or rather to severity of patients, assess all costs and determine if an adjustment is necessary.

We are also concerned about the implications of implementation of the MS-DRGs. We suggest that payment denials for the first 90 days be handled by memo only instead of by withholding payment, so there would be a period of time for hospitals to transition to the MS-DRGS and make appropriate corrections to processes.

Again, thank you for the opportunity to share these comments on the proposed changes to the Hospital IPP Systems and FY 2008 rates.

CMS-1533-P-373 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Kathy Vickers

Date & Time: 06/12/2007

Organization : Kathy Vickers

Category : Nurse

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

Both my father and my brother had/have brain tumors called Glioblastoma Multiforme.

I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases

involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Kathy Vickers

CMS-1533-P-374 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Sean Thoennes

Date & Time: 06/12/2007

Organization : Mr. Sean Thoennes

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a friend of a brain tumor patient, and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

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Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

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Thank you for your consideration of this important matter!

CMS-1533-P-375 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Carol Johansmeyer

Date & Time: 06/12/2007

Organization : Mrs. Carol Johansmeyer

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Please do not delete the billing code for gliadel wafers for people with brain cancer. My husband has had glioblasoma for 3 1/2 years. He received gliadel wafers in his surgery and is doing well. It would be totally cruel if we would deny this treatment to people who need it. It has been proven in studies to help in such a horrible disease. We need to look for more treatments to help these people instead of taking away their options.