

JUN 12 2007

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June 11, 2007

By Federal Express

Tracking No. 7925 0208 1136

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: File - CMS-1533-P
Wage Index

Dear Sir or Madam:

These comments are submitted on behalf of Vinson & Elkins L.L.P. and our clients concerning CMS's proposed change in method of implementing the budget neutrality requirement for the effects of the rural floor.

Section 4410(a) of the Balanced Budget Act of 1997 ("BBA") establishes a wage index rural floor, stating that for purposes of section 1886(d)(3)(E) of the Social Security Act, "the area wage index applicable . . . to any hospital which is not located in a rural area . . . may not be less than the area wage index applicable . . . to hospitals located in rural areas in the State in which the hospital is located." BBA section 4410(b) requires an adjustment to assure "that the aggregate payments made under section 1886(d) of the Social Security Act . . . in a fiscal year for the operating costs of inpatient hospital services are not greater or less than those which would have been made in the year if this section did not apply."

In prior years, CMS implemented the budget neutrality requirement for the effects of the rural floor through an adjustment to the standardized amount. *See, e.g.,* 72 Fed. Reg. 24680, 24787 (May 3, 2007). Although we have reason to believe that CMS used the wrong data in making the budget neutrality adjustment in prior years, assuring budget neutrality of the rural floor through adjustment to the standardized amount appears to be methodologically

sound, at least insofar as the method is described in CMS's prior rules. As described in CMS's prior rules, an adjustment for the effects of the rural floor was included, for at least some years, in an adjustment that was permanently built into the standardized amount for annual DRG recalibrations, changes to the relative DRG weights, and updates to the wage index.¹ As discussed in the prior rules, CMS used a payment simulation model to calculate that single, cumulative budget neutrality adjustment factor. The FY 2007 rule, for example, states that the payment simulation model "used FY 2005 discharge data to simulate payments and compared aggregate payments using the FY 2006 relative weights and wage indexes to aggregate payments using the FY 2007 relative weights and wage indexes." 71 Fed. Reg. 48147 (Aug. 18, 2006). The FY 2007 rule also states that CMS included the effects of the rural floor in the agency's "calculation of the wage update budget neutrality factor." *Id.*

Although CMS's prior method for calculating the rural floor budget neutrality adjustment appears to have been proper, CMS's application of the method was flawed due to the use of inappropriate data in CMS's calculations of the budget neutrality adjustment factors for prior years. This data error caused an inappropriate duplicating effect between the budget neutrality adjustment that is permanently built into the standardized amount for a year and each successive year's further adjustment to the standardized amount.

CMS's prior rules never addressed the specific data or data factors that the agency employed in the payment simulation model it used to calculate the budget neutrality adjustment for DRG recalibrations, changes to the DRG weights, and updates to the wage index together with the effects of the rural floor.² Nonetheless, the data error was addressed in a comment on the FY 2007 rule, after the error was discovered through informal communication with CMS staff on another related subject. CMS did not address that

¹ As discussed in the enclosed letter of May 21, 2007 requesting additional information concerning CMS' proposed change in the implementation of the rural floor budget neutrality adjustment for FY 2008, and in the appendices to that letter, it is unclear whether CMS made any budget neutrality adjustment at all for the effects of the rural floor for years prior to FY 2004, the specific data used to calculate such an adjustment for any year since implementation of the rural floor in 1998, and what budget neutrality adjustment factor was calculated specifically for the effects of the rural floor in any year since 1998. Additional copies of that letter and the appendices to the letter are enclosed.

² As discussed in the enclosed letter of May 21, 2007, and in Appendix II to that letter, CMS' prior rules did not describe or illustrate important details of the agency's calculation of the budget neutrality adjustments that were made to the standardized amounts in order to implement the budget neutrality requirements of section 4410(b) of the BBA. CMS' prior rules only generally described in abstract terms the conceptual, methodological approach for calculating a single, cumulative budget neutrality adjustment factor for the effects of annual DRG recalibrations, changes to the relative DRG weights, and updates to the wage index. CMS' prior rules did not specifically identify what data were used to calculate that adjustment factor.

comment or the data error in the preamble to the 2007 rule, however, and it appears that the error was not corrected for FY 2007.

CMS's use of an inappropriate data factor in its calculations of the rural floor budget neutrality adjustments for prior years systematically overstated the amount taken out of the standardized amount for each year to account for the effects of the rural floor. Because those adjustments were permanently built into the standardized amount, CMS's error has had a compounding or duplicating effect on the current standardized amount which is substantially less than what it should be.

Comment 1: CMS SHOULD FULLY EXPLAIN THE BASIS AND PURPOSE FOR THE PROPOSED CHANGE AND DISCLOSE KNOWN ERRORS IN THE CALCULATION OF RURAL FLOOR ADJUSTMENT FOR PRIOR YEARS.

The proposed rule does not address the basis or purpose for CMS's proposed change in the method for implementing the rural floor budget neutrality requirement for FY 2008 and subsequent years. *See* 72 Fed. Reg. 24787-92. The proposed rule states that CMS has determined that "an adjustment to the wage index would result in a substantially similar payment as an adjustment to the standardized amount, as both involve multipliers to the standardized amount, and both would be based upon the same modeling parameters." *Id.* at 24792. Given that statement, there is no apparent reason on the face of the proposed rule for CMS's proposal to change the method of implementing the budget neutrality requirement for the effects of the rural floor. We are concerned that CMS is proposing to change its method in order to obscure its effort to avoid the error committed in prior years without expressly admitting that the calculations for prior years were wrong or identifying CMS's use of an inappropriate data factor in the payment simulation model for prior years.

- CMS Should Fully Explain the Basis and Purpose for the Proposed Change in Method for Implementing the Rural Floor Budget Neutrality Requirement.

We request that CMS fully explain the basis and purpose for the proposed change in the method for implementing the rural floor budget neutrality requirement so that hospitals can fully evaluate whether the correction adequately addresses the error in CMS's calculation of the rural floor budget neutrality adjustments for prior years. Toward that end, we further request that CMS provide the information requested in the enclosed letter dated May 21, 2007 with respect to both CMS's proposed new method for FY 2008 and subsequent years and its implementation of the rural floor budget neutrality requirement for prior years. Without that information, which is not addressed in CMS's prior rules, it is impossible for

hospitals to fully understand or meaningfully comment on the proposed change in methodology.

- CMS Should Disclose Any Known Errors in the Agency's Calculations of the Budget Neutrality Adjustments for the Effects of the Rural Floor in Prior Years.

As noted above, it appears that the real reason underlying CMS's proposed change in the method of implementing the rural floor budget neutrality adjustment is to avoid repetition of a data error in the calculations of the adjustments for the effects of the rural floor in prior years, without disclosing or identifying the data error. If CMS has determined that there was an error in its calculations of the budget neutrality adjustments for prior years, then CMS should disclose such error, or errors, to affected hospitals and identify the impact of its error on the standardized amount. Disclosure of this information is necessary for hospitals to fully understand the basis, purpose, necessity and adequacy of both the proposed change in method of implementation of the rural floor budget neutrality requirement and the proposed "Rural Floor Adjustment" to the standardized amount for FY 2008, as indicated in the proposed rule at 72 Fed. Reg. 24839 including the appropriateness of such adjustment and whether it represents a correction for errors in prior year adjustments and/or is a by-product of CMS' change to the proposed method .

Comment 2: THE PROPOSED CHANGE IN METHOD IS NEITHER NECESSARY NOR SUFFICIENT TO FIX THE DATA PROBLEM WITH CMS's PAST CALCULATIONS OF THE BUDGET NEUTRALITY ADJUSTMENT, AND IT MAY CREATE OTHER PROBLEMS.

CMS's proposed change in method is neither necessary nor sufficient to fix the data error in CMS's calculation of the budget neutrality adjustment to the standardized amount for the effects of the rural floor in prior years. In addition, the proposed change in method may create other problems.

If a budget neutrality adjustment to the standardized amount is "in keeping" with section 4410(b) of the BBA (and the proposed rule states that CMS believes that it is), then CMS should not change its existing method of implementing the rural floor budget neutrality

requirement through adjustments to the standardized amount.³ Given CMS's construction of the statute, CMS should simply fix the error stemming from the agency's use of an inappropriate data factor in its calculations for prior years. That problem should be addressed and corrected not only in the calculation of the current year's standardized amount but also for prior years (as discussed below).

- The Proposed Change in Method Is Not Necessary to Fix or Avoid the Data Error in CMS's Calculation of the Budget Neutrality Adjustment For FY 2008.

Within the last several months, several hundred (if not thousands) of hospitals appealed CMS's calculation of the standardized amount for FY 2007, contesting CMS's calculation of the budget neutrality adjustment for the effects of the rural floor. After those appeals were filed, CMS proposed to change its method of implementation of the rural floor budget neutrality adjustment. It appears that there is no genuine purpose or basis for the proposed change in method, as CMS acknowledges in the proposed rule that the existing method of implementation through adjustment to the standardized amount and the proposed new method of implementation through adjustment to the wage index "would result in substantially similar payment." 72 Fed. Reg. 24792. We are concerned, therefore, that CMS is attempting to mask an attempt to fix or avoid the data error in CMS's calculations of adjustments to the standardized amount for the effects of the rural floor in prior years. We are troubled that CMS would attempt to do this without identifying or admitting the error in its prior calculations.

We agree, of course, that CMS should fix the data error in CMS's calculation of the rural floor budget neutrality adjustment for prior years. But, CMS need not change its method of implementation of the rural floor budget neutrality requirement in order to fix that problem. To fix that problem, CMS need only use appropriate data factors in the payment simulation model that is used to calculate the adjustment to the standardized amount for DRG recalibrations, changes to the relative DRG weights, and updates to the wage index.

³ In the notice of the proposed rule, CMS acknowledged that the agency applied "a budget neutrality adjustment to the standardized amount" for the effects of the rural floor in prior years and stated the agency's belief that "such an adjustment is in keeping with the statute." 72 Fed. Reg. 24792. We express no comment or opinion in this letter on the validity of that construction of the statute. Assuming that CMS is correct in its construction of the statute, however, there is no apparent reason for CMS' proposed change in the method of implementing the rural floor budget neutrality adjustment for FY 2008 and subsequent years.

- The Proposed Change in Method Is Insufficient to Fix the Effect of CMS's Data Error for FY 2007 and Prior Years.

While the proposed change in method might avoid the data error in CMS's calculation of the rural floor budget neutrality adjustment for FY 2008, the proposed change in methodology – from an adjustment to the standardized to an adjustment to the wage index – does not fully correct the problem for prior, current or future fiscal years stemming from the data error in CMS's calculation of budget neutrality adjustments for the effects of the rural floor in prior years. Even if the proposed change in method avoids the data error that occurred in CMS's prior calculations, the standardized amount for FY 2008 and subsequent years will still be improperly understated because the prior-year adjustments for the effects of the rural floor were permanently built into the standardized amount.

The rule includes a positive adjustment to the standardized amount through the proposed "Rural Floor Adjustment" of 1.002214 to the standardized amount for FY 2008, as reflected in the notice of the proposed rule at 72 Fed. Reg. 24839. However, given the lack of information and explanation regarding this adjustment it is not possible to ascertain whether this adjustment is a one-time adjustment that is a by-product of the change to the new method or an adjustment to compensate for some of the duplications which occurred in prior years. Accordingly, due to the lack of information provided about the add-back in the notice of the proposed rule, it is impossible for hospitals to meaningfully comment on whether the add-back to the standardized amount is adequate. The proposed rule provides no explanation whatsoever of the basis or purpose of the proposed add-back to the standardized amount, nor the relationship, if any, between the add-back and the proposed change in method for calculating the rural floor budget neutrality adjustment, nor the impact of the data error in CMS's calculations of the rural floor budget neutrality adjustments for prior years. If the proposed add-back to the standardized amount is intended to reverse the prior-period adjustments to the standardized amount for the effects of the rural floor in more than one prior year, then the amount of the add-back appears to be substantially too low.

- The Proposed Change in Method May Create Other Problems with the Calculation of the Budget Neutrality Adjustment for the Effects of the Rural Floor

Without full disclosure of the proposed new method, the particular data that would be used to compute the proposed new rural floor budget neutrality adjustment for FY 2008 and subsequent years, and the proposed add-back to the standardized amount, it is not possible for hospitals to meaningfully comment on all potential problems that may arise from the proposed change in method because CMS has not afforded hospitals adequate notice of the

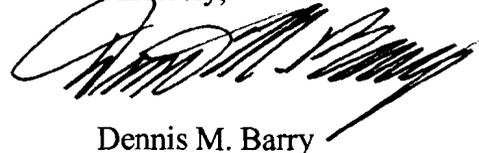
proposed changes. Nonetheless, we are concerned that the proposed change in method may create other problems with the calculation of the rural floor budget neutrality adjustment. As discussed above, it is not necessary for CMS to create additional potential for further problems in order to address the data error in CMS's calculations of the rural floor budget neutrality adjustments for FY 2007 and prior years. If the underlying data error is not corrected in CMS's calculations, the proposed change in method could remove either too much or too little from prospective payment system amounts paid to hospitals. Further, even if the underlying data is corrected, the change in method itself can result in different payment effects than an adjustment to the standardized amount because the labor-related share of the wage index differs among hospitals. 72 Fed. Reg. 24729.

Comment 3: CMS SHOULD CORRECT THE EFFECTS OF KNOWN ERRORS IN THE CALCULATIONS FOR PRIOR YEARS AND PAY HOSPITALS THE ADDITIONAL SUMS DUE FOR COST REPORTING PERIODS THAT ARE STILL SUBJECT TO CORRECTION.

Even if CMS's proposed add-back to the standardized amount for FY 2008 were sufficient to reverse the effect of all previous adjustments to the standardized amount for the effects of the rural floor (and it does not appear to be), the proposed change in method and the proposed add-back to the standardized amount would not compensate hospitals for underpayments for prior years, stemming from the data error in CMS's calculations of the rural floor budget neutrality adjustments for prior years. This is not an instance when CMS has used the "best data available" to establish prior-year rates, because correct data for the calculation of the budget neutrality adjustments for the effects of the rural floor in prior years were available to CMS when the agency calculated the prior-period adjustments to the standardized amounts. See *Alvarado Community Hospital v. Shalala*, 155 F.3d 1115, 1125 (9th Cir. 1998); see also *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1020-23 (D.C. Cir. 1999). CMS simply used inappropriate data factors when the correct data was available for the proper calculation of the rural floor budget neutrality adjustments for prior years. In this circumstance, CMS should correct the effects of known errors in its calculations of the rural floor budget neutrality adjustments in all prior years (through and including FY 2007) and make retrospective payments of the additional sums due to all affected hospitals for all affected cost reporting periods beginning before October 1, 2007 that are not yet finally settled or are subject to reopening under 42 C.F.R. § 405.1885.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis M. Barry", written over a horizontal line.

Dennis M. Barry

Enclosures

cc: Marc Hartstein by E-mail

DC 678973v.3

Vinson & Elkins

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May 21, 2007

By Federal Express

Tracking No. 7929 9046 3190

Marc Hartstein
Centers for Medicare & Medicaid Services
7500 Security Boulevard
C4-07-04
Baltimore, MD 21244

Re: Request For Additional Information Needed to Comment on CMS'
Proposed Budget Neutrality Adjustment to the Wage Index For the Effects
of the Rural Floor in the Proposed IPPS Rule For FY 2008 (CMS-1533-P)

Dear Mr. Hartstein:

We are writing to request that CMS provide additional information regarding CMS' proposed change in implementation of the budget neutrality requirement of section 4410(b) of the Balanced Budget Act of the 1997 ("BBA") concerning the wage index rural floor. See 71 Fed. Reg. 24680, 24787-92 (May 3, 2007). For the reasons discussed in more detail in attachments I and II, CMS' notice of proposed rulemaking for FY 2008 and its final IPPS rules for prior years since FY 1998 do not provide sufficient information to afford hospitals with adequate notice of, or a meaningful opportunity to comment on, CMS' proposed change in implementation of the budget neutrality requirement of section 4410(b) of the BBA. In order to permit our client hospitals with a meaningful opportunity to comment on the proposed change, we respectfully request that CMS provide us the additional information requested in section A below regarding CMS' proposal for FY 2008 and in section B below regarding the agency's implementation of the budget neutrality requirement in the final IPPS rules for prior years since FY 1998. In view of the impending deadline for submission of comments on the proposed IPPS rule for FY 2008, we request that CMS furnish the additional information requested below as soon as possible.

**A. Additional Information Needed Concerning CMS' Proposed
Change For FY 2008 And Subsequent Years**

1. If CMS has determined that "an adjustment to the wage index would result in a substantially similar payment as an adjustment to the standardized amount," as

indicated in the proposed rule, what is the basis and purpose for CMS' proposal to change its implementation of the budget neutrality requirement of section 4410 of the BBA?

2. What, if any, analysis or modeling has CMS performed to determine or verify that an adjustment to the wage index would result in "substantially similar payment" as an adjustment to the standardized amount?

3. If CMS has performed such an analysis, how were the payment effects modeled and what wage data, standardized amounts or other data were used in modeling the payment effects of an adjustment to the wage index as compared to an adjustment to the standardized amounts?

4. Additionally, if CMS has performed an analysis of the payment effects of an adjustment to the wage index as compared to an adjustment to the standardized amounts, what was the magnitude of the difference in payments, and what factor or factors resulted in the difference?

5. What standardized amounts would be applied to the FY 2006 discharge data and FY 2008 wage indices in the payment simulation model that CMS proposes to use to compute a budget neutrality adjustment to the wage index for the effects of the rural floor for FY 2008? Is CMS proposing to use the standardized amount for FY 2007, or the standardized amount for FY 2008, or some other payment rate data in the payment simulation model that would be used to determine the rural floor budget neutrality adjustment to the wage index for FY 2008?

6. If CMS is proposing to use a FY 2007 or FY 2008 standardized amount in the payment simulation model, is CMS proposing to use the standardized amount as adjusted by the budget neutrality adjustment factors for outliers and geographic reclassifications in FY 2007 or FY 2008?

7. What other adjustments, if any, would be made to the standardized amount used in the payment simulation model?

8. The proposed rule states that the proposed rural floor budget neutrality adjustment would be applied to post-reclassification wage indices, but the proposed rule does not specifically state whether the proposed payment simulation model used FY 2008 wage indices after reclassifications or FY 2008 wage indices before reclassifications. Which FY 2008 wage indices were used in the payment simulation model?

9. What adjustments, if any, does CMS propose to make to the FY 2008 wage indices before application of the rural floor budget neutrality adjustment to the wage index for FY 2008?

10. What adjustments, if any, does CMS propose to make to the FY 2008 wage indices after application of the rural floor budget neutrality adjustment to the wage index for FY 2008?

11. How would the proposed method for calculating the rural floor adjustment to the wage index be applied for subsequent years after FY 2008? What wage data or wage indices would CMS use in its payment simulation model for years after FY 2008? For example, assuming the same wage indexes, relative weights, location, standardized amounts and payments depicted for the three hospitals in CMS' hypothetical example at 72 Fed. Reg. 24792-93, and assuming that data relates to FY 2008, how would CMS calculate the proposed rural floor budget neutrality adjustment for FY 2009? More specifically, with reference to that hypothetical example, would CMS use the wage indexes shown in the third table of CMS' example for FY 2008, 72 Fed. Reg. 24793, as the "pre-floor wage indexes" in the calculation of the rural floor budget neutrality adjustment for FY 2009? If not, what other data would CMS use for those three hypothetical hospitals to calculate the rural floor budget neutrality adjustment to the wage index for FY 2009?

12. In calculating the rural floor budget neutrality adjustment to the wage index for years after 2008, would CMS use wage data or wage indices reflecting the prior-period budget neutrality adjustments to the wage index for the effects of the rural floor or would CMS remove the effect of the prior-year adjustment to the wage index before calculating the rural floor adjustment to the wage index for the next subsequent year?

13. The rate table at 72 Fed. Reg. 24839 depicts an adjustment to the standardized amount for FY 2008 for the "DRG Recalibrations and Wage Index Budget Neutrality Factor." As discussed in Appendix II, CMS included an adjustment for effects of the rural floor in its calculation of that budget neutrality adjustment to the standard amounts (for DRG and wage index changes) for prior years, and those adjustments are factored into the updated standardized amount that would be applied for FY 2008. What, if anything, is CMS proposing as a means to ensure that there is no duplication in the budget neutrality adjustments previously applied to the standardized amounts for the effects of the rural floor in prior years and the proposed budget neutrality adjustment to the wage index for the effects of the rural floor in FY 2008? Is CMS proposing to add anything back to the standardized amount applicable to FY 2008 and future years to account for prior-period budget neutrality adjustments to the standardized amount for the effects of the rural floor?

14. The table at 72 Fed. Reg. 24839 also reflects what is labeled as a "Rural Floor Adjustment" to the standardized amounts of 1.002214 for FY 2008. What is the basis or purpose of that Rural Floor Adjustment for FY 2008?

15. How did CMS calculate the proposed Rural Floor Adjustment of 1.002214 for FY 2008, and what data were used in the calculation?

16. Is the proposed Rural Floor Adjustment of 1.002214 a one-time adjustment for FY 2008 or is CMS proposing to apply a similar adjustment to the standardized amounts for subsequent years after FY 2008? If this is one-time adjustment only for FY 2008, why is not applicable for subsequent fiscal years? If this adjustment is not a one-time adjustment, how would CMS calculate this adjustment to the standardized amount for subsequent fiscal years after FY 2008?

17. If the rural floor applied to some hospitals in FY 2007 and will not apply to those hospitals in FY 2008, is any of the effect of this change in circumstances reflected in CMS' proposed calculation of a budget neutrality adjustment to the wage index for FY 2008? How will CMS account under its proposed methodology for similar changes in circumstances from FY 2008 to FY 2009 in its budget neutrality calculations for FY 2009?

B. Additional Information Needed Concerning CMS' Calculation Of The Rural Floor Budget Neutrality Adjustment For Prior Years

CMS' notice of its proposed IPPS rule for FY 2008 states that since 1998, CMS has adjusted the standardized amounts to implement the budget neutrality requirement of section 4410 of the Balanced Budget Act of 1997 ("BBA"). 72 Fed. Reg. 24787. The proposed rule also indicates that a "discussion and illustration of the calculation of the standardized amounts is shown in the Addendum of every year's IPPS rule." *Id.* at 24787 & n.16. We have reviewed each of the Federal Register notices cited in footnote 16 of the proposed rule, and particularly the page ranges within each of those notices that are cited in footnote 16 of the proposed rule. As discussed further in Appendix II, none of the preambles to the prior IPPS rules for FYs 1998-2007 describe or illustrate important details of the calculation of the budget neutrality adjustments that were made to the standardized amounts in order to implement the budget neutrality requirements of section 4410 of the BBA.¹ In short, each of the prior IPPS rules only generally describes in abstract terms the conceptual approach taken by CMS in calculating a single, cumulative budget neutrality adjustment factor for the effects of annual DRG recalibrations, changes to the relative DRG weights, and updates to the wage index. In some (not all) of the rules for prior years, CMS also has stated that it includes a budget neutrality adjustment for the effects of the rural floor in its calculation of that singular adjustment to the standardized amounts to account for DRG changes and wage updates.

¹ The notice of the proposed rule for FY 2008 provides, in footnote 16, the following citation for a description of the budget neutrality calculation in the IPPS rule for FY 2007: "71 FR 59889-58980, October 11, 2006." This citation is clearly incorrect. First, the cited page range runs backwards. The section of the Addendum to the FY 2007 IPPS rule beginning at 71 Fed. Reg. 59889 discuss the Final FY 2007 Prospective Payment Systems Rates for Hospital Operating and Capital Related Costs; however, the methodology for calculating budget neutrality adjustments to the standardized amounts for FY 2007 is set forth in August 18, 2006 notice, 71 Fed. Reg. 48146-48 (Aug. 18, 2006).

It is unclear, however, whether CMS made any budget neutrality adjustment at all for the effects of the rural floor for years prior to FY 2004, how such an adjustment was calculated for any year since implementation of the rural floor in 1998, and what budget neutrality adjustment factor was calculated specifically for the effects of the rural floor in any year since 1998.

In order to fully assess and meaningfully comment on the proposed changes for FY 2008, hospitals must first know how CMS has calculated the budget neutrality adjustment under the existing methodology so they know what is changing and how the proposed changes may impact them. For example, in order to assess whether the proposed methodology for calculating a budget neutrality adjustment for the effects of the rural floor duplicates rural floor budget neutrality adjustments for prior years, hospitals need to know what adjustment factors CMS applied for the effects of the rural floor in prior years and what data and methods were used to calculate those adjustment factors. Toward that end, we request that CMS furnish the following additional information requested below concerning its calculation of the budget neutrality adjustment for prior years, using the calculation for FY 2007 as an example:

1. For what years since FY 1998 did CMS compute a budget neutrality adjustment for the effects of the rural floor?
2. If CMS did not compute a budget neutrality adjustment for the effects of the rural floor for some or all years prior to FY 2004, did CMS calculate or apply a "catch-up" adjustment in its calculation of the budget neutrality adjustment for the rural floor once CMS began including such an adjustment?
3. With respect to the FY 2006 and FY 2007 wage indexes or wage data that CMS used to calculate an adjustment for the effects of the rural floor in the IPPS rule for FY 2007:
 - Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage data reflecting geographic reclassifications by the MGCRB or of certain urban hospitals that were deemed rural? If so, which fiscal year's data reflected such reclassifications?
 - Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage data reflecting the application of the rural floor? If so, which fiscal year's data reflected the application of the rural floor?
 - Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage index data reflecting the application of the imputed rural floor? If so, which fiscal year's data reflected the application of the imputed rural floor?

- Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage data reflecting the wage index reclassifications required by section 508 of Public Law 108-173, and if so, what, if anything, did CMS factor into the simulation model to ensure that CMS did not affect a budget neutrality adjustment for the effect of these particular wage index reclassifications?
- Did CMS' payment simulation model include FY 2006 wage indexes or wage index data or the FY 2007 wage index data reflect the wage index adjustments required by section 505 of Public Law 108-173, and if so, what, if anything, did CMS factor into the simulation model to ensure that CMS did not affect a budget neutrality adjustment for the effect of these particular wage index reclassifications?
- Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage index data include the effect of the occupation mix adjustment to the wage index?
- Did CMS' payment simulation model include FY 2006 or FY 2007 wage indexes or wage data reflecting the hold harmless adjustment to the wage indexes that applied to some hospitals due to the adoption of new labor market areas?

4. With respect to the standardized amount that CMS used in the payment simulation model to calculate the budget neutrality adjustment for the effects of the rural floor in FY 2007:

- Did CMS use a FY 2006 or FY 2007 standardized amount in the simulation model?
- Did CMS use a standardized amount that was adjusted by the budget neutrality adjustment factors for outliers and geographic reclassifications? If so, where those adjustments the adjustments stated in the Federal Register for that year OR what where those adjustments?
- What, if anything, did CMS factor into the model to account for hospitals whose wage indexes were less than or equal to 1.0000 and whose payments would reflect the application of a hospital's wage index to only 62% of the standardized amount?
- Did CMS use a standardized amount that was adjusted by the budget neutrality adjustment factor for the effect of the rural community hospital demonstration? If so, what was that adjustment?
- Did CMS use a standardized amount that was adjusted by the budget neutrality adjustment factor for the effect of the hold harmless adjustment to the wage indexes that would be applied to

some hospitals due to the adoption of new labor market areas and for the Section 505 adjustment?

5. What budget neutrality adjustment factor, or factors, did CMS compute specifically for the effects of the rural floor and the imputed rural floor (and apart from the adjustments attributable to DRG changes and other wage updates) for FY 2007 or for the other fiscal years since 1988?

6. To what extent, if any, is the proposed "Rural Floor" budget neutrality adjustment factor of 1.002214 to the standardized amount for FY 2008 attributable to the budget neutrality adjustment, or adjustments, to the standardized amounts for prior years for the effects of the rural floor in prior IPPS rules?

7. To what extent, if any, is the proposed "Rural Floor Adjustment" to the standardized amount for FY 2008 attributable to the budget neutrality adjustment, or adjustments, to the standardized amounts for prior years for the effects of the imputed rural floor in prior IPPS rules?

8. If the proposed "Rural Floor Adjustment" to the standardized amount for FY 2008 attributable to the budget neutrality adjustment, or adjustments, to the standardized amounts for prior years, did CMS use the same wage data and standardized amounts to compute the proposed Rural Floor Adjustment to the standardized amount for FY 2008 that CMS used to compute the budget neutrality adjustments to the standardized amounts for prior years?

* * * * *

We appreciate CMS' attention to the above requests for additional information needed to comment on CMS' proposed change in implementation of the budget neutrality requirement in section 4410 of the BBA. As indicated above, we request that CMS provide the information requested as soon as possible so that our client hospitals will have adequate notice of the changes that CMS is proposing and a meaningful opportunity to comment on CMS' proposed new methodology.

Sincerely,



Christopher L. Keough

Attachment I**Summary Of CMS' Description Of Its Proposed Change To The Calculation Of The Rural Floor Budget Neutrality Adjustment Factor for FY 2008**

The notice of the proposed IPPS rule for FY 2008 states that CMS is proposing "a prospective change to how budget neutrality is applied to implement the rural floor for FY 2008 and subsequent years." 72 Fed. Reg. 24680, 24787. The proposed rule does not address the basis or purpose for the proposed change in methodology. *See id.* at 24787-92.

CMS states in the proposed rule that "an adjustment to the wage index would result in a substantially similar payment as an adjustment to the standardized amount, as both involve multipliers to the standardized amount, and both would be based upon the same modeling parameters." *Id.* at 24792. CMS' proposed rule does not address what, if any, modeling was performed to confirm or refute the conclusion that an adjustment to the wage index would result in "substantially similar payment," nor does it address the magnitude of the difference in payments if the proposed budget neutrality adjustment is applied to the wage index instead of the standardized amount. *Id.* It is unclear, therefore, whether CMS performed any modeling or other analysis to determine that an adjustment to the wage index would result in substantially similar payment as an adjustment to the standardized amount, and if so, what modeling or analysis was performed, what data was used in the modeling, and what results were obtained from such modeling or analysis.

Regarding the calculation of the proposed adjustment to the wage index, CMS states in the proposed rule that it would "use FY 2006 discharge data and FY 2008 wage indices to simulate IPPS payments without the rural floor. We would compare these simulated payments to simulated payments using the same data with a rural floor." *Id.* The proposed rule also states that the rural floor budget neutrality adjustment would be applied to post-reclassification wage indices, *id.* at 24799, 25125, but the notice does not specifically state whether the simulated payment model would use FY 2008 wage indices after reclassifications or FY 2008 wage indices before reclassifications. In addition, the proposed rule does not address what other adjustments, if any, would be made to the wage indices before or after application of the budget neutrality adjustment for the effects of the rural floor or how this adjustment to the wage index would be calculated for subsequent years after FY 2008.

The proposed rule also indicates that CMS is proposing what is described by CMS as a "Rural Floor Adjustment" of 1.002214 to the standardized amount for FY 2008. *Id.* at 24839. The proposed rule provides no explanation whatsoever as to the basis, purpose or calculation of that proposed "Rural Floor Adjustment" to the standardized amount. The proposed rule also does not address whether this adjustment to the standardized amount is a one-time adjustment that would be applied only for FY 2008 or whether it would be a recurring, annual adjustment for subsequent fiscal years.

Attachment II**Summary Of CMS' Descriptions Of Its Calculation Of The Rural Floor Budget
Neutrality Adjustment Factors In Prior IPPS Rules**IPPS Rule for FY 1998

The IPPS rule for FY 1998 described three discrete budget neutrality adjustments to the standardized amounts. 62 Fed. Reg. 46038-43 (Aug. 29, 1997). CMS described two of these budget neutrality adjustments – one adjustment for outliers and one adjustment certain rural hospitals deemed urban and for hospitals reclassified to a different area by the MGCRB – as one-time adjustments for each fiscal year. More specifically, the rule stated that the prior-year budget neutrality factors for these two adjustments were removed before updating the standardized amounts for the current year and new budget neutrality adjustments were applied to the updated standardized amounts for FY 1998. *Id.* at 46038-41.

CMS described the third budget neutrality adjustment to the standardized amounts as a single, discrete adjustment factor for the effects of both (i) annual DRG reclassification and recalibration of the relative weights and (ii) annual updates to the wage index. *Id.* at 46039. In relevant part, CMS described this adjustment as follows:

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used historical discharge data to simulate payments and compared aggregate payments using the FY 1997 relative weights and wage index to aggregate payments using the FY 1998 relative weights and wage index. The same methodology was used for the FY 1997 budget neutrality adjustment. . . . Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997731. We adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.999117. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 1997 budget neutrality adjustments.

Id.

CMS' IPPS rule for FY 1998 did not address the rural floor established by section 4410 of the BBA or that statute's budget neutrality requirement. To the contrary, in the above-quotation from the FY 1998 IPPS rule, CMS stated that the budget neutrality adjustment factor for DRG changes and wage updates was calculated using the same methodology that was used for the FY 1997 adjustment, implying that no budget neutrality adjustment was included within the calculation of this adjustment factor for FY 1998. As discussed further below, CMS' IPPS rule for FY 1999 indicated that some kind of budget neutrality adjustment factor for the application of the rural floor was included in the calculation of the budget neutrality adjustment factor for DRG changes and wage updates for FY 1999, and that the same methodology was used to calculate the FY 1998 adjustment. 63 Fed. Reg. 41007 (July 31, 1998). The latter statement in the FY 1999 IPPS rule is internally inconsistent with CMS' description of its calculation of the budget neutrality adjustment factor for FY 1998, and it is unclear which statement was true and which was false.² Moreover, the statement in the FY 1999 IPPS rule also is internally inconsistent with CMS' description of its calculation of the budget neutrality adjustment factor in the IPPS rule for FY 2000, which does not address any adjustment for the application of the rural floor but which also states that the budget neutrality adjustment factor for that year was calculated using the same methodology that was applied for FY 1999. Thus, it is entirely unclear which of these internally inconsistent statements was true.

CMS' FY 1998 IPPS rule also did not address what wage indexes were used for FY 1997 and FY 1998 in computing the simulated payments that were factored into the calculation of the DRG and wage index budget neutrality adjustment factor for FY 1998, as described in the above quotation from the IPPS rule for FY 1998. More specifically, CMS did not address whether either one or both of FY 1997 and FY 1998 wage indexes reflected geographic reclassifications for FY 1997 or FY 1998, or both. These issues have never been addressed in any later IPPS rule either, although CMS' general description of its calculation of the budget neutrality adjustment factor for DRG and wage index changes has remained largely unchanged in later years.

The FY 1998 IPPS rule also did not address what standardized amounts were applied in the simulation model that was used to calculate the budget neutrality adjustment factor for DRG changes and wage updates for FY 1998. More specifically, CMS did not address whether it used the 1997 standardized amounts, with or without budget neutrality adjustments for outliers and geographic reclassifications for FY 1997, or whether it used the updated 1998 standardized amounts, with or without the budget neutrality adjustment factors for outliers and geographic reclassifications. As set forth above, the rule said that "[t]hese budget neutrality adjustment factors [i.e., the budget neutrality adjustments to the standardized amounts and to the Puerto Rico-specific amounts for DRG and wage index changes] are applied without removing the effects of the FY 1997 budget neutrality adjustments;" but, it is unclear whether CMS was referring

² Additional ambiguities in the description of this aspect of budget neutrality adjustment factor the FY 1999 rule are addressed below in the discussion of the IPPS rule for FY 1999.

in that statement only to the FY 1997 budget neutrality adjustments for DRG and wage index changes or whether CMS was referring more broadly to all of the FY 1997 budget neutrality adjustments, including the two separate adjustments for geographic reclassifications and outliers.

IPPS Rule for FFY 1999

CMS' description of its calculation of budget neutrality adjustments in the IPPS rule for FY 1999 is substantively the same as its description of the calculation of these adjustments in the FY 1998 rule, with one significant exception. 63 Fed. Reg. 41006-10 (July 31, 1998). In the FY 1999 rule, CMS changed its description of the calculation of the budget neutrality adjustment factor for DRG and wage updates by including a statement indicating that CMS' calculation included an adjustment for the application of the rural floor established in section 4410 of the BBA. *Id.* at 41007. The relevant paragraph of the Addendum to the rule was changed to read as follows (with the new clause of the first sentence and all other revisions underscored):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, and the requirement in section 4410 of Public law 105-33 that application of the floor on the wage index be budget neutral, we used historical discharge data to simulate payments and compared aggregate payments using the FY 1998 relative weights and wage index to aggregate payments using the FY 1999 relative weights and wage index. The same methodology was used for the FY 1998 budget neutrality adjustment. . . . Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.999006. We adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.998912. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 1998 budget neutrality adjustments. . . .

Id.

The above-quoted description indicates that CMS used the FY 1998 wage index and the FY 1999 wage index in the simulation model that was used to calculate the budget neutrality adjustment factor for DRG changes, wage updates, and the application

of the rural floor. But, it is unclear whether wage index data that CMS used in the simulation model reflected the application of the rural floor for FY 1997 or FY 1998, respectively. CMS description of its calculation of this budget neutrality adjustment factor did not specify whether the simulation model applied the FY 1997 wage index before application of the rural floor for FY 1997 or after application of the rural floor for FY 1997, and it did not specify whether the model used the pre-floor wage index for FY 1998 or the post-floor wage index for FY 1998. These issues also have not been addressed in any later IPPS rule.

IPPS Rule for FY 2000

CMS' description of its calculation of the budget neutrality adjustments in the IPPS rule for FY 2000 is substantively the same as its description of the calculation of these adjustments in the FY 1999 rule, with one significant exception relating to the rural floor. 64 Fed. Reg. 41544-49 (July 30, 1999). In the FY 2000 rule, CMS again changed its description of the calculation of the budget neutrality adjustment factor for DRG changes and wage updates, this time deleting the provision that was added to the description of this calculation in the FY 1999 rule to include an adjustment for the application of the rural floor established in section 4410 of the BBA. *Id.* at 41546. The relevant paragraph of the Addendum to the rule, was changed to read as follows (with clause that was included in the FY 1999 rule and omitted in the FY 2000 rule shown in strikethroughs and all other revisions underscored):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, ~~and the requirement in section 4410 of Public law 105-33 that application of the floor on the wage index be budget neutral~~, we used historical discharge data to simulate payments and compared aggregate payments using the FY 1999 relative weights and wage index to aggregate payments using the FY 2000 relative weights and wage index. The same methodology was used for the FY 1999 budget neutrality adjustment. . . . Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997808. We also adjusted the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.999745. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 1999 budget neutrality adjustments. . .

Id.

CMS' deletion of the language referring to the rural floor from the above-quoted description of the budget neutrality calculation for FY 2000 suggests that CMS did not calculate or apply a budget neutrality adjustment factor for the effect of the rural floor for FY 2000. On the other hand, the FY 2000 rule also states, in the paragraph quoted above, that the calculation for FY 2000 applied the same methodology that was used to calculate the budget neutrality adjustment in the FY 1999 rule, and the FY 1999 rule in turn stated that CMS had included an adjustment for the effects of the rural floor for FY 1999. In view of these contradictory statements, it is unclear whether CMS calculated any adjustment for the effects of the rural floor for FY 2000. And, if CMS did calculate an adjustment for the effects of the rural floor for FY 2000, the FY 2000 rule provided no description whatsoever of the method and data that CMS used to calculate it.

IPPS Rule for FY 2001

CMS' description of its calculation of the budget neutrality adjustments in the IPPS rule for FY 2001 is substantively the same as its description of the calculation of these adjustments in the FY 2000 rule. Like the FY 2000 rule, the FY 2001 rule is silent as to any sort of calculation of a budget neutrality adjustment factor for the effects of the rural floor. 65 Fed. Reg. 47111-16 (Aug. 1, 2000). The relevant paragraph of the Addendum to the rule, describing the calculation of the budget neutrality adjustment factor for DRG changes and wage updates, stated (with revisions from the FY 2000 rule shown in underscoring):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used historical discharge data to simulate payments and compared aggregate payments using the FY 2000 relative weights and wage index to aggregate payments using the FY 2001 relative weights and wage index. The same methodology was used for the FY 2000 budget neutrality adjustment. . . . Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997225. We also adjusted the Puerto Rico-specific standardized amounts to adjust for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.999649. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2000 budget neutrality adjustments. . . .

Id. at 47112.

Here again, nothing in the text of the FY 2001 rule expressly states that CMS calculated any adjustment for the effects of the rural floor for FY 2001. And, if CMS did calculate an adjustment for the effects of the rural floor for FY 2001, the FY 2001 rule provided no description whatsoever of the method and data that CMS used to calculate it.

IPPS Rule for FY 2002

CMS' description of its calculation of the budget neutrality adjustments in the IPPS rule for FY 2002 is substantively the same as its description of the calculation of these adjustments in the FY 2001 and FY 2000 rules. Like the prior rules, the FY 2001 rule is silent as to any sort of calculation of a budget neutrality adjustment factor for the effects of the rural floor. 66 Fed. Reg. 39939-46 (Aug. 1, 2001). The relevant paragraph of the Addendum to the rule, describing the calculation of the budget neutrality adjustment factor for DRG and wage index changes, stated (with revisions from the FY 2001 rule shown in underscoring and strikethroughs):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used ~~historical~~ FY 2000 discharge data to simulate payments and compared aggregate payments using the FY 2001 relative weights and wage index to aggregate payments using the FY 2002 relative weights and wage index. The same methodology was used for the FY 2001 budget neutrality adjustment. ... Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.995821. We also adjusted the Puerto Rico-specific standardized amounts ~~to adjust~~ for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.997209. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2001 budget neutrality adjustments. . .

Id. at 39940.

Again, nothing in the text of the FY 2002 rule expressly states that CMS calculated any adjustment for the effects of the rural floor for FY 2002. If CMS did

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calculate an adjustment for the effects of the rural floor for FY 2002, the FY 2002 rule provided no description whatsoever of the method and data that CMS used to calculate it.

IPPS Rule for FY 2003

CMS amended its usual description of the budget neutrality adjustment for DRG and wage index changes, in section II.A.4.a of the Appendix to the IPPS rule for FY 2003, by adding a new paragraph referring to the rural floor and rural floor budget neutrality requirement in section 4410 of the BBA. 67 Fed. Reg. 50121 (Aug. 1, 2002). The new paragraph referred to the statute's budget neutrality requirement for the rural floor provision, but nothing in the FY 2003 rule addressed whether, or how, CMS computed budget neutrality adjustment factor for the effects of the rural floor.

The new paragraph regarding the rural floor stated:

Section 4410 of Public Law 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is required by section 4410(b) of Public Law 105-33 to be budget neutral.

Id.

The usual paragraph regarding the calculation performed to comply with the statutory budget neutrality requirements for DRG and wage index changes for FY 2003 is substantively the same as the description of the calculation of these adjustments in the FY 2002, FY 2001 and FY 2000 rules, except for new language addressing the inclusion of budget neutrality adjustment factor to account for new payment add-ons for new technology. Like the prior rules, this part of the FY 2003 rule is silent, however, as to any sort of calculation of a budget neutrality adjustment factor for the effects of the rural floor. *Id.* at 50121-22. This part of the rule stated (with changes from the FY 2002 rule shown in underscoring and strikethroughs):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used FY 2001 discharge data to simulate payments and compared aggregate payments using the FY 2002 relative weights and wage index to aggregate payments using the FY 2003 relative weights and wage index, plus the additional add-on payments for the new technology. The same methodology

was used for the FY 2002 budget neutrality adjustment, except for the new technology add-on budget neutrality adjustment. ... Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.993209. We also adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.994027. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2002 budget neutrality adjustments. . . .

Id. at 39940. CMS' mention of an adjustment for the technology add-on payments in the above-quoted description of the calculation of the budget neutrality adjustment factor, and its omission of any reference to an adjustment for the effects of the rural floor, suggests that CMS might not have actually made an adjustment for the effects of the rural floor. In any event, if CMS did calculate an adjustment for the effects of the rural floor for FY 2003, the FY 2003 rule provided no description whatsoever of the method and data that CMS used to calculate it.

IPPS Rule for FY 2004

CMS further revised its description of the budget neutrality adjustment for DRG and wage index changes, in section II.A.4.a of the Appendix to the IPPS rule for FY 2004, by adding a new sentence indicating that a budget neutrality adjustment factor was included in the calculation of wage index budget neutrality factor for FY 2004. 67 Fed. Reg. 45475 (Aug. 1, 2003). The new sentence was added at the end of the paragraph that was first added to the Addendum to the IPPS rule for FY 2003 (quoted above). As revised in the FY 2004 rule, that paragraph read:

Section 4410 of Pub. L. 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is required by section 4410(b) of Pub. L. 105-33 to be budget neutral. Therefore, we include the effects of this provision in our calculation of the wage update budget neutrality factor.

Id. The above-quoted statement that "we include the effects" of the rural floor in the budget neutrality factor is ambiguous. It could mean that CMS included a budget neutrality adjustment for the effects of the rural floor only in the FY 2004 rule and not in IPPS rule for any prior year. This reading of that statement would be consistent with

CMS' description of the calculation of the budget neutrality adjustment in the prior IPPS rules, which did not address an adjustment for the effects of the rural floor.

Additionally, it is unclear whether, or how, CMS actually calculated an adjustment factor for the rural floor in the calculation of its wage index budget neutrality adjustment factor for FY 2004. The usual paragraph regarding the calculation performed to comply with the statutory budget neutrality requirements for DRG and wage index changes for FY 2004 is substantively the same as the description of the calculation of these adjustments in the FY 2003 rule. As in prior year rules, that paragraph is silent as to any sort of calculation of a budget neutrality adjustment factor for the effects of the rural floor. *Id.* at 45475-76. Moreover, that paragraph indicates that CMS calculated the budget neutrality adjustment for DRG and wage index changes using the same methodology that had been used in prior years, and CMS' description of this calculation in the prior rules did not address an adjustment for the effects of the rural floor. This part of the rule stated (with changes from the FY 2003 rule shown in underscoring and strikethroughs):

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used FY 2002 discharge data to simulate payments and compared aggregate payments using the FY 2003 relative weights, and wage index, and new technology add-on payments to aggregate payments using the FY 2004 relative weights and wage index, plus the additional add-on payments for the new technology. The same methodology was used for the FY 2003 budget neutrality adjustment, ~~except for the new technology add-on budget neutrality adjustment.~~

Based on this comparison, we computed a budget neutrality adjustment factor equal to 1.005522. We also adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 1.001661. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2003 budget neutrality adjustments. . . .

Id. Thus, it is unclear whether CMS actually included an adjustment for the effects of the rural floor in its calculation of the budget neutrality adjustment factor for FY 2004. Moreover, even if CMS did include an adjustment for the effects of the rural floor in the

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calculation of the budget neutrality adjustment for FY 2004, the rule provided no description whatsoever of the method and data that CMS used to calculate it.

IPPS Rule for FY 2005

CMS' IPPS rule for FY 2005 indicates that CMS calculated a budget neutrality adjustment for the effects of the rural floor in the calculation of the budget neutrality adjustment factor for DRG and wage index changes 69 Fed. Reg. 49273-82 (Aug. 11, 2004). The FY 2005 rule does not describe in particular how CMS calculated the budget neutrality adjustment specifically for the effects of the rural floor, or what specific data were used to calculate a budget neutrality adjustment for the rural floor. With respect to the rural floor budget neutrality adjustment, CMS stated:

Section 4410 of Public Law 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is required by section 4410(b) of Public Law 105-33 to be budget neutral. Therefore, we include the effects of this provision in our calculation of the wage update budget neutrality factor.

Id. at 49275. CMS also added the following two new sentences to the end of the above-quoted paragraph from FY 2005 rule:

As discussed in section IV.N.6 of the preamble, we are imputing a floor for States that have no rural areas under the labor market definitions that apply within the IPPS. We are also including the effects of this new provision in our calculation of the wage update budget neutrality factor.

Id.

The usual paragraph regarding the calculation performed to comply with the statutory budget neutrality requirements for DRG and wage index changes for FY 2005 is substantively the same as the description of the calculation of these adjustments in the prior IPPS rules. This part of the FY 2005 stated (with changes from the FY 2004 rule shown in underline and strikethroughs):

To comply with the requirement of ~~section 1886(d)(4)(C)(iii) of the Act~~ that DRG reclassification and recalibration of the relative weights be budget neutral, and the requirement in ~~section 1886(d)(3)(E) of the Act~~ that the updated wage index be budget neutral, we used FY 2003

discharge data to simulate payments and compared aggregate payments using the FY 2004 relative weights and wage index, ~~and new technology add-on payments~~ to aggregate payments using the FY 2005 relative weights and wage index, ~~plus the additional add-on payments for the new technology~~. The same methodology was used for the FY 2004 budget neutrality adjustment (although the FY 2004 adjustment included the effects of new technology add-on payments).

Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.999876. We also are adjusting the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 1.000564. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2004 budget neutrality adjustments.

As in the prior rules, above-quoted description of the calculation of the budget neutrality adjustment for DRG and wage index changes in the FY 2005 rule is silent as to any adjustment for the effects of the rural floor.

In addition, the FY 2005 rule provides virtually no meaningful information as to the details of the calculation of the budget neutrality adjustment for FY 2005. While the rule mentions in passing that the adjustment was calculated based on a simulated payments using the DRG weights and wage indexes for FY 2004 and FY 2005, the rule does not address what standardized amounts were used in the model or precisely what wage index data was used for FY 2004 and FY 2005.

IPPS Rule for FY 2006

CMS' IPPS rule for FY 2006, like the FY 2004 and FY 2005 rules, indicates that CMS calculated a budget neutrality adjustment for the effects of the rural floor in the calculation of the budget neutrality adjustment factor for DRG and wage index changes 70 Fed. Reg. 47491-98 (Aug. 12, 2005). But, again, the FY 2006 rule does not describe in particular how CMS calculated the budget neutrality adjustment specifically for the effects of the rural floor, or what specific data were used to calculate that aspect of the budget neutrality adjustment. With respect to the rural floor budget neutrality adjustment, CMS stated:

Section 4410 of Pub. L. 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area

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adjusting the Puerto Rico-specific standardized amount for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amount equal to 0.998993. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2005 budget neutrality adjustments.

The above-quoted descriptions of the calculation of the budget neutrality adjustment for DRG and wage index changes provide virtually no information as to the details of the calculation for FY 2006. Even assuming that a rural floor budget neutrality adjustment was included in this calculation based on the above-described comparison of simulated payments using FY 2004 discharge data and the DRG relative weights and wage index data for FY 2005 and FY 2006, CMS' discussion of this calculation does not address any of the important details concerning its calculation.

IPPS Rule for FY 2007

CMS' IPPS rule for FY 2007 does not describe in particular how CMS calculated the budget neutrality adjustment specifically for the effects of the rural floor, or what specific data were used to calculate that aspect of the budget neutrality adjustment. 71 Fed. Reg. 48145-55 (Aug. 18, 2006). Regarding the rural floor budget neutrality adjustment, CMS stated:

Section 4410 of Pub. L. 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is required by section 4410(b) of Pub. L. 105-33 to be budget neutral. Therefore, we include the effects of this provision in our calculation of the wage update budget neutrality factor.

Id. at 48147. CMS also added the following to the end of the above-quoted paragraph from FY 2007 rule:

As discussed in the FY 2006 IPPS final rule (70 FR 47493), FY 2007 is the third and final year of the 3-year provision that uses an imputed wage index floor for States that have no rural areas and States that have geographic rural areas but that have no hospitals actually classified as rural. We are also adjusting for the effects of this new provision in our calculation of the wage update budget neutrality factor.

Id.

The usual paragraph regarding the calculation performed to comply with the statutory budget neutrality requirements for DRG and wage index changes for FY 2007 is substantively the same as the description of the calculation of these adjustments in the prior IPPS rules. Again, this part of the FY 2007 IPPS rule does not specifically address what data (which wage indexes and standardized amounts) were used in the payment simulation model that was utilized to compute the budget neutrality adjustment for the rural floor, the imputed rural floor and other changes.

This part of the FY 2007 rule stated (with changes from the FY 2006 rule shown in underline and strikethroughs):

To comply with the requirement that DRG reclassification and recalibration of the relative weights ~~be budget neutral~~, and the requirement that the updated wage index be budget neutral, we used FY 2005 discharge data to simulate payments and compared aggregate payments using the FY 2006 relative weights and wage indexes to aggregate payments using the FY 2007 relative weights and wage indexes. The same methodology was used for the FY 2006 budget neutrality adjustment.

Based on this comparison, we computed a tentative budget neutrality adjustment factor equal to 0.997030. We ~~are also~~ are adjusting the Puerto Rico-specific standardized amount for the effect of DRG reclassification and recalibration. We computed a tentative budget neutrality adjustment factor for Puerto Rico-specific standardized amount equal to 0.997968. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2006 budget neutrality adjustments.

The above-quoted descriptions of the calculation of the budget neutrality adjustment for DRG and wage index changes provide virtually no information as to the details of the calculation. The rule only generally describes CMS' calculation of an adjustment based simulated payments using FY 2005 discharge data and the DRG relative weights and wage indexes for FY 2006 and FY 2007. CMS' discussion of the simulation model does not address any of the important details concerning its calculation.

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June 12, 2007

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

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

Dear Ms. Norwalk:

Please accept these comments from the Connecticut Hospital Association (CHA), on behalf of its twenty-nine not-for-profit acute care hospital members, regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates [CMS-1533-P]. The CMS proposed rule sets forth numerous and sweeping operational and policy changes to the hospital inpatient prospective payment system (IPPS). These comments explain the significant effect a number of the proposed changes will have on Connecticut's hospitals and outline strategies to ensure that payments are sufficient to adequately compensate hospitals for their legitimate costs.

I. COMMENT SUMMARY

- **DRG changes:** CHA supports moving to MS-DRGs, but requests the adoption of MS-DRGs be done over a period of four years, as more fully detailed in the comments below. In addition, CHA opposes the application of a "behavioral offset."
- **Capital IPPS:** CHA opposes the elimination of the capital payment update for all urban hospitals, as well as the elimination of the large urban capital payment add-on.
- **Wage Index:** CHA opposes the changes proposed to New England deemed counties and requests that if the changes go forward, that it be made clear that the changes will have no effect on the published rural floor value of 1.2439. Finally, CHA proposes a 1.5% stop loss corridor as means to address one of the requirements of PUB.L. 109-432, i.e., to reduce the volatility of wage indices over time while maintaining budget neutrality.

II. COMMENT DETAIL

A. Impact Analysis

Over the last decade, the policies implemented by the Medicare program have not been kind to Connecticut's hospitals, collectively or individually. The analysis below will illustrate how Connecticut hospitals have been significantly and negatively affected by Medicare rate policies during the past decade.

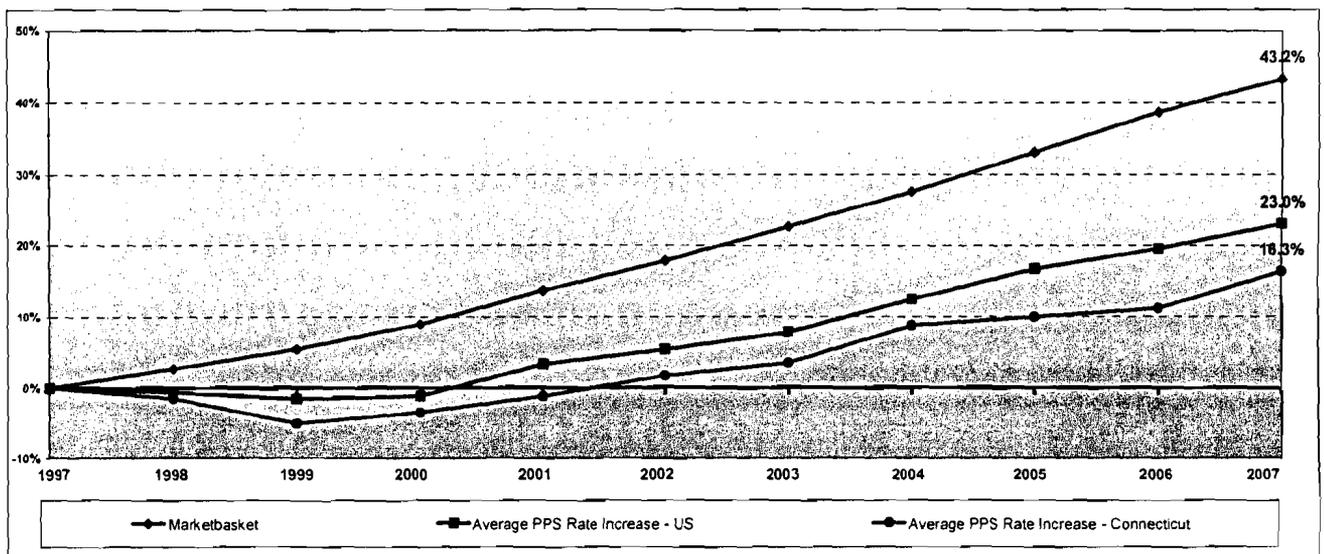
i. Impact on Connecticut over the last decade of CMS payment policy

The goal of a Prospective Payment System should be to create incentives for hospitals to operate efficiently and minimize costs while at same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs. The impact analysis below clearly shows that Connecticut's rates of increase over the last decade have lagged significantly behind the nation and that the rate of increase proposed for Connecticut for 2008 will do little to reverse this past.

First, as Chart 1 below indicates, Connecticut has seen cumulative increases totaling 16.3% over the past decade, an average 1.5% increase per year. Hospitals nationally have seen cumulative increases totaling 23.0% over the same period, an average 2.1% increase per year. During that same period of time, the amount hospitals had to pay for inputs to produce hospital services, according to CMS, increased 43.2%, an average increase of 3.7% per year. Regardless of how you measure Connecticut's situation over the last decade, the conclusion is the same: Connecticut has been left behind.

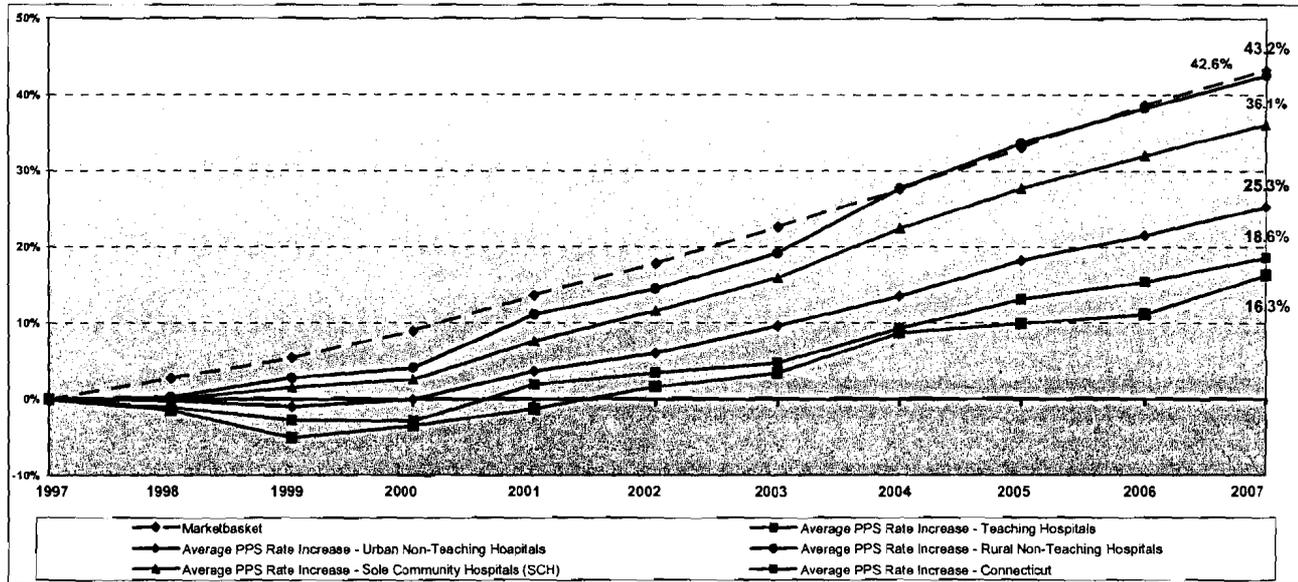
Connecticut's rate of increase has barely covered 40% of what CMS has forecasted as the increase in input costs and has averaged about 71% of what CMS has granted the rest of the nation. This gap has caused Connecticut hospitals to have to find \$2.1 billion in funding to cover Medicare's shortfall in reimbursement of legitimate input cost increases.

Chart I
Cumulative Medicare Hospital Rate Increase vs. Marketbasket Cost Increases
1997 to 2007
Connecticut Compared to the U.S.



Second, as can be seen in Chart II, no matter how you measure it, Connecticut has consistently “come up short” in terms of Medicare reimbursement.

Chart II
Cumulative Medicare Hospital Rate Increase vs. Marketbasket Cost Increases
1997 to 2007
United States by Provider Type vs. Connecticut



ii. What causes Connecticut to fare so poorly?

The significant drivers of payment to Connecticut hospitals are not the payment drivers that policy makers have sought to favor. As a consequence, Connecticut suffers, inappropriately, from having a commitment to teaching, historically high wages that are growing at less than the national average, and a system of care that allows patients to be appropriately transferred (Connecticut’s geometric mean length-of-stay exceeds the national geometric mean for similar cases, undermining the argument that a transfer provision change was necessary to thwart “gaming the system”).

iii. Impact analysis of the Proposed Changes to the IPPS for 2008 on Connecticut

The analysis below illustrates how some Connecticut hospitals will be harmed by the Medicare rate policies proposed for 2008. In the aggregate, the proposed rule will essentially freeze the aggregate level of payment to Connecticut in 2008 at 2007 levels.

Table I

**Connecticut Impact of the Medicare 2008 Inpatient Prospective Payment System (IPPS)
Proposed Rule - Operating & Capital Payments**

	Operating		Capital		Total	
Estimated 2007 IPPS Payments	\$ 1,474,729,000	92.2%	\$ 124,711,000	7.8%	\$ 1,599,440,000	
Market Basket Update Factor	\$ 50,817,000	3.4%	\$ (871,000)	-0.7%	\$ 49,946,000	3.1%
Behavioral Offset	\$ (36,477,000)	-2.5%	\$ (2,920,000)	-2.3%	\$ (39,397,000)	-2.5%
DRG Weights - Expansion & Transition (a)	\$ 3,231,000	0.2%	\$ 273,000	0.2%	\$ 3,504,000	0.2%
IME and Other (Large Urban Add-On Removed)	\$ 3,530,000	0.2%	\$ (1,497,000)	-1.2%	\$ 2,033,000	0.1%
Wage Index & GAF (b)	\$ (12,397,000)	-0.8%	\$ (914,000)	-0.7%	\$ (13,311,000)	-0.8%
Estimated Net Change	\$ 8,704,000	0.6%	\$ (5,929,000)	-4.8%	\$ 2,775,000	0.2%
Estimated 2008 IPPS Payments	\$ 1,483,433,000	92.8%	\$ 118,782,000	7.4%	\$ 1,602,215,000	

(a) Expansion from 538 to 745 DRGs and continuation of the transition to cost-based weights.
(b) Does not include potential reduction to rural floor of \$76 million.

While some policy changes are positive in the aggregate, they do not always affect everyone the same way. Table II illustrates this point by cataloging the wins and losses for each change factor. As Table II shows, some payment changes, such as the market basket, help all hospitals, while other changes help some and hurt others, such as DRG Weight and Wage Index changes.

Table II

**Connecticut Impact of the Medicare 2008 Inpatient Prospective Payment System (IPPS)
Proposed Rule - Positives and Negatives**

	Hospitals Impacted Positively		Hospitals Impacted Negatively		Total	
	Count	Funding	Count	Funding		
Estimated 2006 IPPS Payments					\$ 1,599,440,000	
Market Basket Update Factor	30	\$ 49,946,000	-	\$ -	\$ 49,946,000	3.1%
Behavioral Offset	-	\$ -	30	\$ (39,397,000)	\$ (39,397,000)	-2.5%
DRG Weights - Expansion & Transition (a)	16	\$ 9,544,000	14	\$ (6,040,000)	\$ 3,504,000	0.2%
IME and Other (Large Urban Add-On Removed)	18	\$ 2,529,000	12	\$ (496,000)	\$ 2,033,000	0.1%
Wage Index & GAF (b)	1	\$ 355,000	29	\$ (13,666,000)	\$ (13,311,000)	-0.8%
Net Change	17	\$ 62,374,000	13	\$ (59,599,000)	\$ 2,775,000	0.2%
Estimated 2007 IPPS Payments					\$ 1,602,215,000	
Hospital Net Change	17	\$ 10,905,000	13	\$ (8,130,000)	\$ 2,775,000	0.2%

(a) Expansion from 538 to 745 DRGs and continuation of the transition to cost-based weights.
(b) Does not include potential reduction to rural floor of \$76 million.

In the final analysis, what really matters is the interaction of the various payment factors on overall hospital results. As seen in Table III, the combination of these factors creates a wide range of results in Connecticut, spanning nearly 10.1 percentage points from lowest to highest.

Table III
Hospital Specific Impact of the Medicare 2008
Inpatient Prospective Payment System (IPPS) Proposed Rule

	Percent Change from 2007 to 2008					
	Total Impact	Update Factor	Wage Index & GAF	IME / Other	DRG Changes	Behavioral Offset
Day Kimball Hospital	-4.9%	3.1%	-0.1%	-0.2%	-5.4%	-2.3%
Greenwich Hospital	-2.7%	3.1%	-0.8%	0.1%	-2.7%	-2.4%
Milford Hospital	-1.9%	3.1%	-1.7%	0.0%	-0.9%	-2.4%
Norwalk Hospital	-1.7%	3.1%	-0.8%	0.2%	-1.8%	-2.4%
John Dempsey Hospital	-1.7%	3.1%	-2.9%	0.4%	0.2%	-2.4%
Griffin Hospital	-1.3%	3.1%	-1.7%	0.2%	-0.5%	-2.4%
Saint Mary's Hospital	-1.1%	3.1%	-1.7%	0.2%	-0.3%	-2.4%
Yale-New Haven Hospital	-0.8%	3.1%	-1.7%	0.4%	-0.2%	-2.4%
Saint Francis Hospital And Medical Center	-0.6%	3.1%	-0.1%	0.0%	-1.2%	-2.4%
Sharon Hospital	-0.6%	3.1%	0.0%	-0.2%	-1.0%	-2.4%
The Stamford Hospital	-0.5%	3.1%	-0.8%	0.2%	-0.6%	-2.4%
Hospital of Saint Raphael	-0.5%	3.1%	-1.7%	0.3%	0.3%	-2.4%
Windham Community Memorial Hospital	-0.2%	3.1%	-0.1%	-0.2%	-0.5%	-2.5%
Bridgeport Hospital	0.1%	3.1%	-0.8%	0.2%	-0.1%	-2.5%
Bradley Memorial Hospital	0.2%	3.1%	-0.1%	-0.2%	-0.1%	-2.5%
St. Vincent's Medical Center	0.2%	3.1%	-0.8%	0.2%	0.2%	-2.5%
Bristol Hospital	0.4%	3.1%	-0.1%	-0.2%	0.0%	-2.5%
Danbury Hospital	0.7%	3.1%	-0.8%	0.2%	0.7%	-2.5%
New Britain General Hospital	0.8%	3.1%	-0.1%	-0.1%	0.3%	-2.5%
Lawrence Memorial Hospital	0.9%	3.1%	-0.1%	0.0%	0.3%	-2.5%
MidState Medical Center	1.0%	3.1%	-1.7%	0.0%	2.0%	-2.5%
The Charlotte Hungerford Hospital	1.4%	3.1%	-0.1%	-0.2%	1.1%	-2.5%
Waterbury Hospital	1.5%	3.1%	-1.7%	0.2%	2.4%	-2.5%
Hartford Hospital	1.7%	3.1%	-0.1%	0.1%	1.0%	-2.5%
Middlesex Hospital	2.2%	3.1%	-0.5%	-0.1%	2.3%	-2.5%
Johnson Memorial Hospital	2.3%	3.1%	-0.1%	-0.2%	2.0%	-2.5%
Manchester Memorial Hospital	2.8%	3.1%	-0.1%	-0.2%	2.5%	-2.5%
New Milford Hospital	3.4%	3.1%	3.3%	-0.2%	-0.2%	-2.5%
The William W. Backus Hospital	3.9%	3.1%	-0.1%	0.0%	3.4%	-2.6%
Rockville General Hospital	5.2%	3.1%	-0.1%	-0.2%	5.1%	-2.6%
Connecticut	0.2%	3.1%	-0.8%	0.1%	0.2%	-2.5%

Does not include potential reduction to rural floor of \$76 million.

iv. Impact Analysis Conclusion

In our view, this proposed rule does nothing to reverse the decade long underfunding that Connecticut has experienced. An effort must be undertaken to understand and correct Connecticut's, and other similarly situated states', lagging rates of increase.

B. 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.

Subject to the transition described below, CHA supports meaningful improvements to Medicare's inpatient prospective payment system (PPS) and the 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, thereby allowing providers the ability to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions.

i. 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 comorbidity (CC) list and created up to three tiers of payment for each DRG based on the presence of: a *major* complication or comorbidity (MCC), a *minor* complication or comorbidity, or *no* complication or comorbidity.

CHA supports meaningful improvements to Medicare's inpatient PPS, but time is 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 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.
- In FY 2009, DRG weights should be computed as a blend derived one-third from the MS-DRGs and two-thirds from traditional DRGs.
- In FY 2010, DRG weights should be computed as a blend derived two-thirds from MS-DRGs and one-third from traditional DRGs.
- In FY 2011, DRG weights should be derived using only the MS-DRGs.

ii. 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. **The CHA opposes the "behavioral offset," which will cut payments to Connecticut hospitals by \$40 million in 2008.**

C. Capital IPPS

Medicare is required to pay for the capital-related costs of inpatient hospital services. 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 CAT scanners). This is done through a separate capital PPS. 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 adjusted for indirect medical education (IME), disproportionate share hospital (DSH) and outlier payments.

For FY 2008, CMS proposes eliminating the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut). However, CMS proposes to update capital payments for rural hospitals by 0.8 percent (the capital input price index). In addition, CMS is considering discontinuing the IME and DSH adjustments to capital payments.

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. Capital cuts will disrupt Connecticut hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements with the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties and amounts to Medicare renegeing on the full cost of caring for America's seniors and disabled. **The CHA is opposed to these unnecessary cuts, which ignore how vital capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology.**

D. Wage Index - New England Deemed Counties

At issue is the proposed change to the Hospital Wage Index; specifically, the revision to the proposed Wage Index based on hospital Redesignations for New England Deemed Counties outlined in section III.I (10) of the proposed rule (72 FR 24797 and 24798). Specifically, Connecticut is concerned that the change would reduce the rural floor wage index below the published 1.2439 value.

The proposed regulation notes that current regulations at 42CFR 412.64(b)(1)(ii)(B) list five New England counties that are deemed to be part of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 1395ww[*note*]). The statute requires continuing the 1979 urban classification of these New England hospitals in determining if a hospital is in an urban or rural area for purposes of section 1886(d) of the Social Security Act. The statute states in part:

In determining whether a hospital is in an urban or rural area for purposes of section 1886(d) of the Social Security Act, the Secretary of Health and Human Services shall classify any hospital located in New England as being located in an urban area if such hospital was classified as being located in an urban area under the Standard Metropolitan Statistical Area system of classification in effect in 1979.

The proposed rule states that of the five New England counties, three are part of MSAs while the remaining two areas, one of which is Litchfield County in Connecticut, by regulation would be treated as rural if it were not for the statute that required them to be treated as urban.

For about a quarter of a century, hospitals in Litchfield County, Connecticut have been deemed urban as required by statute and treated as urban for reclassification purposes. The proposed rule states:

... upon further consideration of this issue, we believe the hospitals located within these New England counties should be treated the same as Lugar hospitals. That is, the area would be considered rural but the hospitals within them would be deemed to be urban. ... We note that Tables 2, 3A, 3B, 4A and 4B in the addendum to this proposed rule do not reflect this proposed change; rather, they reflect the wage index based on the current policy.

Over half of the acute care hospitals in Connecticut have a wage index established based on the Connecticut rural floor. As such, negative changes to the rural floor wage index value can have an enormous impact on the state of Connecticut and the ability of Connecticut hospitals to deliver high quality care.

We believe the change is not warranted and is contrary to the plain meaning of the statute. Notwithstanding the foregoing, if CMS intends to go forward with this change, the final rule should make clear that:

1. The proposed change is only to promote consistency within the regulations with regard to the treatment of micropolitan areas;
2. The proposed change to the deemed county status of Litchfield is not designed to reduce the rural floor and, therefore, will have no effect on the resulting index value of 1.2439;
3. The hold harmless provisions of Section 1886(d)(8)(C) of the Act protect rural areas by excluding the wage data of hospitals redesignated to another area if such exclusion increases the rural wage index;
4. The hospitals in Litchfield county will have by regulation the same rights afforded by statute to Lugar hospitals;
5. A change to rural status by a hospital located in Litchfield county will not reduce the Connecticut rural floor because of the hold harmless provision adopted in 2005 for urban to rural reclassifications under section 1886 (d)(8)(E) of the Act (70 FR 47379).

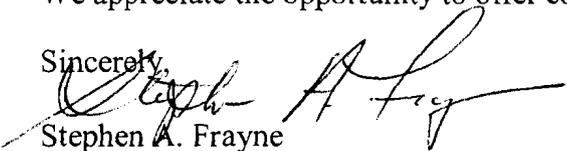
E. Wage Index Study Required Under Pub. L. 109-432

In FY 2009, CMS is required by law to consider several changes to the area wage index. One change to be considered is “methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality.”

Attached for your consideration is a proposal to accomplish this objective. In short, it limits the reduction in a wage index value to no more than 1.5 percentage points year over year. In so doing, it eliminates the possibility of a wage index change wiping out the full market basket update. The cost of such a stop loss provision is about one quarter of one percent of total inpatient Medicare payments. If such a stop loss would have been applied in 2007, 794 hospitals would have been helped – only eight states would have had no hospitals helped.

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

Sincerely,


Stephen A. Frayne

Senior Vice President, Health Policy

SAF:kas

By electronic submission

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March 5, 2007

Mr. Steve Frayne
Senior Vice President, Health Policy
Connecticut Hospital Association
110 Barnes Road
P.O. Box 90
Wallingford, CT 06492

Re: Financial Impact of One and One-Half Percent Annual Stop Loss Floor
in the Medicare Wage Index

Dear Steve:

This letter summarizes our engagement to evaluate the computation of the financial impact of establishing a legislative (or perhaps regulatory) floor which would prevent a hospital from a decrease in the Medicare wage index after adjustment for occupational mix of exceeding 1.5% from one year to the next.

Executive Summary

We estimated the increase in inpatient and outpatient Medicare operating and capital payment of implementing a Stop Loss Floor. The cost of the 1.5% floor is an estimated \$287 million dollars in inpatient and outpatient acute care payment for Federal Fiscal Year (FFY) 2007. The inpatient impact is \$254,000,000 of the total. CMS has estimated total inpatient operating PPS payments of \$107 billion, so the effect of such a floor is less than .24% of total inpatient Medicare payments.

A Stop Loss Floor could be financed by legislative action involving new monies, or it could be implemented in a budget neutral manner. The two attachments summarize the dollar impact by state and by wage Index geographic area (which in some cases crosses state boundaries) based on our two analyses for FFY 2007.

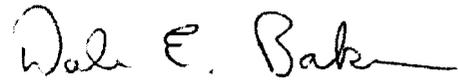
In short, this kind of protection produces great benefit of insuring that wage related changes can't wipe out the legislated annual update to a hospital or a group of hospitals at a cost of less than one quarter of one percent of total Medicare acute care payment per year.

Mr. Steve Frayne
August 28, 2006
Page 2

It is a pleasure to provide this analysis, if you have further questions please do not hesitate to contact us.

Best personal regards,

BAKER HEALTHCARE CONSULTING, INC.

A handwritten signature in black ink that reads "Dale E. Baker". The signature is written in a cursive style with a long horizontal flourish at the end.

Dale E. Baker
President

Attachment

2587DEB

Baker Healthcare Consulting, Inc.
 Statewide Impact of Implementation of Maximum Decrease of 1.5% of Wage Index
 Using FFY 2007 Public Use File & 2007 Wage Indexes

ST	#Hospitals	Total
1 Alabama	22	\$10,484,517
2 Alaska	5	\$1,665,851
3 Arizona	6	\$1,808,984
4 Arkansas	10	\$3,462,853
5 California	34	\$5,696,055
6 Colorado	16	\$5,006,879
7 Connecticut	2	\$1,398,221
8 Delaware	0	\$0
9 Distric of Columbia	0	\$0
10 Florida	43	\$15,721,643
11 Georgia	10	\$4,362,773
12 Hawaii	10	\$2,053,426
13 Idaho	3	\$1,263,941
14 Illinois	3	\$275,124
15 Indiana	19	\$7,933,691
16 Iowa	13	\$10,490,503
17 Kansas	19	\$1,086,717
18 Kentucky	7	\$6,496,878
19 Louisiana	34	\$14,594,134
20 Maine	21	\$11,754,843
21 Maryland	15	\$14,699,455
22 Massachusetts1	0	\$0
23 Michigan	6	\$1,476,132
24 Minnesota	24	\$7,107,687
25 Mississippi	19	\$2,048,686
26 Missouri	0	\$0
27 Montana	7	\$6,439,302
28 Nebraska	10	\$900,154
29 Nevada	12	\$2,649,974
30 New Hampshire	0	\$0
31 New Jersey1	0	\$0
32 New Mexico	13	\$1,149,526
33 New York	0	\$0
34 North Carolina	39	\$17,653,847
35 North Dakota	12	\$5,238,323
36 Ohio	28	\$12,509,805
37 Oklahoma	46	\$8,704,426
38 Oregon	3	\$5,094,889
39 Pennsylvania	40	\$12,928,552
40 Puerto Rico1	47	\$9,109,287
41 Rhode Island1	9	\$7,557,225
42 South Carolina	18	\$9,805,435
43 South Dakota	19	\$3,681,596
44 Tennessee	22	\$3,869,897
45 Texas	70	\$12,582,155

Baker Healthcare Consulting, Inc.
Statewide Impact of Implementation of Maximum Decrease of 1.5% of Wage Index
Using FFY 2007 Public Use File & 2007 Wage Indexes

46 Utah	2	\$275,003
47 Vermont	2	\$5,520,231
49 Virginia	12	\$5,853,785
50 Washington	31	\$18,095,667
51 West Virginia	10	\$6,390,575
52 Wisconsin	0	\$0
53 Wyoming	1	\$379,049
Grand Total	794	\$287,277,695

***Calculations using Published FY2007 Wage Index**

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

CBSA	Total
1 Alabama Rural	\$1,791,034
2 Alaska Rural	\$928,697
3 Arizona Rural	\$656,022
4 Arkansas Rural	\$643,909
5 California Rural	\$0
6 Colorado Rural	\$1,199,480
7 Connecticut Rural	\$570,678
8 Delaware Rural	\$0
10 Florida Rural	\$1,410,798
11 Georgia Rural	\$412,912
12 Hawaii Rural	\$40,245
13 Idaho Rural	\$0
14 Illinois Rural	\$50,297
15 Indiana Rural	\$722,346
16 Iowa Rural	\$3,693,999
17 Kansas Rural	\$662,935
18 Kentucky Rural	\$1,779,037
19 Louisiana Rural	\$1,900,526
20 Maine Rural	\$3,174,402
21 Maryland Rural	\$1,991,362
23 Michigan Rural	\$703,251
24 Minnesota Rural	\$44,786
25 Mississippi Rural	\$1,654,924
26 Missouri Rural	\$0
27 Montana Rural	\$2,299,257
28 Nebraska Rural	\$105,599
29 Nevada Rural	\$575,373
30 New Hampshire Rural	\$0
32 New Mexico Rural	\$1,149,526
33 New York Rural	\$0
34 North Carolina Rural	\$1,779,277
35 North Dakota Rural	\$1,051,607
36 Ohio Rural	\$2,386,792
37 Oklahoma Rural	\$1,923,820
38 Oregon Rural	\$4,751,451
39 Pennsylvania Rural	\$787,373
42 South Carolina Rural	\$2,423,236
43 South Dakota Rural	\$1,344,358
44 Tennessee Rural	\$526,870
45 Texas Rural	\$1,903,691
46 Utah Rural	\$20,968

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

47 Vermont Rural	\$292,410
49 Virginia Rural	\$110,848
50 Washington Rural	\$1,321,504
51 West Virginia Rural	\$950,321
52 Wisconsin Rural	\$0
53 Wyoming Rural	\$379,049
10180 Abilene, TX	\$0
10380 Aguadilla-Isabela-San Sebastián, PR	\$2,110,091
10420 Akron, OH	\$0
10500 Albany, GA	\$0
10580 Albany-Schenectady-Troy, NY	\$0
10740 Albuquerque, NM	\$0
10780 Alexandria, LA	\$0
10900 Allentown-Bethlehem-Easton, PA-NJ	\$0
11020 Altoona, PA	\$1,322,175
11100 Amarillo, TX	\$0
11180 Ames, IA	\$0
11260 Anchorage, AK	\$0
11300 Anderson, IN	\$1,928
11340 Anderson, SC	\$0
11460 Ann Arbor, MI	\$772,881
11500 Anniston-Oxford, AL	\$0
11540 Appleton, WI	\$0
11700 Asheville, NC	\$598,132
12020 Athens-Clarke County, GA	\$1,554,448
12060 Atlanta-Sandy Springs-Marietta, GA	\$0
12100 Atlantic City, NJ	\$0
12220 Auburn-Opelika, AL	\$0
12260 Augusta-Richmond County, GA-SC	\$0
12420 Austin-Round Rock, TX	\$0
12540 Bakersfield, CA	\$0
12580 Baltimore-Towson, MD	\$0
12620 Bangor, ME	\$1,640,834
12700 Barnstable Town, MA	\$0
12940 Baton Rouge, LA	\$5,578,608
12980 Battle Creek, MI	\$0
13020 Bay City, MI	\$0
13140 Beaumont-Port Arthur, TX	\$0
13380 Bellingham, WA	\$2,247,846
13460 Bend, OR	\$343,438
13644 Bethesda-Gaithersburg-Frederick, MD	\$8,597,609
13740 Billings, MT	\$0
13780 Binghamton, NY	\$0
13820 Birmingham-Hoover, AL	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

13900 Bismarck, ND	\$1,343,324
13980 Blacksburg-Christiansburg-Radford, VA	\$0
14020 Bloomington, IN	\$0
14060 Bloomington-Normal, IL	\$0
14260 Boise City-Nampa, ID	\$0
14484 Boston-Quincy, MA	\$0
14500 Boulder, CO	\$0
14540 Bowling Green, KY	\$0
14740 Bremerton-Silverdale, WA	\$1,238,709
14860 Bridgeport-Stamford-Norwalk, CT	\$0
15180 Brownsville-Harlingen, TX	\$0
15260 Brunswick, GA	\$0
15380 Buffalo-Niagara Falls, NY	\$0
15500 Burlington, NC	\$338,331
15540 Burlington-South Burlington, VT	\$5,227,821
15764 Cambridge-Newton-Framingham, MA	\$0
15804 Camden, NJ	\$0
15940 Canton-Massillon, OH	\$0
15980 Cape Coral-Fort Myers, FL	\$0
16180 Carson City, NV	\$0
16220 Casper, WY	\$0
16300 Cedar Rapids, IA	\$0
16580 Champaign-Urbana, IL	\$0
16620 Charleston, WV (WV Hospitals)	\$0
16700 Charleston-North Charleston, SC	\$0
16740 Charlotte-Gastonia-Concord, NC-SC	\$6,075,213
16820 Charlottesville, VA	\$0
16860 Chattanooga, TN-GA	\$101,884
16940 Cheyenne, WY	\$0
16974 Chicago-Naperville-Joliet, IL	\$0
17020 Chico, CA	\$0
17140 Cincinnati-Middletown, OH-KY-IN	\$0
17300 Clarksville, TN-KY	\$0
17420 Cleveland, TN	\$108,266
17460 Cleveland-Elyria-Mentor, OH	\$0
17660 Coeur d'Alene, ID	\$1,062,767
17780 College Station-Bryan, TX	\$0
17820 Colorado Springs, CO	\$0
17860 Columbia, MO	\$0
17900 Columbia, SC	\$0
17980 Columbus, GA-AL	\$0
18020 Columbus, IN	\$1,335
18140 Columbus, OH	\$0
18580 Corpus Christi, TX	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

18700 Corvallis, OR	\$0
19060 Cumberland, MD-WV	\$1,499,854
19124 Dallas-Plano-Irving, TX	\$6,472,455
19140 Dalton, GA	\$0
19180 Danville, IL	\$0
19260 Danville, VA	\$0
19340 Davenport-Moline-Rock Island, IA-IL	\$0
19380 Dayton, OH	\$0
19460 Decatur, AL	\$0
19500 Decatur, IL	\$0
19660 Deltona-Daytona Beach-Ormond Beach, FL	\$0
19740 Denver-Aurora, CO	\$0
19780 Des Moines, IA	\$5,947,066
19804 Detroit-Livonia-Dearborn, MI	\$0
20020 Dothan, AL	\$0
20100 Dover, DE	\$0
20220 Dubuque, IA	\$0
20260 Duluth, MN-WI	\$0
20500 Durham, NC	\$9,106,920
20740 Eau Claire, WI	\$0
20764 Edison, NJ	\$0
20940 El Centro, CA	\$0
21060 Elizabethtown, KY	\$0
21140 Elkhart-Goshen, IN	\$387,948
21300 Elmira, NY	\$0
21340 El Paso, TX	\$0
21500 Erie, PA	\$0
21604 Essex County, MA	\$0
21660 Eugene-Springfield, OR	\$0
21780 Evansville, IN-KY	\$0
21820 Fairbanks, AK	\$737,154
21940 Fajardo, PR	\$58,696
22020 Fargo, ND-MN	\$1,952,810
22140 Farmington, NM	\$0
22180 Fayetteville, NC	\$0
22220 Fayetteville-Springdale-Rogers, AR-MO	\$0
22380 Flagstaff, AZ	\$926,120
22420 Flint, MI	\$0
22500 Florence, SC	\$1,680,800
22520 Florence-Muscle Shoals, AL	\$1,893,930
22540 Fond du Lac, WI	\$0
22660 Fort Collins-Loveland, CO	\$3,167,121
22744 Fort Lauderdale-Pompano Beach-Deerfield Beach, FL	\$672,840
22900 Fort Smith, AR-OK	\$2,618,901

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

23020 Fort Walton Beach-Crestview-Destin, FL	\$0
23060 Fort Wayne, IN	\$5,610,005
23104 Fort Worth-Arlington, TX	\$1,354,582
23420 Fresno, CA	\$0
23460 Gadsden, AL	\$0
23540 Gainesville, FL	\$0
23580 Gainesville, GA	\$0
23844 Gary, IN	\$0
24020 Glens Falls, NY	\$0
24140 Goldsboro, NC	\$0
24220 Grand Forks, ND-MN	\$890,582
24300 Grand Junction, CO	\$0
24340 Grand Rapids-Wyoming, MI	\$0
24500 Great Falls, MT	\$2,232,935
24540 Greeley, CO	\$0
24580 Green Bay, WI	\$0
24660 Greensboro-High Point, NC	\$13,865
24780 Greenville, NC	\$0
24860 Greenville, SC	\$5,119,140
25020 Guayama, PR	\$74,803
25060 Gulfport-Biloxi, MS	\$220,325
25180 Hagerstown-Martinsburg, MD-WV	\$310,317
25260 Hanford-Corcoran, CA	\$0
25420 Harrisburg-Carlisle, PA	\$0
25500 Harrisonburg, VA	\$0
25540 Hartford-West Hartford-East Hartford, CT	\$827,543
25620 Hattiesburg, MS	\$118,085
25860 Hickory-Lenoir-Morganton, NC	\$0
26100 Holland-Grand Haven, MI	\$0
26180 Honolulu, HI	\$2,013,181
26300 Hot Springs, AR	\$230,619
26380 Houma-Bayou Cane-Thibodaux, LA	\$0
26420 Houston-Sugar Land-Baytown, TX	\$0
26580 Huntington-Ashland, WV-KY-OH	\$8,555,836
26620 Huntsville, AL	\$211,598
26820 Idaho Falls, ID	\$120,777
26900 Indianapolis, IN	\$0
26980 Iowa City, IA	\$0
27060 Ithaca, NY	\$0
27100 Jackson, MI	\$0
27140 Jackson, MS	\$0
27180 Jackson, TN	\$37,771
27260 Jacksonville, FL	\$0
27340 Jacksonville, NC	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

27500 Janesville, WI	\$0
27620 Jefferson City, MO	\$0
27740 Johnson City, TN	\$0
27780 Johnstown, PA	\$481,647
27860 Jonesboro, AR	\$150,003
27900 Joplin, MO	\$0
28020 Kalamazoo-Portage, MI	\$0
28100 Kankakee-Bradley, IL	\$224,826
28140 Kansas City, MO-KS	\$0
28420 Kennewick-Richland-Pasco, WA	\$222,390
28660 Killeen-Temple-Fort Hood, TX	\$0
28700 Kingsport-Bristol-Bristol, TN-VA	\$0
28740 Kingston, NY	\$0
28940 Knoxville, TN	\$3,020,029
29020 Kokomo, IN	\$0
29100 La Crosse, WI-MN	\$0
29140 Lafayette, IN	\$0
29180 Lafayette, LA	\$0
29340 Lake Charles, LA	\$0
29404 Lake County-Kenosha County, IL-WI	\$0
29460 Lakeland, FL	\$0
29540 Lancaster, PA	\$0
29620 Lansing-East Lansing, MI	\$0
29700 Laredo, TX	\$0
29740 Las Cruces, NM	\$0
29820 Las Vegas-Paradise, NV	\$2,074,601
29940 Lawrence, KS	\$0
30020 Lawton, OK	\$0
30140 Lebanon, PA	\$0
30300 Lewiston, ID-WA	\$0
30340 Lewiston-Auburn, ME	\$1,095,025
30460 Lexington-Fayette, KY	\$0
30620 Lima, OH	\$1,453,163
30700 Lincoln, NE	\$719,459
30780 Little Rock-North Little Rock, AR	\$0
30860 Logan, UT-ID	\$0
30980 Longview, TX	\$0
31020 Longview, WA	\$0
31084 Los Angeles-Long Beach-Glendale, CA	\$0
31140 Louisville, KY-IN	\$0
31180 Lubbock, TX	\$1,569,096
31340 Lynchburg, VA	\$0
31420 Macon, GA	\$0
31460 Madera, CA	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

31540 Madison, WI	\$0
31700 Manchester-Nashua, NH	\$0
31900 Mansfield, OH	\$2,276,948
32420 Mayagüez, PR	\$599,500
32580 McAllen-Edinburg-Mission, TX	\$138,854
32780 Medford, OR	\$0
32820 Memphis, TN-MS-AR	\$0
32900 Merced, CA	\$0
33124 Miami-Miami Beach-Kendall, FL	\$152,149
33140 Michigan City-La Porte, IN	\$0
33260 Midland, TX	\$0
33340 Milwaukee-Waukesha-West Allis, WI	\$0
33460 Minneapolis-St. Paul-Bloomington, MN-WI	\$7,062,901
33540 Missoula, MT	\$1,907,110
33660 Mobile, AL	\$0
33700 Modesto, CA	\$428,518
33740 Monroe, LA	\$0
33780 Monroe, MI	\$0
33860 Montgomery, AL	\$6,587,954
34060 Morgantown, WV	\$1,200,679
34100 Morristown, TN	\$82,654
34580 Mount Vernon-Anacortes, WA	\$617,819
34620 Muncie, IN	\$1,210,129
34740 Muskegon-Norton Shores, MI	\$0
34820 Myrtle Beach-Conway-North Myrtle Beach, SC	\$0
34900 Napa, CA	\$0
34940 Naples-Marco Island, FL	\$0
34980 Nashville-Davidson--Murfreesboro, TN	\$0
35004 Nassau-Suffolk, NY	\$0
35084 Newark-Union, NJ-PA	\$0
35300 New Haven-Milford, CT	\$0
35380 New Orleans-Metairie-Kenner, LA	\$7,115,000
35644 New York-White Plains-Wayne, NY-NJ	\$0
35660 Niles-Benton Harbor, MI	\$0
35980 Norwich-New London, CT	\$0
36084 Oakland-Fremont-Hayward, CA	\$0
36100 Ocala, FL	\$302,014
36140 Ocean City, NJ	\$0
36220 Odessa, TX	\$0
36260 Ogden-Clearfield, UT	\$0
36420 Oklahoma City, OK	\$3,410,259
36500 Olympia, WA	\$0
36540 Omaha-Council Bluffs, NE-IA	\$85,269
36740 Orlando-Kissimmee, FL	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

36780 Oshkosh-Neenah, WI	\$0
36980 Owensboro, KY	\$0
37100 Oxnard-Thousand Oaks-Ventura, CA	\$1,817,983
37340 Palm Bay-Melbourne-Titusville, FL	\$1,989,705
37460 Panama City-Lynn Haven, FL	\$0
37620 Parkersburg-Marietta-Vienna, WV-OH	\$328,005
37700 Pascagoula, MS	\$55,352
37860 Pensacola-Ferry Pass-Brent, FL	\$0
37900 Peoria, IL	\$0
37964 Philadelphia, PA	\$0
38060 Phoenix-Mesa-Scottsdale, AZ	\$0
38220 Pine Bluff, AR	\$0
38300 Pittsburgh, PA	\$10,337,357
38340 Pittsfield, MA	\$0
38540 Pocatello, ID	\$80,397
38660 Ponce, PR	\$1,234,658
38860 Portland-South Portland-Biddeford, ME	\$5,844,583
38900 Portland-Vancouver-Beaverton, OR-WA	\$0
38940 Port St. Lucie-Fort Pierce, FL	\$916,049
39100 Poughkeepsie-Newburgh-Middletown, NY	\$0
39140 Prescott, AZ	\$226,843
39300 Providence-New Bedford-Fall River, RI-MA	\$7,557,225
39340 Provo-Orem, UT	\$0
39380 Pueblo, CO	\$640,279
39460 Punta Gorda, FL	\$0
39540 Racine, WI	\$0
39580 Raleigh-Cary, NC	\$323,846
39660 Rapid City, SD	\$1,087,402
39740 Reading, PA	\$0
39820 Redding, CA	\$0
39900 Reno-Sparks, NV	\$0
40060 Richmond, VA	\$5,727,198
40140 Riverside-San Bernardino-Ontario, CA	\$0
40220 Roanoke, VA	\$0
40340 Rochester, MN	\$0
40380 Rochester, NY	\$0
40420 Rockford, IL	\$0
40484 Rockingham County-Strafford County, NH	\$0
40580 Rocky Mount, NC	\$0
40660 Rome, GA	\$0
40900 Sacramento--Arden-Arcade--Roseville, CA	\$0
40980 Saginaw-Saginaw Township North, MI	\$0
41060 St. Cloud, MN	\$0
41100 St. George, UT	\$254,035

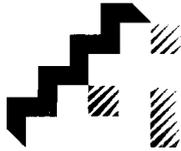
Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

41180 St. Louis, MO-IL	\$0
41420 Salem, OR	\$0
41500 Salinas, CA	\$0
41540 Salisbury, MD	\$2,395,063
41620 Salt Lake City, UT	\$0
41660 San Angelo, TX	\$0
41700 San Antonio, TX	\$0
41740 San Diego-Carlsbad-San Marcos, CA	\$1,357,502
41780 Sandusky, OH	\$0
41884 San Francisco-San Mateo-Redwood City, CA	\$0
41900 San Germán-Cabo Rojo, PR	\$0
41940 San Jose-Sunnyvale-Santa Clara, CA	\$0
41980 San Juan-Caguas-Guaynabo, PR	\$4,388,763
42020 San Luis Obispo-Paso Robles, CA	\$0
42044 Santa Ana-Anaheim-Irvine, CA	\$0
42060 Santa Barbara-Santa Maria, CA	\$2,092,052
42100 Santa Cruz-Watsonville, CA	\$0
42140 Santa Fe, NM	\$0
42220 Santa Rosa-Petaluma, CA	\$0
42260 Sarasota-Bradenton-Venice, FL	\$0
42340 Savannah, GA	\$2,348,009
42540 Scranton--Wilkes-Barre, PA	\$0
42644 Seattle-Bellevue-Everett, WA	\$6,072,540
43100 Sheboygan, WI	\$0
43300 Sherman-Denison, TX	\$0
43340 Shreveport-Bossier City, LA	\$0
43580 Sioux City, IA-NE-SD	\$876,479
43620 Sioux Falls, SD	\$1,212,622
43780 South Bend-Mishawaka, IN-MI	\$0
43900 Spartanburg, SC	\$0
44060 Spokane, WA	\$5,430,737
44100 Springfield, IL	\$0
44140 Springfield, MA	\$0
44180 Springfield, MO	\$0
44220 Springfield, OH	\$0
44300 State College, PA	\$0
44700 Stockton, CA	\$0
44940 Sumter, SC	\$0
45060 Syracuse, NY	\$0
45104 Tacoma, WA	\$0
45220 Tallahassee, FL	\$0
45300 Tampa-St. Petersburg-Clearwater, FL	\$0
45460 Terre Haute, IN	\$0
45500 Texarkana, TX-Texarkana, AR	\$0

Baker Healthcare Consulting, Inc.
 Impact of Implementation of Maximum Decrease of 1.5% of Wage Index by Wage Index
 Geographic Area Using Final FFY 2007
 Public Use File && 2007 Wage Indexes

45780 Toledo, OH	\$6,306,069
45820 Topeka, KS	\$111,627
45940 Trenton-Ewing, NJ	\$0
46060 Tucson, AZ	\$0
46140 Tulsa, OK	\$3,189,768
46220 Tuscaloosa, AL	\$0
46340 Tyler, TX	\$1,109,411
46540 Utica-Rome, NY	\$0
46660 Valdosta, GA	\$39,826
46700 Vallejo-Fairfield, CA	\$0
46940 Vero Beach, FL	\$159,334
47020 Victoria, TX	\$0
47220 Vineland-Millville-Bridgeton, NJ	\$0
47260 Virginia Beach-Norfolk-Newport News, VA-NC	\$15,739
47300 Visalia-Porterville, CA	\$0
47380 Waco, TX	\$0
47580 Warner Robins, GA	\$0
47644 Warren-Farmington Hills-Troy, MI	\$0
47894 Washington-Arlington-Alexandria, DC-VA-MD-WV	\$0
47940 Waterloo-Cedar Falls, IA	\$0
48140 Wausau, WI	\$0
48260 Weirton-Steubenville, WV-OH	\$51,155
48300 Wenatchee, WA	\$944,122
48424 West Palm Beach-Boca Raton-Boynton Beach, FL	\$10,118,755
48540 Wheeling, WV-OH	\$14,501
48620 Wichita, KS	\$312,155
48660 Wichita Falls, TX	\$34,066
48700 Williamsport, PA	\$0
48864 Wilmington, DE-MD-NJ	\$0
48900 Wilmington, NC	\$523
49020 Winchester, VA-WV	\$0
49180 Winston-Salem, NC	\$0
49340 Worcester, MA	\$0
49420 Yakima, WA	\$0
49500 Yauco, PR	\$642,775
49620 York-Hanover, PA	\$0
49660 Youngstown-Warren-Boardman, OH-PA	\$0
49700 Yuba City, CA	\$0
49740 Yuma, AZ	\$0
Grand Total	\$287,277,695

* Calculations using Published FY2007 Wage Index



**CATHOLIC
HEALTHCARE
PARTNERS**

June 12, 2007

Honorable Leslie E. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

REF: CMS -1533-P

RE: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year 2008 Rates: Proposed Rule

Dear Ms. Norwalk:

On behalf of Catholic Healthcare Partners (CHP) and our affiliated twenty-six acute care hospitals and fourteen Long Term Care facilities, we appreciate the opportunity to comment on the proposed rule for 2008 Medicare Prospective Payment System (PPS) for inpatient admission.

This year's proposed rule embarks healthcare into a new direction that fully merges DRG severity refinements with complication-comorbidity revisions and increased quality and safety standards and transparency. As such, these changes pose not only financial challenges for our hospitals, but also require operational changes in Registration/ Admission Services, Health Information Management, Financial Analysis, Quality, Patient Safety and Administrative services.

We appreciate CMS willingness to work with healthcare providers to address ongoing issues and problematic policies that hamper efficient and effective use of our finite healthcare resources. Specifically, we appreciate the clarifications provided in this proposed rule regarding EMTALA transfers during pandemic and declared state of emergencies, the Occupational Mix survey process, and the definition of "in custody".

The proposed 2008 Inpatient Prospective Payment System (IPPS) rule "raises the bar" for healthcare providers across the spectrum of hospital services provided. As dedicated stewards of healthcare, we support CMS overall initiatives to promote greater patient access to safe and effective medicine and the development of evidence-based standards of care for all providers. However, these initiatives demand significant time from staff, along with financial resources to enact the changes in the proposed rule.

78

JUN 11 2007

615 Elsinore Place
Cincinnati, Ohio
45202

Phone ■ 513 ■ 639 ■ 2800
Fax ■ 513 ■ 639 ■ 2700



In addition, we are very concerned that the proposed rule, were it to be implemented as written, would result in an FY'08 IPPS inflation update of less than one-tenth of one percent for CHP. At a time when an increasing percentage of CHP hospitals are being paid less than the costs of providing services to the Medicare population, the practical impact of the proposed rule will be to retard our efforts to implement constructive changes that have been shown to better serve Medicare patients and deliver better value for taxpayers.

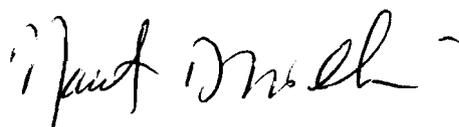
Specifically we are providing comment on the following proposed changes with a goal of offering a more balanced approach to necessary changes – changes that support the strategic direction of CMS goals without negatively impacting the needs of the Medicare patients we serve:

- 1) DRG Reform and Proposed MS DRGs
- 2) DRG Reclassifications - Behavioral Offset
- 3) Capital Payment
- 4) Medicare Wage Index
- 5) Hospital Quality Data
- 6) Hospital –Acquired Conditions
- 7) Capital IPPS
- 8) IME Adjustment
- 9) Replaced Devices
- 10) Physician Ownership in Hospitals
- 11) Patient Safety – Emergency Services
- 12) Services Furnished to Beneficiaries in Custody of Penal Authorities

Attached you will find our specific comments and recommendations on the topics contained within the proposed rule.

Catholic Healthcare Partners appreciates the opportunity to submit comments for your consideration. If you staff has any questions about these comments, please feel free to contact me at 513-639-0129 or via e-mail at mdwilliams@health-partners.org, or Cheryl Rice, CHP Corporate Director of Corporate Responsibility at 513-639-0116 or via e-mail at clrice@health-partners.org.

Sincerely,



Matthew D. Williams
Vice President, External Relations
Catholic Healthcare Partners

Attachment

Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year 2008 Rates;
Proposed Rule [CMS-1533-P] 72 Federal Register 85 May 3, 2007
Point of Contact: Cheryl Rice, Corporate Director of Corporate Responsibility
Catholic Healthcare Partners, Cincinnati OH 45202 513.639.0116 clrice@health-partners.org

DRG Reform and Proposed MS DRGs

CMS has been working with providers for the past several years to implement changes to DRG structure to account for severity, resource utilization and medical advances. The proposed rule, if adopted, would result in the implementation of an across-the-board DRG severity-adjusted methodology, as well as, major revisions to medical complications-comorbidity conditions that have been in place for the past twenty years. We recognize that in order to better monitor health care services and emerging medical trends, provide equitable reimbursement for rendered services, and account for improvements in overall health care quality and patient safety the current methodology of DRG payment needs to be adjusted to account for changes in healthcare delivery.

The conversion from the current CMS-DRG to the proposed MS-DRG methodology would result in the most significant change to the Inpatient Prospective Payment System (IPPS) since its implementation in the 1980s. The proposed publicly available MS-DRG system accommodates more severity levels and maintains a 3-digit DRG schema and historic distributions based on technology and resources. However, we are disappointed that CMS did not wait until the commissioned proprietary-severity DRG RAND and charge-compression RTS studies were complete and available for public review before proposing yet another new DRG methodology. Under the proposed rule, we find ourselves in the awkward position of being required to implement a DRG system that has the potential to radically change hospital finances and operations without the benefit of having information on the full range of DRG systems available and their associated merits. By moving to MS-DRGs prior to the release of the RAND report, the proposed rule would require the implementation of an interim system for FFY08 and then re-implementing an entirely new system in FFY 2009.

Moving to a new severity DRG system not only results in changes to DRG payment, but also requires a substantial financial investment by providers to retrain clinical, coding and financial staff; a retool of hospital patient information systems; and revise clinical and financial modeling and reporting software to account for the new methodology. Essentially, CHP will be required under the proposed rule to absorb significant costs twice – once by the DRG payment change and a second time by the additional financial resources that must be provided to ensure proper implementation of a new system. Catholic Healthcare Partners (CHP) requests that CMS allows for a five year timeframe between the implementation of the MS-DRG methodology and the implementation of another DRG severity system.

DRG Reclassifications – Behavioral Offset

CMS has repeatedly stated that billing and coding should be “as accurate as possible”. Unfortunately, the agency’s proposed “behavioral offset” runs counter to such a policy. In short, the proposed “behavioral offset” would penalize hospitals for compliance with the very coding changes that the agency is seeking.

Our lived experience indicates that it will take time for staff to become fully comfortable with new coding conventions and to fully understand the impact of the DRG changes proposed for FY'08. This coming year will be no exception, particularly given the implementation of simultaneously sweeping changes both in ICD-9 complications-comorbidity and severity DRGs processing.

CMS has assumed in the proposed rule that the experience of hospitals in the state of Maryland, with an admittedly unique payment structure (i.e. APR-DRGs), is wholly reflective of what will happen in the future with hospitals across the country under the MS-DRG system. In addition, the agency assumes that an arbitrary percentage payment reduction, even if the hasty generalization used to justify the reduction is correct, should be uniformly applied to all hospitals.

We are concerned that the result of the proposed rule, particularly with the inclusion of the cut through the behavioral offset, will be to stunt our advancements in patient safety, quality, and value that have been achieved in recent years on behalf of Medicare beneficiaries and taxpayers. For instance, CHP has been an active participant in national health quality and patient safety initiatives positively impacting the care received by Medicare beneficiaries. Four of CHP's hospitals are participating in the CMS / Premier Hospital Quality Incentive Demonstration, where our performance has been in the top decile in select measures.

We believe that the better course would be for CMS to establish a reasonable “case-mix tolerance threshold” in the final FY'08 IPPS rule whereby the agency could appropriately focus on those coding practices that result in an unusual swing in case-mix relative to the size and nature of their hospital services. Hospitals that are compliant with new coding conventions and are accurately assigning appropriate severity-adjusted DRGs would not be financially penalized for accurate coding. On the other hand, hospitals found to be “upcoding” or inappropriately coding should be held accountable for their actions. And, those hospitals not coding appropriately resulting in underpayment could be made aware of potential coding problems. CMS has at its disposal both the new MAC/FI and RAC resources to perform the necessary auditing and monitoring of case-mix, as well as, FATHOM and PEPPER reporting systems to screen and communicate to providers' case-mix and severity-adjusted DRG group anomalies.

Capital IPPS

Hospitals typically prepare annual budgets to account for payment variances associated with annual capital and wage index adjustments. However, hospitals also prepare multi-year strategic plans that include financial considerations for plant maintenance and renovations; IT costs for electronic health conversions; new technology investments and medical service enhancements over a much broader period of time (i.e. 5-20 years).

Although CMS contends that capital PPS margins have been increasing based on 1996 and 1997 margins, many providers have seen significant capital margin *decreases* in more recent periods (1998 to 2004). The limited timeframe used in CMS capital analysis does not account for the

full capital cycle (i.e. 15-20 years) that is used by most hospitals in their budget and planning projections. As CMS has mandated new health quality and safety standards, hospitals have risen to the challenge and made necessary capital and process improvements to meet required changes.

However with overall Medicare margins decreasing, and often times in the negative, hospitals are subsidizing Medicare operating losses with resources that would have otherwise been devoted to capital improvements associated with medical innovation. As a result, hospitals are delaying certain IT and capital improvements and scheduling improvements and ongoing maintenance over a much longer time period. If capital margins are reduced as proposed, CMS would be unintentionally stifling care innovation and introducing new safety issues associated with aging facilities and equipment. As the average age of a plant increases and hospitals continue to delay capital investments in order to sustain everyday operations, the need for adequate capital funding will increase – not decrease.

We recommend that CMS expand its capital margin review to include more recent and broader timeframes (i.e. 15-20 year) and to consider capital policy revisions relative to other payment reductions made to current standard amount components. Specifically, we request CMS eliminate the proposed FY08 freeze on capital payments for urban hospitals (i.e. -0.8% cut) along with negative 2.4% Behavioral Offset as noted previously.

Medicare Wage Index

While the FY'08 proposed rule is less severe regarding Medicare wage index payments to CHP facilities than in recent years, we maintain our long-standing view that the wage index is not functioning properly. Our greatest concern with the Medicare wage index is that it creates national competition for talent while too often creating arbitrary barriers in competition for local talent.

The Medicare Payment Advisory Commission (MedPAC) discussion of the Medicare wage index over the past year has been helpful to raise awareness of the issue. We are pleased that the Commission has highlighted specific concerns in their deliberations that we share.

In particular, we would request that CMS carefully consider revising the Medicare wage index in the final FY'08 rule with the following policy goals in mind:

- **Reduce the volatility of the Medicare wage index from year to year for specific facilities.**
- **Reduce the wide fluctuation in wage index payments among certain adjacent or nearby geographic areas, which is creating winners and losers among hospitals without a subsequent increase in quality, safety, or value.**
- **Reduce the nationwide fluctuation in wage index payments to a more manageable level (i.e. 20 percent).**
- **Minimize the potential of hospitals to exist in Medicare wage indices that hamper their ability to become competitive in their respective real labor markets.**

Hospital Quality Data

CHP supports CMS' drive toward achieving greater accuracy in the validation process and efficiencies in data submission and processing of quality data as recommended by the RHQDAPU program. We support CMS' efforts to increase transparency in public reporting and the disclosure of hospitals that collectively report quality data under the same Medicare Provider Number (MPN). We support CMS' proposals regarding new hospital participation and reporting under the RHQDAPU program, as well as, the expanded quality measures for FY 2009.

DRGs: Hospital-Acquired Conditions

A fundamental goal of any healthcare provider is to promote and restore patient health and to do no harm. Therefore, the proposed reporting of Hospital-Acquired Conditions makes sense from an overall care management perspective. However, providers can encounter cases on a daily basis with underlying and latent medical conditions that do not manifest themselves at the time of admission, despite the best diagnostic efforts of staff. This reality makes it extremely difficult to prevent or predict every negative medical condition. For this reason, not every complication or infection acquired during an inpatient hospital stay should be considered a "hospital-acquired condition" for DRG payment reduction purposes.

It is reasonable to expect that providers embrace evidence-based, medical prevention guidelines considered to be "best practice" by the larger medical community and "effective" in the reduction of preventable complications and infections. It is unreasonable to hold providers, under the threat of reduced DRG payment, where there is no consistent standard for detection and/or prevention of complications or infections.

CHP supports the consideration of the proposed six Hospital-Acquired Conditions that have associated evidence-based prevention guidelines for FY 2008. Specifically, we support the consideration of the Hospital-Acquired Conditions of (1) Catheter associated urinary tract infections, (2) Pressure ulcers-Decubitus ulcers, (3) Object Left in Surgery, (4) Air embolism, (5) Blood Incompatibility and (6) Staphylococcus aureus septicemia to satisfy the DRA provisions. Furthermore, we support future expansion of Hospital-Acquired Conditions only when all of the statutory selection criteria are met – especially the presence of proven, evidence-based prevention guidelines.

IME Adjustment

In 2007, CMS provided crucial clarification to counting rules for residents' time associated with Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) payment calculations. In 2008, CMS again proposes continued refinements to resident payment policy. Full and appropriate payment for resident orientation, resident medical services and residency program oversight costs is essential for the continued development of the next generation of medical professionals and the creation of safe, properly supervised medical practicum.

Unfortunately, the proposed elimination of vacation time and sick leave from the IME and direct GME payments pose yet another reduction to residency program payments. Unlike non-

teaching hospitals, teaching hospitals accept patient loads based on their ability to provide professional medical coverage with both staff physicians and residents. Teaching hospitals will continue to bear the added financial burden of providing coverage when residents are unable to perform services due to vacation and sick leave.

CMS should not remove resident time associated with vacation or sick leave from the DGME and IME time calculations. By maintaining vacation time and sick leave in DGME and IME calculations, CMS is ensuring a “minimal” payment to help offset costs for care coverage that must be provided by another medical professional. CHP supports CMS decision to maintain time spent in resident orientation within the DGME and IME calculations and requests that CMS reconsider its decision to eliminate vacation time and sick time from the calculation in order to sustain adequate resident program payments for FY08 and beyond.

Replaced Devices

CHP appreciated CMS’ billing and OPPS coverage clarifications provided in 2007 regarding replacement devices. The instructions were clear and relatively simple to implement. Although we support in general CMS’ initiative to provide a similar policy for inpatient replacement devices, we are concerned that CMS is establishing a different policy standard for inpatient cases. Specifically, we are concerned with the proposal to reduce IPSS DRG payment when “partial credit” is granted by the manufacturer or supplier equal to 20% or more of the cost of device. Hospitals need consistent policy provisions, regardless of inpatient or outpatient designation in order to gain operational efficiencies and minimize the potential for errors in processing, billing and reporting. **CHP recommends that CMS limit DRG payment reductions to those devices receiving “full credit” only or consider amending the OPPS coverage rules to include both “full” or “partial” credit to ensure consistency in policy provision.**

Physician Ownership in Hospitals

The recent growth of Specialty Hospitals has been an ongoing concern for most acute care hospitals not only for the potential “cherry-picking” of profitable services, but also concern over operational bias due to inconsistent application of operational standards and Medicare Conditions of Participation within Specialty Hospitals. The Deficit Reduction Act of 2005 required greater transparency of physician investment information in Specialty Hospitals in an effort to inform patients of potential patient care conflict of interest concerns.

CHP supports in greater transparency of physician investment information in Specialty Hospitals and a reasonable method of public disclosure that would empower patients to make informed decisions about their health care while eliminating an unnecessary administrative burden for hospital administration. Potential “reasonable” methods of public disclosure could include: (1) a posted sign near registration or scheduling centers that states the hospital has physician-owners and a listing of current owners is available upon request; or (2) a simple written statement on requisition or admission /scheduling forms indicating that the hospital has physician-owners and instructions for requesting a list of physician-owners.

This is very similar to existing Medicare regulations that require hospitals to identify skilled nursing facilities (SNFs) in which the hospital holds a financial interest when providing patients with a list of post-acute SNFs from which the patient chooses. Hospitals are already required to do this and have done so for a number of years. Physicians should be required to comply with an equal level of transparency when recommending admission to a facility in which the physician holds a financial interest.

The proposed rule would require both hospitals and physicians to provide notification to patients of physician ownership interests. Regardless of the final definition of “ownership interest”, the proposed rule provisions place an undo burden on the hospital to ensure physician compliance.

The proposed rule would make hospitals accountable for ensuring that physician-owners are routinely providing ownership disclosures to their private patients at the time a referral is made to the specialty hospital. “Accountability” is established by the conditioning of continuation of medical staff membership to the issuance of physician ownership disclosures. The only way that hospitals could ensure required physician disclosures are being provided under the proposed rule is to ask patients at the time of registration or admission if they received a disclosure or to conduct audits of external physician practices and private practice medical records. Questioning patients at the time of registration or admission may cause unnecessary alarm in patients and may cause the patient to reconsider receiving necessary medical treatment. Likewise, it is an unreasonable expectation and outside a hospital’s scope of authority to audit private physician practices.

CHP recommends that CMS amend the proposed policy provision regarding ownership disclosure as a condition of continued medical staff membership. Specifically, we recommend that CMS place the full burden of disclosure on the physician who is solely responsible for his or her personal decision-making and professional integrity. Specifically, we propose that CMS consider the following physician actions: (1) require the physician to sign a hospital attestation statement at the time of credentialing or privileging acknowledging their responsibility to issue to their private patients ownership disclosures; (2) require the physician to maintain a copy of their patient disclosures within their private patient records; and (3) require the physician at the time of their initial application for an federal NPI or PIN and/or acceptance of Medicare Assignment to attest to their responsibility to inform patient of any ownership interests in not only specialty hospitals but any other healthcare entity or supplier (e.g. Joint Venture) where they direct patient referrals or purchases.

By expanding the disclosure of financial interests beyond specialty hospitals, CMS can guarantee that overall conflicts of interest related to professional care is being addressed in all healthcare environments for Medicare beneficiaries and patients. To ensure compliance with these disclosure requirements, MAC-Carriers could request as part of routine medical record review and/or professional billing audits a copy of the physician-ownership disclosure and/or hospital attestation statements. Non-compliant physicians could then be dealt with directly by the MAC-Carrier who is an authorized agent of CMS for enforcement.

Patient Safety – Emergency Services

The provision of highly trained emergency medical staff and responsive ED departments is a fundamental service maintained by most acute care hospitals dedicated to serving the medical needs of their community. Unfortunately, CMS has recently encountered a limited number of healthcare facilities who failed to adequately prepare staff and plan for medical emergencies resulting in the improper use of 911 services and EMTALA violations.

CHP supports CMS' concern for patient safety and the need for appropriate emergency response and preparation in all locations, including those healthcare entities without a dedicated Emergency Room and/or a physician present on a 24/7 basis. We support the development of minimum emergency response service standards in general, however we are concerned that the proposed CMS policy changes aimed at establishing "uniform minimum" emergency response standards may conflict with, duplicate or exceed current State law or scope of practice requirements.

CHP recommends that CMS coordinate their development of minimum "emergency" medical response standards with interested professional organizations and State authorities overseeing medical emergency response. We also recommend that CMS provide further clarification of its proposed policy regarding disclosure of physician presence in the hospital less than a 24/7 basis. It is unclear from the current text whether the disclosure is required "if there is the possibility at anytime" a physician is not onsite or limited to just those instances (e.g. a specific day) when a physician is not onsite. We also request that CMS elaborate on how it plans to monitor whether or not a healthcare entity is performing and documenting the necessary disclosures. It is not apparent from the text whether CMS expects a separate signed notice or a general notice included with other registration / admission documents outlining basic provisions for unexpected emergency medical care.

Services Furnished to Beneficiaries in Custody of Penal Authorities

CHP appreciates CMS' willingness to clarify the meaning of "in custody" within this proposed rule to help address ongoing payment issues with Medicare beneficiaries under the authority of federal, state, and local law enforcement. However, we are concerned that the expansion of the "in custody" to include individuals who have escaped from confinement, on parole, on probation, or released on bail places an unreasonable burden on hospitals. There is no incentive for patients with any of these status designations to come forward and honestly disclose their status.

The basic premise of the policy in this case is flawed. According to the Claims Processing Manual Pub 100-04 Chapter 1 Section 10.4, Medicare is only obligated to pay for medical services for beneficiaries in custody when law enforcement agencies agree to require patients under penal authority to repay the cost of their medical services and repayment is enforced uniformly applied to all individuals under penal authority.

The reality is that law enforcement is not in the collection business or overly concerned with billing for medical services. Law enforcement is understandably concerned with avoiding

resource diversion for medical care of persons wherever possible. By ignoring or failing to perform either or both of the two conditions for payment outlined above, law enforcement essentially opts out of the ability of a hospital to access payment for penal patients when legally authorized under Medicare laws and rules. As a result, the burden of seeking compensation for medical care rendered to patients under penal authority ultimately falls back on the healthcare provider regardless of the Medicare provisions under Sections 1862(a) (2) and (3) of the Social Security Act. Unless there are greater incentives on law enforcement to attempt to fulfill their obligations under 42 CFR 411.4(b), any clarifications of the “in custody” definition will only add to the financial burden of healthcare providers.

CHP recommends that CMS develop a payment policy that facilitates the ability of healthcare providers to receive appropriate and reasonable compensation for medical services rendered to patients under the penal authority. Furthermore, we recommend that CMS not expand the “in custody” definition unless there is a means to verify the official status of the patient under the penal authority.

JUN 11 2007

WakeMed 

Finance Administration
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Raleigh, NC 27610

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919 350-8344
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June 7, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

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

Dear CMS,

The purpose of this letter is to comment on the Centers for Medicare and Medicaid Services' proposed rule for the FY 2008 hospital inpatient prospective payment system. I work for WakeMed Health System in Raleigh, North Carolina. WakeMed is an 870 bed private, non-profit health system. WakeMed consists of two acute care hospitals, one inpatient rehabilitation facility, two skilled nursing facilities, one home health agency, two outpatient facilities, and six outpatient rehabilitation facilities. This proposed rule has a significant impact on our health system. We are specifically concerned about the following provisions:

DRG Reform and Proposed MS-DRGs

I agree that Medicare Severity DRGs (MS-DRGs) should be adopted for discharges occurring on or after October 1, 2007 without a transition period. MS-DRGs are a significant improvement in recognizing severity of illness and resource usage over the current DRG system. Hospitals have had sufficient notice to prepare for this change.

The implementation of MS-DRGs is the most significant change to the inpatient prospective payment system since its inception. Personnel at our Health System are spending significant hours preparing for the adoption of MS-DRGs and attempting to evaluate the financial impact in FY 08. I am concerned that even before the adoption of MS-DRGs, CMS' contractor, the Rand Corporation, is evaluating alternatives to MS-DRGs that could be implemented in FY 09. If CMS does choose an alternative DRG system, the personnel at our system would again have to spend significant hours analyzing and preparing for its implementation. While any alternative DRG system would be budget neutral, the impact on an individual hospital could be significant. Thus, CMS' consideration of alternative DRG systems has resulted in uncertainty in our long-term financial forecasts and operational planning as we are not sure which DRG system will be in place in FY 09 and beyond.

CMS expects hospitals to change their coding practices and increase their case mix as a result of MS-DRGs. Accordingly, CMS is proposing a 2.4% inpatient payment reduction in FY 08 and 09 to offset the expected increase. I strongly oppose the payment reduction. At WakeMed Health Systems, we already code accurately and appropriately. There are no initiatives planned to adjust coding practices.



Finance Administration
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Thus, as our case mix will remain constant, our inpatient hospitals will then experience a 2.4% payment reduction under this provision. This payment reduction is significant. It will hamper our health systems adoption of health information technology, the upgrading of facilities and equipment and provision of charity care. This payment reduction needs to be eliminated.

DRGs Hospital-Acquired Conditions

The Deficit reduction Act of 2005 requires CMS to identify at least two preventable complications of care that would cause patients to be assigned to a higher paying DRG. Starting in FY 08, the act requires CMS to not pay for the preventable complication. CMS has identified the following six conditions for implementation.

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

This provision will have a significant impact on our health system due to the complexity of patients admitted to our acute hospitals. It will be difficult for our hospital as well as other hospitals to identify and accurately code for these conditions. For example, stage I pressure ulcers are difficult to detect at admission. Also hospitals may follow the prevention guidelines on infections and the patient will still get an infection. Certain infections are beyond the control of the hospital. Accordingly, I urge CMS to reduce the conditions from six to the number required by law, two.

Please contact Christine Sibley at 919 350-7974, Christine Craig at 919-350-2951 or Thomas Meehan at 719 564-0108 if you have any questions.

Sincerely,

Rebecca Andrews
Vice President, Finance

cc: Christine Sibley
Christine Craig
Thomas Meehan

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JUN 11 2007

National Surgical Hospitals

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May 29, 2007

Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1553-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Administrator Norwalk:

National Surgical Hospitals ("NSH"), representing multiple physician owned healthcare facilities nationwide, is pleased to offer comments on the proposed rule for the fiscal year 2008 inpatient prospective payment system ("IPPS"). As the nation's leading developer and manager of specialty surgical hospitals, we are pleased to provide information relevant to CMS' examination of issues related to specialty hospitals.

There are a number of key issues addressed in this comment regarding the newly proposed rules outlined in CMS-1553-P. This comment discusses the following: 1) DRG Reclassifications, 2) Hospital Acquired Conditions, 3) Proposed Disclosure Rules, 4) Regulatory Requirements, and 5) Rule Enforcement.

1. DRG Reclassifications

NSH supports the recommendation and agrees that hospitals providing services to more complex patients should be reimbursed in a manner that reflects the nature of that care. While we do not want to see a payment system that rewards hospital inefficiency, it is reasonable that Medicare reimbursement policy assures that services are appropriately compensated.

Over time, some DRGs have become more profitable than others. Making adjustments in the rates to restore balance to the entire inpatient payment system is a needed step. We endorse the efforts of CMS to achieve these goals through adoption of hospital specific weights and severity adjusted DRGs.

2. Hospital Acquired Conditions

Following Congressional direction, CMS is proposing to identify a number of preventable events (i.e. infections, pressure ulcers, object left in surgery). If these events occur during a hospital stay, the hospital would not receive an extra DRG payment to cover the costs generated by the preventable error.

NSH shares CMS' concern about the quality of the hospital environment for many patients. This is one of the many reasons that physicians establish their own facilities, to gain better control over post-operative care and reduce or eliminate other conditions such as infections that can be prevented. NSH believes that hospitals today have too few incentives to create a safer patient care environment. The six conditions that have been identified represent critical risks and their prevention will greatly improve patient outcomes. It is appropriate that CMS penalize the hospital by refusing to pay for the additional costs that result from preventable events. Unless hospitals are motivated in a significant way, there is little likelihood they will improve their behavior.

The hospitals in this country are too often filled with risks for their patients. Additional emphasis must be placed on patient safety and quality care. The CMS proposed penalty is a necessary first step in forcing improvement across all facilities.

3. Proposed Disclosure Rules

NSH supports rules regarding disclosure of emergency medical service availability and physician interests, but would stress the importance of applying such a stipulation to all hospitals. If the intent of CMS is to gain full disclosure, "in the interest of the health and safety of individuals who are furnished services in these institutions," then the boundaries of disclosure should not stop at physician owned or specialty hospitals. It would be patently unfair to impose the administrative burden of disclosure on a few hospitals when the issue of conflicts of interest is pervasive in all hospitals.

We are proud of our physician involvement in our hospitals and don't hesitate to disclose their financial interests to the public. In fact, most of the hospitals operated by NSH are already gladly disclosing their physician ownership. Likewise, NSH facilities participated in the CMS survey, which included the release of their financial data, and are willing to cooperate with CMS on an on-going basis.

However, disclosure of physician ownership interests in the proposed rule is structured too narrowly. As drafted, the rule fails to address the real issue with which CMS and Congress are concerned – financial conflicts of interest in the hospital-physician relationship. Disclosure should apply to every hospital and all financial interests including significant salaries, bonuses, medical directorships, consulting arrangements as well as any other arrangement conferring a material financial benefit upon a physician by a hospital. The terms "ownership interests" and "investment interests" are far too narrow. If CMS's concern is for the patient's healthcare due to conflicts of interest, all possible conflicts should be disclosed. Patients deserve to know what payments are being made by the hospital to their doctors and for what purpose. We simply ask that CMS require disclosure of financial arrangements and on-site physician coverage of all hospitals, whether or not physician-owned.

NSH is concerned that CMS is suggesting regulation of only specialty hospitals when the issue belongs to the entire hospital industry. A narrow focus on physician owned specialty hospitals misses the mark and would be highly discriminatory, lacking both legal and logical justification. While specialty hospitals are of interest to CMS, partly because of section 507 of Pub. L. 108-173, the statutory definition of hospital and the Medicare hospital certification requirements do not provide for a separate set of rules for different types of hospitals. Singling out specialty hospitals for a more stringent disclosure standard presents substantial equal protection concerns.

Additionally, NSH strongly opposes the proposal to make hospitals accountable for the disclosure practices of physicians. While NSH can agree to patient disclosure, with each hospital accountable for its own compliance, it is over-reaching to make proper physician disclosure to patients a "condition of continued medical staff membership." Hospitals have no effective means to police medical staff members in this manner, nor is it fair to shift accountability from individual physicians to the facility. This rule would place a heavy burden on hospitals to oversee physician office practices. The enforcement mechanism suggested by CMS is extremely unfair in that the hospital would be required to invoke its medical staff disciplinary system, with all of the attendant due process protections, to enforce an administrative disclosure requirement. Hospitals should not be penalized because a physician fails to make proper disclosure. It is excessive to place a hospital's Medicare participation at risk because an independent physician fails to make proper disclosure to a patient.

4. Regulatory Requirements

CMS asked for comment on whether or not the regulatory requirements that govern the type of clinical personnel and emergency equipment that must be present in the hospital should be strengthened. In the interests of patient safety, NSH would support a requirement that standardized the type and training of clinical personnel available in any Medicare certified hospital. Likewise we endorse setting minimum requirements for equipment as well.

We do not think a federal mandate on the hours that emergency rooms are open is needed. Such a requirement should come from the state or EMS district in which the hospital is located. The need for ER services varies greatly from one area to another and we believe that state and local authorities are in a better position to properly judge the level of emergency care required.

5. Rule Enforcement

CMS asked for comment on whether these changes best effectuated through changes are to the Medicare provider agreement regulations or whether it would be more appropriate to include these changes in the conditions of participation requirements applicable to hospital and critical access hospitals.

We find it is easier to manage and ensure compliance if CMS implements these changes via the Conditions of Participation (COP), rather than CMS provider enrollment. This preference is based primarily on practicality. NSH often refers to the COP in ensuring its practices, policies

and possible changes are Medicare compliant. The provider enrollment rules are only referenced when a healthcare facility initially enrolls, with no subsequent review of compliance.

We appreciate the opportunity to respond to the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "John G. Rex-Waller". The signature is written in a cursive style with a horizontal line underneath the name.

John G. Rex-Waller
Chief Executive Officer
National Surgical Hospitals



Ozarks Medical Center

We're making a healthy difference.

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June 7, 2007

JUN 11 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1533-P
May 3, 2007, IPPS Proposed Rule
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2008 proposed rule published in the May 3, 2007, **Federal Register**. We are a rural referral center/sole community hospital located in south-central Missouri. We operate 98 beds and have over 50% Medicare inpatient utilization each year. Our comments are as follows:

DRG Reform and Proposed MS-DRGs

CMS proposes a massive restructuring of the DRG system to comprehensively adjust DRGs for severity of illness. It is apparent CMS has done a tremendous amount of analysis to develop MS-DRGs, and it is difficult to argue with the logic of adjusting DRGS to better reflect the severity of patient illnesses.

CMS is charged by statute with making adjustments to standardized amounts to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix. We understand CMS has discretion to make standardized amount adjustments for changes that are likely to occur. However, absent strong evidence that such changes are likely, we urge CMS to avoid making negative adjustments to the standardized amount.

A recent study commissioned by the Missouri Hospital Association demonstrated that the 80 general acute-care hospitals in the state lost an average of \$1.9 million each on Medicare inpatient services during the most recent year of data available, for cost reporting periods beginning in federal fiscal 2005. This represents a deterioration of 40%

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Services located at: 1100 Kentucky Ave. • West Plains, Mo. • 417-256-9111
www.ozarksmedicalcenter.com

over the negative inpatient margin experienced in the previous year. The negative Medicare outpatient, skilled nursing and home health margins average an additional \$2.1 million for each Missouri hospital.

Hospitals cannot continue to sustain such large negative margins serving Medicare patients without quality of care being impacted. Wherever CMS has discretion to adjust hospital payments, we urge restraint be used to avoid further damaging hospitals' financial conditions.

We recognize the difficulty CMS has in estimating the changes in case-mix that could occur under MS-DRGs due to improved documentation and coding by hospitals. However, hospitals have been documenting and coding secondary diagnoses since the implementation of DRGs in the early 1980s. To assume any significant increase in the coding of secondary diagnoses under MS-DRGs is, we believe, unwarranted.

CMS is proposing dramatic reductions in the standardized amount of 2.4% per year for the next two years to reflect the possible increase in case-mix under MS-DRGs due to improved documentation and coding. CMS bases this proposal on an analysis of the changes in case-mix experienced by Maryland hospitals after implementing APR DRGs.

We are concerned with the magnitude of the proposed adjustment, based on the hypothetical assumption that implementation of MS-DRGs nationwide will mirror the implementation of APR DRGs in Maryland. We believe the differences between the two systems are significant enough that it is improper to conclude the case-mix changes will be similar under the two systems. In particular, CMS notes that APR DRGs are an all-payer system, applying to all third party payers, and that Maryland hospitals were provided with training and extensive feedback during the implementation of APR DRGs.

As hospitals have known for several years that CMS has been evaluating severity-adjusted DRGs, we believe some increase in coding is already built into the MS-DRG weights CMS proposes. The short timeframe between publication of a final rule in August 2007 and implementation on October 1, 2007, leaves little time for any additional improvement in coding within the next year.

CMS will be able to evaluate the first few months' data under MS-DRGs to determine the need for adjustment to FY2009 standardized amounts in next year's proposed rule. Such an adjustment could be based on actual data, rather than speculating on the need for such a dramatic adjustment for FY2008.

If after evaluating public comments this year, CMS determines an adjustment to the standardized amount is warranted, we recommend CMS reevaluate the approach used to determine the 4.8% adjustment proposed over the next two years. CMS has noted a dramatic case-mix increase of 9.6% for two teaching hospitals in Maryland, compared to a modest case-mix increase of only 3.2% for the rest of Maryland. CMS blends these two increases together based on 25% weighting for the teaching hospitals and 75% for other hospitals to arrive at the final 4.8% adjustment proposed.

If there is in fact such a dramatic difference between the improved documentation (and case-mix) experienced by teaching hospitals compared to nonteaching hospitals, CMS should develop separate factors for adjusting payments to each category of hospitals, rather than penalizing nonteaching hospitals. To maintain a single set of standardized amounts, CMS could remove the penalty on nonteaching hospitals either through a separate payment add-on for nonteaching hospitals, or through negative adjustment to MS-DRG weights for those MS-DRGs expected to be experienced disproportionately by teaching hospitals.

Smaller, nonteaching hospitals, and rural hospitals in general, will suffer particularly from the proposed FY 2008 changes. We believe that many of our patients do not have the additional complications to code, thus we will not participate in the anticipated coding creep. CMS' proposal will result in us being penalized first by the basic implementation of the MS-DRGs, and penalized again by the across the board 4.8% reduction in the standardized amount. We will be penalized for anticipated coding creep to which we will not contribute. Thus, we believe we should be protected from any adjustment to standardized amounts for anticipated documentation or coding improvements. This could be accomplished, at least for the rural hospitals, by a rural add on as is now present in other prospective payment systems.

Because of these various concerns with the MS-DRG proposal, we support the recommendation of the American Hospital Association for the adoption of a four-year transition period for these changes, to ensure that rural hospitals are adequately prepared for these significant changes.

One additional aspect of the documentation and coding adjustment is the impact on the hospital-specific rate update for sole community and Medicare-dependent hospitals. CMS does not formally state a budget neutrality factor for the hospital-specific rate and omitted it from the October 11, 2006 Final IPPS Rule. As a general comment for future years, we request CMS formally state this factor in the IPPS proposed and final rules.

As a specific comment this year, we request CMS not apply the 2.4% documentation and coding adjustment to the hospital-specific rate. The biggest factor influencing this adjustment is the increased case-mix experienced by Maryland teaching hospitals. As very few sole community and Medicare-dependent hospitals are teaching hospitals, they should not be subjected to this adjustment in determining the budget neutrality factor applied to their hospital-specific rates.

Finally, CMS proposes an outlier fixed-loss cost threshold of \$22,940, compared to the current threshold of \$24,485. This reduction is due to the expected increased accuracy under the MS-DRG system. CMS reduces the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases, which CMS has estimated to be 5.1% for the last several years. As MS-DRGs should result in a significant improvement in payment accuracy, there should be a significant reduction in the number of outlier cases. We are concerned that CMS has not reduced the

threshold enough. As actual payments have now been less than the 5.1% estimate for several years, we request CMS revise its approach and further reduce the fixed-loss cost threshold for fiscal 2008.

DRGs: Relative Weight Calculations

CMS reviews the results of the RTI study on charge compression. While we believe using cost report information to establish cost-based DRG weights represents an improvement over the previous charge-based weights, we recognize changes can be made to improve the cost reporting process.

We believe the flexibility to establish new standard cost centers can provide more accurate data for future DRG weight determinations. We also believe adjustment to revenue codes reported on standard UB-04 claims forms may also be appropriate to better match charges on claims forms with the charges (and costs) reported on the Medicare cost report.

With any proposed revisions to the Medicare cost report, we encourage CMS to recognize the primary use of the cost report is to determine an individual hospital's costs of treating Medicare patients. Over 1,200 critical access hospitals must be allowed the ability to properly report their costs to receive accurate reimbursement. Sole community and Medicare-dependent hospitals periodically are provided opportunities for new base years to determine hospital-specific payment rates, and many state Medicaid plans and other payers rely on cost report data to determine hospital reimbursement rates.

Thus, we ask CMS to proceed cautiously with any cost report changes to avoid unintended consequences for CAHs or other hospitals for which cost reports still determine a significant portion of current reimbursement.

Replaced Devices

CMS proposes to reduce the DRG payment in certain cases where a device is replaced without cost to the hospital for the device or with full or partial credit for the removed device. CMS proposes to apply this policy only to those DRGs where the implantation of the device determines the base DRG assignment and where the hospital receives a credit equal to 20 percent or more of the cost of the device.

The IPPS is, by design, a system of averages. The payments hospitals receive are designed to approximate the costs of treating an average patient with a specific condition. These averages already consider the true net costs incurred by hospitals to treat patients with replaced devices, without the need for a reduced DRG payment for such services. We request CMS not finalize this policy.

survey in the wage index computation. Specifically, Lines 9.03, 22.01, 26.01 and 27.01 of Worksheet S-3 should be included in Steps 2 and 3 of the wage index computation, if not already included.

Hospital Reclassifications and Redesignations

CMS has provided a great deal of flexibility to hospitals seeking reclassification to another area for wage index purposes. However, one problem remains over which the hospitals have no control. If hospitals qualify to reclassify to two different areas, they must choose one area as the primary reclassification location. Given fluctuations in wage index values, the primary area chosen one year may not be the preferable reclassification location in the actual year the reclassification takes effect. CMS should use its discretion to allow a hospital to reclassify to the best eligible location based on the proposed reclassified wage index published in the applicable IPPS proposed rule.

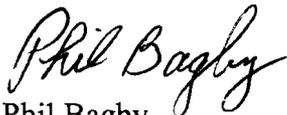
Hospital Quality Data

While we see the value of reporting quality data, we are also concerned that hospitals should not be overwhelmed with continual expansion of the number and types of elements to be reported. As previously mentioned, hospitals are suffering from increasingly negative margins serving Medicare patients, and do not have the financial resources to comply with ever-increasing reporting requirements. Thus, we urge CMS to use restraint by not proposing any additional expansion to the quality reporting requirements in 2009.

* * *

We appreciate this opportunity to comment on these important proposals. If you have any questions concerning our comments or require further information, please contact me at 417-256-9111 extension 6010.

Sincerely,



Phil Bagby
President & CEO

Cc: Senator Christopher Bond
Senator Claire McCaskill
Representative Ike Skelton
Representative Jo Ann Emerson

JUN 11 2007



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June 07, 2007

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

Re: DRG Reassignment for the CHARITÉ® Artificial Disc: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, CMS-1533-P

Dear Ms. Norwalk:

DePuy Spine is pleased to submit comments to the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on the Medicare Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year 2008 Rates (Federal Register/Vol. 72/Thursday, May 3, 2007/Proposed Rule). DePuy Spine is an operating company of DePuy, Inc., a member of the Johnson & Johnson family of companies and a leading manufacturer of orthopedic and spine implants. We are known throughout the medical world for the development, manufacture, and marketing of innovative solutions for a wide range of spinal pathologies.

Spinal Disc Devices

We appreciate that in the Proposed FY08 IPPS Rule (72 FR 24733), CMS responded to our request to consider reassigning procedures to implant the CHARITÉ Artificial Disc to DRGs 497 and 498, Spinal Fusion Except Cervical, on the basis that these patients are clinically coherent and consume similar resources. Although CMS did not find that the data supported this requested change, it has proposed to assign the CHARITÉ Artificial Disc and other spine devices to the highest severity category for Back and Neck Procedures Except Spinal Fusion within the Medicare Severity-DRG (MS-DRG) system. We support this change.

In its analysis of FY06 Medicare discharge data using the MedPAR file, CMS found that the average charges for the CHARITÉ Artificial Disc and the other devices examined were higher than for other Back and Neck Procedures Except Spinal Fusion, but lower than the average for cases in the proposed MS-DRGs for spinal fusions. CMS found a total of 53 cases that used the CHARITÉ Artificial Disc. Average charges for these cases were \$26,481 for 6 cases with a CC or MCC, and \$37,324 for 47 cases without a CC or MCC. CMS, as well as DePuy Spine, found it counterintuitive that average charges for cases in the higher severity level are lower. The Med/Surg Supplies average charges were only \$15,792 and \$26,656, respectively.

In the available FY05 MedPAR data, there were a total of 54 cases that used the CHARITÉ Artificial Disc. Average charges were \$61,650 for 23 cases with a CC and \$53,802 for 31 cases without a CC. The Med/Surg Supplies average charges were \$31,054 and \$28,791, respectively. At this time, it is unclear why the average charges in the FY06 MedPAR data are so much less than in the FY05 MedPAR data. Based on the Med/Surg Supplies mean charge, it may be that the hospitals did not fully charge for the device. We will continue to analyze these anomalies and appreciate CMS's willingness to review the most appropriate DRG assignment for these new technologies.

We would continue to point out that both traditional spinal fusion procedures and insertion of the total artificial spinal discs are used to treat degenerative disc disease in a clinically similar patient population using an anterior surgical approach. A further clinical similarity is that a total discectomy is performed before proceeding to either fusion instrumentation or insertion of the artificial disc. Although the current description of DRGs 497 and 498 (and proposed MS-DRGs 459 and 460) specify a spinal fusion procedure, CMS has in the past revised preexisting DRGs to accommodate new technologies and procedures to treat similar conditions.¹

Charge Compression

DePuy Spine also supports the regression-based adjustment for charge compression to remove a bias in the calculation of "estimated costs" that currently exist under the Medicare IPPS. This adjustment would improve the accuracy of the calculations under the system today and under any of the payment weight methodologies under consideration for 2008 or 2009. The methodology was evaluated and validated by the Research Triangle Institute (RTI) in a CMS-commissioned report to examine this adjustment and other methods to improve the accuracy of the data. The RTI experts agreed that a regression-based statistical adjustment appropriate and could be implemented quickly.

The RTI report estimated that the effect of correcting the DRG relative weight for charge compression in spinal DRGs range from (2.5%) for DRG 500 to 8.4% for DRG 498. This suggests there is a large effect of charge compression within these DRGs that have implantable devices. Therefore, in order to improve the payment accuracy of these DRGs, we urge CMS to implement the regression-based adjustment for charge compression in FY 2008.

DePuy Spine appreciates CMS's recognition of emerging spine technologies and the analytic efforts that have resulted in the proposal to move cases with procedure codes 84.65 into proposed MS-DRG 490 (Revised title: "Back and Neck Procedures Except Spinal Fusion with CC or MCC or Disc Devices"). We believe that these changes are a positive step in appropriately recognizing resource utilization and clinical complexity.

Sincerely,



Susan Kelly, MBA
DePuy Spine, Inc.
Director of Reimbursement

¹ For example, in the FY 2007 final rule, CMS revised the definition of DRG 543 from "Craniotomy with Implant of Chemotherapy Agent or Acute Complex CNS Principal Diagnosis" to include a major device implant (71 FR 47942).

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June 7, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via Express Mail
Certified, Return
Receipt Requested

ATTENTION: CMS-1533-P

Comment Regarding DRGs: Hospital-Acquired Conditions Comments

Surgical Site Infections

This comment is submitted in response to the Proposed Rule encompassing the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates that was published in May 2007. In particular, this comment addresses the inclusion of surgical site infections as a hospital-acquired condition. For the reasons set forth below, **CMS should move forward with the adoption of specific ICD 9 codes that identify surgical site infections and consider surgical site infection for inclusion as a hospital acquired condition.**

The Deficit Reduction Act of 2005 requires CMS to limit higher DRG payments for certain hospital acquired conditions. By October 2007, CMS must select at least 2 conditions that are high cost or high volume, that result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and that could have reasonably been prevented through the application of evidence-based guidelines. For discharges occurring on or after October 2008, hospitals will not receive additional payments for cases in which one of the selected conditions was not present on admission.

The May 2007 proposed rule sets forth 13 conditions as possible "hospital acquired conditions." Surgical site infections are discussed in the proposed rule as a possible hospital acquired condition. The proposed rule reflects, however, that at this time CMS is not proposing to include surgical site infections as a hospital acquired condition for FY 2008 because the ICD 9 code that would include surgical site infections is not exclusive to surgical site infections. ICD 9 code 998.59 is used for other post-operative infections. The rule indicates that surgical site infections will be reevaluated for inclusion as a hospital acquired condition for FY 2009. Surgical site infections met all of the other criteria that CMS was using to evaluate inclusion as a hospital acquired condition.

CMS should proceed to create new ICD 9 codes that specifically identify surgical site infections so that it can be included as a hospital acquired condition. The proposed rule reflects that the codes should identify the location or nature of the postoperative wound infection. New ICD 9 codes could be adopted that specifically identify a post operative infection as a surgical site infection.

As acknowledged in the proposed rule, there are evidence-based measures to prevent the occurrence of surgical site infections which are currently measured and reported as part of the Surgical Care Improvement Program. The CDC has published a Guideline for Prevention of Surgical Site Infection. The CDC categorizes surgical site infections into 3 categories: Superficial Incisional SSI, Deep Incisional SSI, and Organ/Space SSI. New ICD 9 codes could be adopted that track the CDC categories.

In addition to the prevention measures identified as part of SCIP and those identified in the CDC Guideline, I-Flow Corporation would like to make CMS aware of additional prevention measures that can dramatically reduce the risk of surgical site infection.

A multi-center study measuring infection rates and lengths of stay comparing a continuous local anesthetic for post-operative pain control compared to opioid management is currently underway. Under lead investigator Dr. Alan Thorson of Creighton University Medical Center, a 16 medical center infection surveillance study is being conducted following colorectal procedures. As presented recently at the annual meeting of the Surgical Infection Society, preliminary results of the study reflect that surgical site infection risk decreases dramatically with the use of the ON-Q continuous local anesthetic system compared to opioid management.¹ Preliminary results also reflect a statistically significant decrease in the length of stay for patients who received continuous local anesthetic infusions compared to opioid management. The implied cost savings based on these two outcomes is tremendous. These preliminary results are based upon 120 patients who have already completed the 30-day follow up according to the study protocol. As reported at the meeting, the infection rate for patients receiving continuous infusion of a local anesthetic via ON-Q Silversaker™ catheter to treat pain was 0%, while the infection rate for patients receiving opioid management was 22.9%. The length of stay for ON-Q patients was 5.05 days, the length of stay for patients receiving opioid management was 6.9 days. While this study is ongoing, these preliminary results are dramatic.

In addition, a large-scale meta-analysis of 50 studies performed with the ON-Q device was also presented at the 2007 annual meeting of the Surgical Infection Society. The results of this meta-analysis by Dine, et al. revealed a surgical site infection rate with the use of the ON-Q to be significantly lower than expected rates of infection in surgical patients (0.7% vs. 2.11% as reported by the CDC for those procedures $p < 0.0001$).² The patient population in the Dine meta-analysis was 4,030 patients.

Surgical site infections account for 14-16% of all hospital-acquired infections and are a common complication of care. These infections are a significant cause of

readmission and extended lengths of stay. Kirkland KB et al. found that surgical site infections prolong hospital stay by 12 days and increase costs by upwards of \$5,038.⁶ Perencevich EN et al. note that costs associated with surgical site infections are in excess of \$5,000 for infections diagnosed after discharge.⁷ Continuous infusion devices, such as the ON-Q, when used as part of a multimodal protocol to reduce surgical site infections can further reduce the risk of these infections. This in turn will lead to improved outcomes for patients and decreased costs to institutions and payors by limiting or eliminating costly complications from surgical site infections.

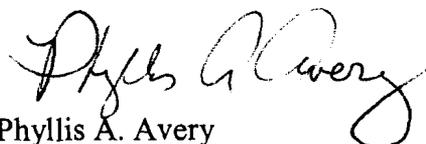
The use of continuous local anesthetic infusion pumps for post-operative pain management appears to reduce the risk of surgical site infection through significantly better pain control, decreasing the need for opioid analgesic agents, an increase in tissue oxygen delivery and perfusion, and continuous lavage of the surgical site with a solution that has antimicrobial properties. The potential for more consistent pain relief while eliminating the side effects associated with opioids and decreasing the cellular and physiologic stress response to pain can enhance the overall response to the trauma of surgery and reduce the risk of surgical infections. Opioid management of pain has been shown to have a deleterious effect on the immune response.^{3,4} At the Surgical Infection Society meeting in 2006, Alverdy et al. revealed evidence that the organisms responsible for these infections become more virulent in the presence of opioids.⁵

These studies reflect that there are additional prevention measures that can be and should be adopted to reduce the rate of surgical site infections.

As a result, CMS should move forward with the adoption of specific ICD 9 codes that identify surgical site infections and consider surgical site infection for inclusion as a hospital acquired condition.

Respectfully submitted,

Avery Law Offices, PLLC
on behalf of I-Flow Corporation


Phyllis A. Avery

¹ Dine AP. Multicenter Infection Surveillance Study Following Colorectal Procedures. Results of Preliminary Analysis. Presented: Surgical Infection Society Annual Meeting, Toronto, CA April 2007.

² Dine AP Johnson S, Saint John B,. Reduced rates of surgical site infection with the use of continuous incisional infusions of local anesthetics with ON-Q PainBuster: A meta-analysis of clinical studies. Presented: Surgical Infection Society Annual Meeting, Toronto, CA April 2007.

³ Yokota T, Uehara K, Nomoto Y. Intrathecal morphine suppresses NK cell activity following abdominal surgery. Can J Anesth 2000; 47(4):303-8.

⁴ Horn SD, Wright HL, Couperus JJ, Rhodes RS, Smout RJ, et al. Association between patient-controlled analgesia pump use and postoperative surgical site infection in intestinal surgery patients. *Surgical Infections* 2002;3:109-18.

⁵ Alverdy JC, Frei R. Could you be killing patients with kindness? Morphine and bug combine to increase risk of death. *General Surgery News* 2006;33:11. Presented at Surgical Infection Society Annual Meeting, La Jolla, CA 2006.

⁶ Kirkland KB et al, The impact of surgical infections in the 1990's: attributable mortality, excess length of hospitalization, and extra costs. *Infection Control Hosp Epidemiol* 1999; 20:725-730.

⁷ Perencevich EN, Sands KE, Cosgrove SE, Guadagnoli E, Meara E, Platt R. Health and economic impact of surgical site infections diagnosed after hospital discharge *Emerg Infect Dis.* 2003;9:196-203.



JUN 11 2007

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North Carolina Hospital Association

June 7, 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

The North Carolina Hospital Association (NCHA) represents more than 100 acute care hospitals in the State of North Carolina. NCHA welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed inpatient payment rules displayed on April 13, 2007. Our comments focus on three main areas: DRG reform and proposed MS-DRGs, the proposed behavioral offset adjustment and hospital-acquired conditions.

DRG Reform and Proposed MS-DRGs

The Centers for Medicare & Medicaid Services in fiscal year 2006 began significant efforts to reform the diagnosis-related groups 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.

Our member hospitals continue to express concern around continuous change while the CMS study from the RAND Corporation is still incomplete. The administrative cost to hospitals related to continuous changes each year are extraordinary. Considering the advances in clinical services at hospitals, a change to reflect the medical advances are needed but why make sufficient change again this year prior to completely understanding a CMS sanctioned study to provide to the industry the best solution to the aging DRG program.

Hospitals continue each year to reduce cost to our community while adopting to the payment system changes. NCHA would request reconsideration on making any changes to the DRG system codes and mapping until a complete review of the RAND study can be reviewed and discussed by the industry, hopefully within the next year.

Behavioral Offset

If CMS implements the proposed MS-DRG system for fiscal year 2008 the idea of proposing a reduction for “behavioral offset” for coding practices without documented evidence appears as a attempt to achieve specific budget cuts. Until MS-DRGs or another DRG alternative 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. The North Carolina Hospital Association opposes the “behavioral offset,” which will cut payments to North Carolina hospitals by \$84.7 million for fiscal year 2008 alone.

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.

NCHA believes the proposed “behavioral offset” should not be implemented by CMS at this time. Once the MS-DRGs are fully implemented or other significant DRG system changes, 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 any 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 of the changes

Hospital-Acquired Conditions

The Deficit Reduction Act requires CMS to identify by October 1, 2007 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 reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG. That is, the case would be paid as though the secondary diagnosis were not present. Finally, the DRA requires hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007. 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.

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.

Conditions to include for FY 2009. The NCHA believes 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. America's hospitals are committed to patient safety and strive to ensure that these events do not happen.

Conditions not ready for inclusion for FY 2009. The other three conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – present serious concerns for FY 2009. The correct identification of all three of these conditions will rely on the correct identification and coding of conditions that are present on admission. CMS proposes to rely on the present-on-admission coding that it had originally planned to implement starting October 1, 2007, but which has now been pushed back to January 1, 2008 due to technical difficulties. Implementing a present-on-admission coding indicator will be a major challenge for hospitals. 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.

Coding accuracy can only be achieved when physicians have been educated about the need to carefully identify and record, in an easily interpretable manner, whether pressure ulcers, urinary tract infections or staphylococcus aureus are present on admission. To date, we are unaware of any efforts by CMS to initiate such an education process. Only after reasonable reliability in physician identification and recording of the complications that are present on admission are achieved can claims be coded in such a way that CMS could accurately identify those cases that should not be classified into the higher-paying DRGs. 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 the DRA. We urge CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections and staphylococcus aureus until after it has taken the necessary steps to permit accurate identification of the relevant cases.

In addition, these conditions are high cost or high volume, but they may not always be reasonably preventable. There is good evidence to suggest that, even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. There is concern among infection control experts that the definitions of some of these conditions need to be reviewed and updated before they can be implemented successfully in a hospital reporting program. Additionally, we believe that hospitals face significant challenges in diagnosing these conditions accurately on admission and coding for them at that time. Our specific concerns with each of the three conditions follow.

- **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. 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, after talking with infectious disease experts, 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.

Thank you for considering NCHA's comments to the FY 2008 proposed inpatient PPS rule. If you have questions regarding NCHA's comments, you may contact Amelia Bryant at (919) 677-4225.

Sincerely,

NORTH CAROLINA HOSPITAL ASSOCIATION

A handwritten signature in black ink that reads "Millie R. Harding". The signature is written in a cursive style with a large initial "M".

Millie R. Harding
Senior Vice President

Cc: Amelia Bryant, FHFMA
Director of Financial Services

NCHA Member Hospitals

June 8, 2007

VIA FEDERAL EXPRESS

Center for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS 1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

Jefferson Regional Medical Center, a 373 bed acute care facility located in suburban Pittsburgh, Pennsylvania, wishes to add its voice to the collective body of serious concern regarding the proposed Inpatient Acute Care Rule for Medicare PPS.

First, we applaud the breadth of your proposal and the willingness of CMS to improve financial, clinical and operational performance via a series of what certainly could be termed revolutionary changes. Unfortunately, we take exception to a number of the proposed provisions as outlined below.

I. DRG Reclassification(s)

In the promulgated federal fiscal years 2006 and 2007 final rules recommendations numbered 1-3 have or will continue to be implemented in fiscal year 2008. Here are our issues with those rules (as proposed):

A. Base DRG Weights on Costs (vs. Charges) with Three-Year Phase In (Transition):

For the second year of a three-year phased implementation you engaged RTI (consulting firm) for recommendations on improving the accuracy and predictive value of cost-based DRG's. The consultant detailed a proposed expansion of Hospital Cost Centers (grouped) from 13 (thirteen) to 19 (nineteen). These cost centers include:

- Disaggregating emergency services from the catchall all other departments
- Disaggregating blood products from the catchall all other departments
- Separating implantable supplies from other supplies
- Separating IV solutions from other drugs
- Separating CT and MRI from other radiology services

CMS, despite recognizing the superior cost predictive value of the proposed changes, declined to adopt these changes. Your rationale included how RTI's proposed changes will interact with other proposed changes and you express concern about the combined impact of all changes. This appears disingenuous as CMS is proposing so many changes that the interaction of the various components cannot be estimated. You express concern about instability in IPPS payments over several years (RTI vs. HSRVcc methodologies) caused by switching systems, yet your severity adjusted proposed rule specifically raises the possibility of radically different and administratively complex and burdensome systems being sequentially implemented and discarded. Your concern regarding IPPS payment stability appears selective given the substantial redirective nature and the absolute decline in reimbursement for capital. Additionally, you write regarding making changes to cost reports to accommodate RTI's recommendation: "We have limited information systems resources and we will need to consider whether the time constraints ... in conjunction with the inconvenience ... will justify the infrastructure cost to our information systems of incorporating these variables." Hospitals find the defense of scarce resources, compressed implementation lead times and cost justification vis a vis outcomes an interesting option for CMS given the fact that it is manifestly unavailable to hospitals who have similar issues. CMS expresses a mandate to improve cost and resource predictive value and then ignores fully developed recommendations of its own consultant. We urge expedited implementation of the 19 cost center approach ASAP to better predict costs. It is unacceptable that you do not use the best, most granular level detailed cost information that yields the most predictive cost information. We also urge the early adoption of carving out intermediate (step-down) level nursing care costs. You also note that the trend towards redistributing payments away from surgery towards medicine is partially reversed using the refined RTI methodology. The search for objective reality should take CMS wherever the best available data leads it. Finally, you note that changes to cost reporting formats may be required and that would take time to implement. CMS is NOT giving the provider community time to respond to the far more revolutionary severity adjustment system (or vendors for that matter) yet requests additional time for its changes.

B. DRG Reform and Proposed MS DRG's

CMS stated that a preliminary review of the Rand Corporation's review of alternative DRG classification systems (four systems) notes that Rand utilizes a linear regression model to explain and predict costs using each system and comparing it to the current state. All systems (including CMS new proposed MS DRG's) improve the predictive value (i.e. R2 or correlation coefficient) from the current state. CMS proposes a variant of the APR DRG system grafted into a proposed DRG classification system. Administrative simplification, open system architecture, timeliness of update, vendor's ability to accommodate changes given the legacy of coding and billing systems are all considerations for selection criteria to be balanced against predictive accuracy.

With regard to CMS redefining the complication/comorbidity (CC's) lists, the proposal makes a comprehensive set of changes and essentially remove the vast majority of chronic (as opposed to acute exacerbations) conditions from consideration as CC's. It is unclear (and no stated criteria were included) whether any rigorous analysis of the CC's removed had any impact on explaining variations in resource utilization. Simple, transparent criteria like a CC causing a specific or defined variation in ALOS or costs should have been used and disclosed rather than "medical judgment and mathematical formulation" without specificity.

We note that CMS reserves the right to implement an interim system (MS DRG's) and then subsequently replace it with another system (one of the four commercial systems). We find that to be an administrative nightmare, creating provider and vendor unsolvable issues. CMS has control over the largest component of the health care sector of the economy and its decisions will have a profound impact on the payment and delivery of inpatient healthcare in this country. The provider and vendor community deserves and demands rational, well thought-out, tested and evaluated methodologies, NOT partially formulated interim and long-term solutions. We urge CMS to complete its study, carefully evaluate its findings and only then implement the objective best severity adjusted DRG system taking into account all variables. An interim solution followed by an entirely different final solution is impossible. CMS and other federal entities have impressed a series of unfunded mandates and other administratively burdensome requirements (HIPAA, POA, ICD-10, NPI, mandated E/R level coding, quality indicators) that have seriously impeded an already highly regulated provider community. I highly recommend COLLAPSE by Jared Diamond (Pulitzer Prize Winning Author) which details how systems or civilizations respond (or do not respond) to rapid changes. The salient point is that rapid change creates a fatigue that fatally weakens the entity for the next change. This should be required reading for governmental entities and agencies. It is our belief that CMS is creating a dangerous, unstable environment with its exponential changes.

JRMC urges a modified implementation of MS DRG's based on objective and disclosed CC criteria and/or a careful evaluation of all competing systems. We urge CMS to finalize its systems selection and only then promulgate its rule. Delaying severity adjustment and implementing year two of the cost based weights, in addition to implementing the hospital acquired conditions and staging for "value based purchasing", are reasonable goals for fiscal year 2008.

If CMS chooses to go forward with its requirement to implement MS DRG's, we urge a three to four year phase-in on the recalibrated weights to mitigate the impact on providers. We recommend FFY 2008 be used to identify, prepare and test the new classification system. The next three years shall represent a blend of DRG weights conceptually similar to the transition from charge to cost based weights. Each of the three years would have a 1/3 phase in or blending of weights.

II. Behavioral Offset

JRMC strenuously objects to the two year behavioral offset as erroneous in concept, offensive to the integrity of providers, and counterintuitive to the proposed MS DRG system.

First, citing the Maryland experience is misleading because the increase in CMI is directly attributable to a documentation improvement analogous to what has already occurred with the rest of the nation's hospital community over the entire life of Medicare PPS. Since Maryland was not subject to a PPS DRG system and a laboratory for other experiments in payment systems, it is our belief that their experience is (1) irrelevant, (2) misleading, and (3) similar to the evolutionary though process already experienced by the rest of the nation. Since that is most probably true, the base CC capture experience by U.S. hospitals is much higher and hence opportunities to improve on such base are minimal.

Second, it is counterintuitive that by removing the vast majority of chronic and temporary/transitory CC codes that the remaining high-end residual CC's would be subject to significant DRG creep. To give hospitals credit for their sophistication on the one hand, and then infer that significant major CC's and CC's were missed, is contradictory.

Third, on page 75 of your proposed rule you noted that of the five proposed systems MS DRG's (CMS' proposal) has the "lowest risk of case mix index increase" (i.e. creep), yet CMS proposes to remove 2.4% for two years (each) of the hospital update.

Fourth, in a survey of Western PA Hospitals conducted by this author, 100% of directors of medical records departments indicated that their more sustained effort is to code all diagnoses, not just simply to obtain CC's. Hence, the probability of incremental coding for dollars is minimal.

Fifth, CMS asserts the Hospital's ability to immediately upcode, yet the final rules will not be published for sometime. This proposal represents the greatest change in DRG history with mind numbing complexity. To assume mastery and optimization immediately is ludicrous.

The Maryland experience was based on APR DRG's whereas CMS proposes MS DRG's. APR DRG's consider multiple CC's and the interaction amongst principal and secondary diagnoses and procedures whereas MS DRG's does not include such a system. Multiple CC's do not yield more revenue than a single CC under MS DRG's. Using either the Rehabilitation or Psychiatric Provider experiences are also irrelevant because those are entirely new systems with coding conventions that had no impact or reimbursement previously (cost based reimbursement).

III. Capital Component Update

In CMS' proposed rule it makes substantial changes to the capital component to the base rate. CMS notes a disparity between urban and rural hospitals and propose economic redistribution with a 0.0% inflation update, removal of the 3% large urban add-on, the (2.4%) behavioral offset and, as always, the use of the GAF update. Finally, CMS proposes the elimination of capital IME/DSH adjustments. CMS cites ongoing continuing positive margins for capital from 1996 to 2004 and the programs ability to recoup savings.

First, inflationary updates for capital need to occur. Many hospitals are in the process of significant eHIM (EMR) system implementations that require significant capital expenditures and many other costly cyclical expenditures. Also, significant advances in diagnostic imaging for the advancement of patient care require enormous investments.

Second, we believe the behavioral offset to be inappropriate as detailed previously.

Third, we believe there is a methodology flaw that may explain the margins experienced by large urban hospitals. That flaw is the GAF which is applied to the entire base capital component. The GAF flaw is that capital expenses are less bricks and mortar (subject to local variations) and more diagnostic imaging equipment and software expenditures, both of whom are not subject to CBSA/MSA cost fluctuations but represent nationally determined expenses. Since many/most MSA/CBSA's in major metropolitan areas have a GAF greater than 1, this may create artificial profitability. In Western Pennsylvania a GAF of 0.8668 artificially deflates capital reimbursement.

CMS notes a 5.1% margin on capital payments as justification to reduce payments whereas a negative margin of (5.4%) overall on the acute care program. JRMC would gladly accept the 5.4% overall increase to make whole overall in addition to whatever is done with capital.

JRMC's recommendations for capital update are as follows:

- **0.8% update to rural and urban**
- **Elimination of behavioral offset (2.4% reduction)**
- **Rebasing of GAF to account for mix of bricks/mortar/equipment/software**
- **Three year phase out of large urban update with rurals receiving help on a commensurate basis**

Capital expenses by its nature require a multi-year commitment and are cyclical in nature. Radical changes, including purposeful reengineering to redistribute reimbursement are not conducive to long-term stability and planning, both central to capital planning.

IV. Hospital Acquired Infections

There appears to be a lack of clinician consensus on what constitutes accurate identification of cases where the condition was Hospital acquired. Significant practice pattern changes including screenings, diagnostic testing and prophylactic treatment of patients leading to antibiotic resistant organisms are to be expedited. Another unintended consequence will be the treatment of compromised elderly often admitted from skilled nursing facilities that may have access jeopardized due to access. Considerations include the probability of pre-existing conditions impacting this rule and quality benchmarks and hence avoidance of this most vulnerable segment of beneficiaries.

JRMC urges the early adoption of ICD-10 to capture coding nuances and additional specificity.

CONCLUSION

JRMC recommends the following:

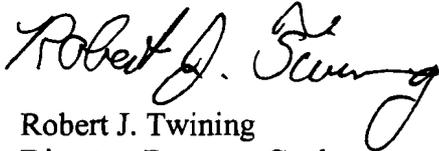
- Full market basket with no behavioral offset
- Continuation of transition to cost based weights using best available methodologies
- Careful, deliberate selection of severity adjusted DRG's in final form only
- **If MS DRG's are implemented, a multi-year blending of weights to cushion the impact should be implemented**
- Mandated criteria for CC inclusion/exclusion based on impact on ALOS/resource utilization
- All hospitals to have capital update
- Rebasement of GAF to reflect capital mix of bricks/mortar, equipment and software
- Three year phase out of large urban update for capital
- Early publication of hospital acquired condition payment changes with clear consensus on applicability
- Full and fair disclosure of "value based purchasing" criteria (i.e. pay for performance)

CMS has a moral, ethical and fiduciary responsibility to the program, hospitals, recipients and the health care sector of the economy. Its proposal, while ambitious, is severely flawed in its implementation and does not take into account the complexity and the multi-collinearity of variables. For those of us who wished for severity adjustment and quality measures this provides a cautionary example of "be careful what you wish for" and the "devil is in the details". CMS' backdoor attempts to cut reimbursement via behavioral offsets should be seen for what they are. The principle rule of medicine is "first do not harm". You have proposed economic and administrative harm to a healthcare delivery system that has only recently recovered by the BBRA of 1997, regulatory changes that proved devastating to hospitals and its patients. JRMC has modeled the impact of these changes for all payors paying Medicare DRG's. The payment reduction from full market basket, on an annualized basis, is in excess of \$3 million. The reduction

Center for Medicare and Medicaid Services
Department of Health & Human Services
June 8, 2007
Page 7

(again from full market basket) is almost (3.9%). The impact of DRG recalibration alone is in excess of \$1.4 million on an annualized basis or 3.1 basis points of CMI or a 2% decline. These payment reductions effectively wipe-out our operating margin and threaten JRMC's ability to provide its patients with the future programs, equipment and technologies that will be required. JRMC believes that its administrative and clinical costs will also demonstrably increase and that the opportunity for artificial DRG case mix index increase is minimal or non-existent. You should and could have done better.

Sincerely,



Robert J. Twining
Director, Revenue Cycle,
Managed Care & Decision Support

RJT:laa

cc: Brian Aiello, IKON
Ronald Boron, M.D.
Janet Cipullo
Richard Collins, M.D.
Robert Frank
Judy Hall
James Hoover
Robert Horn
Thomas Timcho
Louise Urban

JUN 11 2007

June 7, 2007

Centers of Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS Proposed Inpatient Prospective Payment Rule

Dear Ms. Norwalk:

The purpose of this letter is to express our strong opposition to three of the proposed Inpatient Prospective Payment System (IPPS) regulations. We ask that these provisions be excluded or revised in the final regulation.

The first provision is the implementation of a 2.4% "Behavioral Offset" reduction in all operating and capital payments for inpatient hospital services for Medicare patients. This proposed reduction would impact our facility by an estimated \$375,000 per year for the next two years.

The second provision is the implementation of the new Medicare-Severity DRGs (MS-DRGs) which will impact our facility by \$453,000.

The third provisions relates to Capital reductions.

Detailed below are our reasons for strenuously objecting to these changes:

BEHAVIORAL OFFSET

The Behavioral Offset is based on the CMS belief that hospitals will change/game their coding practices to gain higher payments under the classification system MS-DRGs. If you turn the clock back to 1983 and the beginning years of IPPS, coding changes by hospitals were never of this magnitude, therefore, CMS has no basis for this proposed reduction. As CMS is aware, hospitals are already experts in coding for payment and have little ability to change their classification and coding practices. If you are concerned about gaming the system, those actions would be fraudulent and penalties already exist to deal with those issues. It is wrong to impact the whole industry based on an unproven belief.

Based on information we have read and reviewed, CMS believes this change is necessary due to what was experienced in Maryland when they moved to a new coding system. The problem with this belief is an apples and oranges comparison since Maryland's system is not even the same classification system that CMS is proposing.

The Behavioral Offset as proposed by CMS is not even a mandated change but CMS has chosen to propose its implementation. To make such a major change without proven actual and measurable evidence is inappropriate, sets a precedent for the future and is simply bad policy.

MEDICARE-SEVERITY DRGs

Two of the stated goals for implementing a new DRG classification system were better align payments with severity of illness and provide a definitive response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address proliferation of physician-owned, limited-service hospital.

Our facility is located 200 miles from the nearest tertiary facility and 100 miles from a facility about half our size. We are classified as both a Rural Referral Center and Sole Community Hospital. Additionally we do have a specialty hospital in our community.

I find it hard to accept that a move to the new classification system is going to assist our facility. First, a preliminary analysis reflects an annual reimbursement decrease of \$453,000 yet we provide a full range of services and many specialties. Secondly, the specialty hospital will be impacted very little given their inpatient business since it is essentially all orthopedic and back surgery. The specialty hospital's annual report notes a favorable payer mix, low Medicaid utilization, physician owner referrals, very high margins and many other reasons why they are so profitable. This new classification system appears to do just the opposite of what was intended. I also bring into focus why a specialty hospital would not want an emergency room or non-surgical patients since they increase operating costs. For which reimbursement is lower.

If the new classification system does stay in the final rules, I strongly recommend a phased-in approach. A transition period of at least four years should be considered. CMS has already established numerous precedents when major revisions to reimbursement are made. These precedents include Outpatient Perspective Payment System (OPPS), ambulance fee schedule, inpatient rehabilitation, inpatient psychiatric services and many more.

CAPITAL IPPS

As a rural hospital, our increase is 0.8 percent. With CMS, the President, Congress and individuals promoting an Electronic Medical Record, the key question is: "How does a hospital find the capital dollars"? We are in a conversion mode and it is disheartening to see CMS unwilling to participate in these costs let alone keep pace with the technology that patient's mandate.

SUMMARY

In summary, the three subjects addressed above have a severe impact on our organization and the industry. I respectfully request CMS to:

- Not implement the "Behavior Offset" since it is not factually based and appears to simply be a method to unilaterally cut funds from the budget.
- Not implement the Medicare-Severity DRGs but if implemented, provide at least a four year phase-in.
- Increase the capital percent to assist in the funding of technology and the Electronic Medical Record.

If you have any questions, please contact me at 605-622-5272.

Sincerely,



Geoff Durst
Vice President of Finance

Cc: Ron L. Jacobson, President and CEO
Board of Directors



TEXAS HEALTH RESOURCES

JUN 11 2007

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June 8, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
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 Texas Health Resources (THR) and its 13 faith-based, nonprofit community hospitals throughout north Texas, including Harris Methodist Hospitals, Arlington Memorial Hospital and Presbyterian Healthcare System, we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (IPPS).

The proposed rule's major changes include: 1) expansion of the set of quality measures that hospitals must report to receive full payment update; 2) restructuring diagnosis-related groups (DRGs) to better account for patient severity; 3) implementing new disclosure requirements for physician-owned specialty hospitals; 4) recalibrating DRG weights to pay hospitals based on a blend of two-thirds cost-based weights and one-third charge-based weights for FY 2008—moving to a full cost-based system for FY 2009; 5) cutting the standard payment rate by 2.4 percent to compensate for anticipated “upcoding” under the new severity-adjusted system; and, 6) eliminating certain capital-related cost provisions that urban hospitals have used for facility and information technology (IT) investments.

THR specifically opposes the proposed “behavioral offset” cuts related to the move to severity-adjusted DRGs and the cuts to capital payments, and we would like to highlight the harm these cuts would cause to our hospitals and the patients we serve. Further, THR recommends that CMS monitor hospital billing to determine if the anticipated coding changes materialize and then make any necessary adjustments.

Diagnosis-Related Groups

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and it would overhaul the complication or comorbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both fiscal years 2008 and 2009—\$24 billion over five years—to eliminate

what CMS claims 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 FY 2008 weight based on costs and one-third based on charges.

THR supports meaningful improvements to Medicare's IPPS. While we believe that the MS-DRGs provide a viable framework for patient classification, a reasonable transition period 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.

THR is 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 the consideration of possible future cuts to the indirect medical education and disproportionate share hospital (DSH) adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

THR estimates that the 2.4 percent cut and reduction to capital alone would result in a combined loss to our system of nearly \$9.4 million for one year (FY 2008). The combined loss over five years would be more than \$84.2 million. 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 our mission of improving the health of the people in the communities we serve even more challenging and difficult.

Thank you for the opportunity to share our comments. If we can provide you or your staff with additional information, please do not hesitate to contact Joel Ballew, Director of Government Affairs, at 817-462-6794 or by e-mail at JoelBallew@TexasHealth.org.

Sincerely,



Douglas D. Hawthorne, FACHE
President and CEO
Texas Health Resources



American Society for Bariatric Surgery
100 SW 75th Street, Suite 201
Gainesville, FL 32607

JUN 11 2007

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June 7, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Inpatient Prospective Payment Systems
and Fiscal Year 2008 Rates

Dear Ms. Norwalk:

The American Society for Bariatric Surgery (ASBS), which represents the foremost American surgeons to advance the art and science of bariatric surgery, is pleased to submit comments and recommendations in response to the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates issued in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) on May 3, 2007.

The ASBS is concerned about changing DRG 288 for obesity surgery, to DRGs 619, 620, 621, which would severity-adjust the payment schedule for inpatient hospital reimbursement. We fully support efforts to base payments on patient severity but the proposed changes do not appear to achieve that goal.

We agree that the morbidly obese may differ in the severity of co-morbidities or complications that they carry; it is a fact that all of the morbidly obese Medicare obese population will have at least one serious co-morbidity. In fact, according to the present Bariatric Surgery National Coverage Decision issued by CMS in February 2006, Medicare will only cover bariatric surgery in a beneficiary who is morbidly obese (BMI>35) with a minimum of one co-morbidity.

The categorization of which co-morbid conditions or complications fall into DRG 619, 620 and 621 is of concern to the ASBS.

DRG 619

CMS is proposing that DRG 619 cover “O.R. procedures for obesity with major comorbidity/complication”. Under DRG 619, ICD-9 codes 250.10-250.13, 250.20-250.23, 250.30-250.33 and 414.12 are considered “Major complications”. In every day surgical practice, these are conditions that many surgeons would classify as “contraindications” to performing bariatric surgery in a patient and therefore are incongruous and non-applicable to a DRG assignment.

DRG 620.

CMS is proposing that DRG 620 cover “O.R. procedures for obesity with comorbidity/complication”. Under DRG 620, ICD-9 codes 414.02-414.04, 414.06-414.07, 414.10 and 414.19 similarly would be conditions that make bariatric surgery contraindicated and are incongruous with every day surgical practice. These codes also do not seem to be applicable to a DRG assignment.

DRG 621.

CMS is proposing that DRG 621 cover “O.R. procedures for obesity without complications”. This includes ICD-9 codes 250.00-250.93 (Diabetes mellitus), 327.23 (obstructive sleep apnea), 401.0-405.99 (Hypertensive disease), and 571.5-571.9 (cirrhosis of liver, biliary cirrhosis nonalcoholic). These medical conditions are serious complications of obesity that are classified in surgical practice as “Complications” or “Major Complications. We recommend that these ICD-9 codes be classified under DRG 620 (with Complications) or DRG 619 (with Major Complications).

We must remember that these patients do not have these medical conditions alone, but in fact suffer from these serious medical conditions in the presence of morbid obesity, while undergoing major abdominal surgery. Therefore, the surgical, anesthetic and nursing care required peri-operatively for these patients is at a much higher level of care than the lean patient with or without these co-morbidities. For example, the post-operative morbidly obese patient with obstructive sleep apnea is at a higher risk for postoperative complications and therefore must be monitored overnight in a specialized setting (ie. Intermediate care unit, step-down unit, intensive care unit) which requires higher level nursing care and respiratory therapy.

Another example is the post-operative morbidly obese patient who has diabetes mellitus, who requires frequent serum glucose monitoring and insulin administration due to the alteration in gut hormones and caloric intake. There is a significant increase in level of care that is required by the nursing and ancillary staff in the operating room, the recovery room and the hospital units to care for the morbidly obese surgical patient who has any of the following co-morbidities: Diabetes Mellitus (any type), Hypertension (any type), Obstructive Sleep Apnea, Coronary Atherosclerosis, Osteoarthritis (any type), Obesity Hypoventilation Syndrome, History of Thromboembolism and Asthma. These conditions in the setting of the morbidly obese patient undergoing bariatric surgery are of greater

medical and nursing significance and therefore require a higher level of care by all hospital-related personnel. Operative time is longer for this population due to the increased monitoring necessary by the anesthesia team (ie. Arterial catheter monitoring, Central venous catheter monitoring, fiberoptic intubation).

For these reasons, the ASBS recommends that DRG 620 and DRG 619 should be redefined to include ICD-9 codes for: Diabetes Mellitus (DRG 620), Hypertension (DRG 620), Obstructive Sleep Apnea (DRG 620), Coronary Atherosclerosis (DRG 619), Osteoarthritis (DRG 620), Obesity Hypoventilation Syndrome (DRG 620), History of Thromboembolism (DRG 620) and Asthma (DRG 619).

We hope that CMS can resolve this issue before it implements changes and we would appreciate the opportunity to review and comment on the modified proposal before it is implemented.

We thank CMS for their consideration of this matter to ensure that ASBS members continue to provide high quality care to Medicare beneficiaries.

Sincerely,

A handwritten signature in black ink that reads "Philip R. Schauer MD". The signature is written in a cursive, flowing style.

Philip Schauer, MD
Professor of Surgery, Cleveland Clinic and
President, American Society for Bariatric Surgery



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MGI PHARMA
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June 8, 2007

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

Re: CMS-1533-P -- DRGs: Intracranial Stents/Craniotomy with Gliadel® Wafer
(polifeprosan 20 with carmustine implant)

Dear Ms. Norwalk:

MGI PHARMA ("MGI") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital inpatient prospective payment system ("IPPS") proposed rule for fiscal year ("FY") 2008 (the "Proposed Rule"). Our comments focus on the proposed Medicare Severity Diagnosis Related Group ("MS-DRG") assignment for intracranial stents, particularly the proposed MS-DRG assignment of craniotomy cases involving the implantation of a chemotherapeutic agent, such as the Gliadel® Wafer.

MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients. We share CMS's goal of ensuring that the IPPS payment system does not have the effect of discouraging the use of clinically-necessary services based on reimbursement levels, and we agree that clinical considerations should be paramount in treatment considerations. For this reason, we are concerned that the proposed coding and payment policy for craniotomy procedures involving the implantation of Gliadel Wafers could impose an unintended barrier to patients. In addition, the proposal may be misaligned with the National Comprehensive Cancer Network ("NCCN®") Clinical Practice Guidelines in Oncology™¹ stating that the insertion of implantable BCNU wafers (which includes Gliadel Wafer) are part of the standard of care for the treatment of malignant brain tumors as an adjunct to surgery.

I. Background on the Gliadel Wafer

Gliadel Wafer is the only implantable chemotherapy agent approved by the FDA for the treatment of malignant brain tumors. This treatment is approved for newly diagnosed patients with high-grade malignant glioma and for patients with recurrent glioblastoma multiforme, which is the most fatal form of primary brain tumor. Gliadel therapy offers a real possibility of long-term survival for patients with brain tumors due to the fact that it is implanted at the time of surgery. Limitations of systemic chemotherapies often are due to the resiliency of the blood brain barrier. That is why insertion of implantable BCNU wafers (which includes Gliadel Wafer) is recognized in the NCCN® Guidelines as part of the standard of care for the treatment of malignant brain tumors as an adjunct to surgery.

¹ The NCCN® Guidelines are the recognized standard for clinical policy in the oncology community.

brain barrier. That is why insertion of implantable BCNU wafers (which includes Gliadel Wafer) is recognized in the NCCN® Guidelines as part of the standard of care for the treatment of malignant brain tumors as an adjunct to surgery.

CMS created ICD-9-CM procedure code 00.10 (Implantation of Chemotherapeutic Agent) to describe the insertion of the Gliadel Wafer, effective October 1, 2002. In FYs 2003 and 2004, there was no specific DRG for Gliadel cases, and the inadequate reimbursement for the existing craniotomy DRGs at that time led some hospitals to discontinue the provision of Gliadel therapy.

In the Medicare IPPS final rule for FY 2005, CMS recognized that the Gliadel Wafer “represents a significant medical technology that currently offers clinical benefits to patients and holds out the promise of future innovation in the treatment of these brain tumors.”² To provide adequate compensation to hospitals for the resources associated with the Gliadel Wafer, CMS established DRG 543 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis). The improved reimbursement provided by DRG 543 has enabled hospitals to continue to offer this important therapy to Medicare beneficiaries with malignant brain tumors as an adjunct to surgery and radiation.

II. Proposed FY 2008 MS-DRG Assignment for the Gliadel Wafer

In the FY 2008 Proposed Rule, CMS proposes to adopt a severity-adjusted DRG system, called the Medicare-Severity DRGs (“MS-DRGs”), which necessitates the restructuring of many current DRGs. Under the MS-DRG proposal, CMS would replace DRG 543 with the following two new MS-DRGs:

MS-DRG 23 (Craniotomy With Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis With MCC)

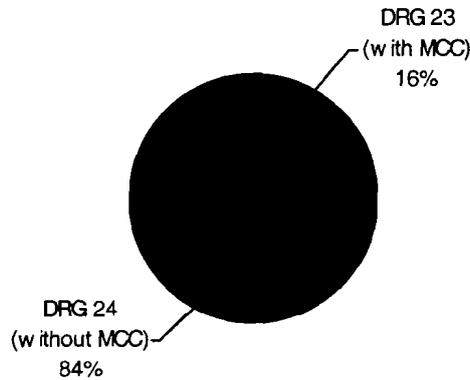
MS-DRG 24 (Craniotomy With Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis Without MCC)

Unfortunately, these MS-DRGs and associated payment levels do not reflect resource use linked to case complexity (e.g., implantation of the Gliadel Wafer). Instead, the proposed MS-DRGs only take into account severity of the patient’s secondary diagnosis (i.e., with or without major complication or comorbidity). Therefore, the vast majority of Gliadel cases³ would be assigned to the lower-paying MS-DRG 24, which likely would severely under-compensate hospitals for the implantation of Gliadel Wafers and associated resources. In fact, an analysis of the 2006 Medicare Provider Analysis and Review (“MEDPAR”) file estimates that under the Proposed Rule, 84 percent of Gliadel cases would be assigned to the lower-paying MS-DRG 24, as illustrated below:

² 69 Fed. Reg. 48,958 (August 11, 2004).

³ For purposes of this comment letter, defined as any DRG 543 case with ICD-9-CM code 00.10.

Current Distribution of Gliadel Cases Under Proposed MS-DRGs (n = 502)

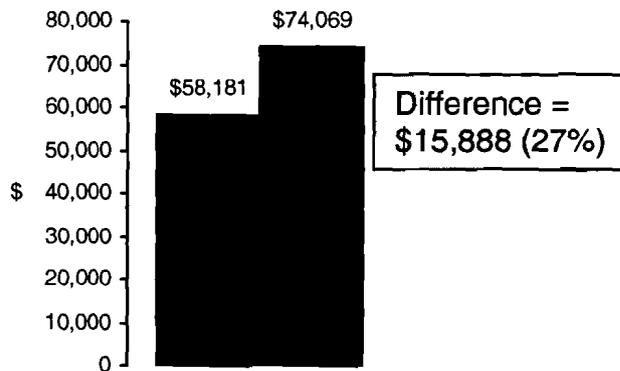


Source: Covance analysis of 2006 MEDPAR file conducted May 2007.

We believe that the average costs associated with Gliadel cases would significantly exceed what we estimate would be the FY 2008 national average payment rate for MS-DRG 24. Accordingly, hospitals would not be fully compensated for furnishing the Gliadel Wafer, and Medicare beneficiary access to this therapy could be seriously jeopardized.

Furthermore, assigning the majority of Gliadel cases to MS-DRG 24 would not recognize the significant difference in resources required for Gliadel cases without MCCs versus other cases without MCCs, since the standardized average charges for Gliadel cases without MCCs (\$74,069) are 27 percent greater the average charges for non-Gliadel cases without MCCs (\$58,181), as illustrated in the following chart:

Average Standardized Charges for Gliadel and Non-Gliadel Cases Without MCCs



- Average Standardized Charges for Non-Gliadel Cases Without MCCs
- Average Standardized Charges for Gliadel Cases Without MCCs

Source: Covance analysis of 2006 MEDPAR file conducted May 2007.

We are concerned that assigning the majority of Gliadel cases to MS-DRG 24 is inappropriate in light of the charge data, and could undermine CMS efforts to ensure that Medicare payment policy does not drive clinical decision-making.

III. Recommendation for Restructuring MS-DRGs 23 and 24

CMS has acknowledged that there are situations in which severity measurements may not account for resources associated with complex cases. For instance:

- CMS recognizes the increased complexity and costs associated with spinal disc devices, although the resources are independent of patient severity. Because the average charges for spinal disc device cases without complication or comorbidity are similar to cases with a higher severity level (MS-DRG 490), CMS recommended in the proposed FY 2008 IPPS rule to include cases with spinal disc devices in MS-DRG 490 and revise the title to reflect disc devices (Back and Neck Procedures Except Spinal Fusion with CC or MCC or Disc Devices).⁴
- Likewise, CMS is proposing to redefine proposed MS-DRG 129 as “Major Head and Neck Procedures With CC or MCC or Major Device” to recognize the higher average charges associated with cochlear implants, even though the majority of cochlear implant cases do not have a CC or MCC and otherwise would be assigned to the lower-paying proposed MS-DRG 130.⁵
- CMS also is proposing to assign intestinal transplant cases without an MCC to proposed MS-DRG 005, rather than MS-DRG 006, to which these cases otherwise would be assigned. CMS proposes this change because the average charges and lengths of stay for these intestinal transplant cases are more comparable to the average charges and lengths of stay for all cases assigned to proposed MS-DRG 005 than to MS-DRG 006. To accommodate this change, CMS is proposing to redefine the proposed MS-DRG 005 as “Liver Transplant with MCC or Intestinal Transplant.”⁶

We recommend that CMS apply this same logic to craniotomy cases in order to recognize the resource use associated with implantation of the Gliadel Wafer. To that end, the proposed craniotomy MS-DRGs should be revised as follows:

MS-DRG 23 (Craniotomy with Acute Complex Central Nervous System Principal Diagnosis With MCC or Major Device Implant) (emphasis added)

MS-DRG 24 (Craniotomy with Acute Complex Central Nervous System Principal Diagnosis Without MCC)

This revision to the proposed MS-DRGs would ensure that Gliadel Wafer cases are appropriately classified with cases with similar costs, ensure that payment policies do not interfere with best clinical practices, and safeguard Medicare beneficiary access to this important technology.

⁴ See 72 Fed. Reg. 24,733-4 (May 3, 2007).

⁵ See 72 Fed. Reg. 24,728-9 (May 3, 2007).

⁶ See 72 Fed. Reg. 24,726 (May 3, 2007).

We appreciate your consideration of our comments, and would be pleased to answer any questions you may have.

Sincerely

A handwritten signature in black ink, appearing to read "Dave Melin", with a long horizontal flourish extending to the right.

Dave Melin
Vice President, Corporate and Government Affairs

cc: Marc Hartstein
Amy Gruber

part, the public has been left in the dark about their local hospital's record on infections. Public disclosure of the rate of infection will allow consumers to make more informed health care decisions and will create strong incentives for hospitals to improve care and make infection-prevention a higher priority. The mere fact of disclosure being debated in state houses around the U.S. has stimulated action within hospitals as they realize their infection record could soon be published. **Pennsylvania, in particular, has implemented a comprehensive hospital infection reporting system, and now the Governor has proposed as a logical second step, further actions be taken to reduce and eliminate infections as part of State health insurance reform³.** There is much hospitals can do that they are not doing to address this serious and costly problem. Public disclosure is a key component to making that happen.

The data that is being developed in the states with mandatory reporting argues for a similar, aggressive effort at the national level, to ensure that in the near future all residents of the United States will have the information necessary to reward quality hospitals and avoid dangerous hospitals.

Similarly, proposals such as this one (CMS-1533-P) to withhold payment to hospitals for treating the consequences of events that should never happen, will have a significant effect in motivating hospitals to take more aggressive actions to prevent infections and other careless acts that have a devastating effect on patients and our nation's health care system.

Further, it is imperative that the final rule include strong consumer protections to prohibit health care providers from billing patients for any treatment resulting from a hospital-acquired infection or other event that has been identified by CMS for non-payment. Also, there should be a prohibition of any discriminatory practices by the hospital to avoid patients they perceive at risk for infection or other event on the list. If CMS believes these protections are already covered by current Medicare law, references to those specific provisions in existing law would be warranted.

SUMMARY:

Our comments will concentrate on Consumers Union's strong support of:

- the proposal to expand the number of quality measures to be reported as a condition of receiving the full Medicare update, particularly the hospital-acquired infection process and outcomes measures;

\$27.5 billion in additional expenses onto the country's healthcare system in hospital costs alone." The MRSA Issue, Emerging, the newsletter of Plexus Institute, Winter 2006,
<http://www.plexusinstitute.org/NewsEvents/News/show.cfm?id=206>

³ <http://www.governor.state.pa.us/governor/cwp/view.asp?a=1113&q=451076&governorNav=|32021|> and House Bill 700

<http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?year=2007&sind=0&body=H&type=B&BN=0700>

- the six procedures for which Medicare and beneficiary/consumers will not pay the added cost of hospital acquired infections;
- consideration to add selected surgical site infections and vascular catheter-associated infections for the initial year, followed with strong consideration of ventilator associated pneumonia in 2009;
- and in particular, taking bold steps to address the growing Methicillin-resistant staphylococcus aureus (MRSA) crisis.

While many states have been acting to reduce the rate of hospital-acquired infections (HAI), it is particularly appropriate that Medicare do more in this area given the findings of the Pennsylvania Health Care Cost Containment Council (PHC4) that 76 percent of the infections identified by hospitals as being acquired in their facilities were billed to Medicare and Medicaid, with Medicare paying for most (67%).⁴

SPECIFIC COMMENTS

DRGs: HOSPITAL-ACQUIRED CONDITIONS

We strongly support the aggressive implementation of Section 5001(c) which

...requires the Secretary to identify, by October 1, 2007, 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 consumers, the key words are 'at least'. We urge CMS to indicate that within a few years time, all the conditions identified and listed will be subject to 5001(c) non-payment, and that CMS will begin a process of adjusting codes and requiring testing for present on admission (POA) conditions (like MRSA), so that all of these quality problems will be addressed in the very near future.

CMS has done an excellent job in listing the many unacceptable events that should never happen and which certainly should not be paid for.

However, while CMS has articulately identified many of the deadly infection problems the nation is facing, the proposed solutions to these problems lack urgency.

The notice stated, "while we have ranked...conditions, there may be compelling public health reasons for including conditions that are not at the top of our list." There certainly are such compelling reasons to include MRSA. The spread of MRSA is so serious that

⁴"Reducing Hospital-acquired Infections: The Business Case," PHC4 Research Brief, Issue No. 8, November 2005, www.phc4.org.

more must be done to identify it both prior to admission and if it is acquired in a facility. In 1972, only two percent of staph infections were antibiotic resistant. By 2003, MRSA made up nearly 60 percent of all staph infections. According to the CDC, MRSA accounts for sixty to 65% of hospital-acquired staph infections.⁵ Despite more than 95,000 Medicare cases with average charges of \$31,088, this infection is rated near the bottom of the CMS listing, and no action is proposed because of coding problems. We understand that there are many complicating factors with regard to including MRSA, but the lack of action among hospitals to prevent the occurrence of these deadly infections is simply unacceptable, some would say criminal. This is an epidemic that fails to respond to most antibiotics available today and CMS needs to take serious action immediately. We urge that CMS convene a special work group to make hospital acquired MRSA a higher priority.

We make similar comments about other hospital-acquired infections not likely to be included in the first year of 5001(c) events:

- **Surgical Site Infections (SSI):** Every state reporting law includes SSIs related to selected surgeries. This is one area on which most hospitals concentrate their infection control efforts, yet it remains a significant problem. The CDC recently estimated that approximately 20 percent of hospital-acquired infections are SSIs – or 274,000 SSIs each year -- two in every 100 procedures.⁶ We urge CMS to identify SSIs associated with several common procedures - for example, hip and knee replacement surgeries - and include at least some of these in the first year.
- **Ventilator Associated Pneumonia (with an estimated extra cost to the health care system of \$2.5 billion):** We urge CMS to keep working on this and to push for improved ways to identify when nosocomial VAP occurs and for amending the current CDC definition of VAP. For too long, experts in the medical field have complained about this unworkable definition and it needs to be dealt with quickly. The results from the Institute for Healthcare Improvement's 100,000 Lives campaign clearly indicate that effective prevention practices exist. This is the deadliest of hospital-acquired infections and needs to be addressed.
- **Vascular Catheter-Associated infections (with a quarter million cases per year):** We appreciate that CMS is planning to create a code(s) to identify this condition and support adding it in 2009.

As the CMS analysis shows, it is relatively easy to include in the 5001(c) conditions (1) catheter-associated urinary tract infections, (2) pressure ulcers, (3) serious preventable events, (4) air embolism, and (5) blood incompatibility, and Staphylococcus aureus Bloodstream Infection/Septicemia. To act immediately on all six of these conditions will be a major step forward for patient quality—and savings for taxpayers. We support including all six of these conditions on the initial list.

⁵ "MRSA in Healthcare Settings," http://www.cdc.gov/ncidod/dhqp/ar_MRSA_spotlight_2006.html, 2006.

⁶ Klevens, Monina R., p. 163.

We strongly support including catheter-associated urinary tract infections (UTI). Only one state reporting system (Pennsylvania) is requiring hospitals to track UTIs and very few hospitals focus infection control efforts on them. Including UTIs on this initial non-payment list will no doubt finally give hospitals the impetus to do something about this very common, costly, yet easily preventable, hospital-acquired infection. This item alone will have a huge impact on reducing infection rates.

We also strongly support the inclusion of Staph aureus bloodstream infections (septicemia), another high volume, high cost hospital-acquired infection, with a death rate of about 41% or 12,000 fatalities a year and an extra cost of \$9.5 billion. We appreciate the discussion of the complexities of the coding problems, but with human and financial costs so high, we urge that resolving these coding problems be made a priority and that CMS list Septicemia as comprehensively as possible.

We support 5001(c) and do not believe patients and taxpayers should pay for such poor quality of care. We appreciate the agency's willingness to work through the technical coding and paperwork problems that exist in many of these situations. Ultimately, hospitals need to do a better job of identifying conditions patients bring with them when admitted to the hospital and, more important, of identifying those patients who are infected or injured while hospitalized. Public reporting laws and Medicare non-payment for the treatment of these injuries will bring about these long-needed changes. A hospital could then be rewarded (or penalized) for its bottom line infection rate and performance, and consumers could 'vote with their feet' in rewarding the higher quality institutions. We realize that this goal may take several years, but it is a journey worth starting.

REPORTING HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE [412.64(D)(2)]

We strongly support the expansion of the quality items that must be reported in order to receive the full payment update (i.e., not face a reduction of 2 percentage points) to include five anti-infection process measures. For calendar year 2009, we support the inclusion of three new infection prevention measures:

- SCIP Infection 4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose;
- SCIP Infection 6: Surgery Patients with Appropriate Hair Removal;
- SCIP Infection 7: Colorectal Patients with Immediate Postoperative Normothermia.

In the CMS listing of additional measures that might be considered, we urge you to proceed to include additional infection prevention measures, regardless of whether they have been formally agreed to through the sometimes overly-lengthy consensus process. Specifically, we support the inclusion of urinary catheter-associated urinary tract infection (UTI) for ICU patients as an outcome measure. This is the most common hospital-acquired infection and most hospitals are unaware of the extent of the problem

within their facilities. Pennsylvania hospitals, the only state that requires tracking UTIs, identified 11,265 UTIs in 2005, with a statewide infection rate of 7.2 per 1000 cases and a mortality rate of 8.7. The length of stay for these patients was four times longer than the average patient.

Most importantly, it is time to give the public information on hospital specific HAI rates. Pennsylvania, Missouri and Florida are doing it and other states will soon follow. There is no reason for Medicare to be lagging so far behind in this life-saving and money-saving effort. The CMS notice references an effort underway by the NQF to consider the recommendation of reporting various infection rates. This must be treated with more urgency: on average, about 10 Americans per hour are dying from HAI.⁷ . We cannot afford to wait for further study, as infections are growing more resistant to treatment faster than we as a nation are addressing the issue.

With respect to the CMS desire to 'retire' quality measures that are no longer relevant, Consumers Union would say that as much as it supports and appreciates the inclusion of the various infection prevention process measures, they should all eventually be replaced with a comprehensive public reporting of HAI infection rates. Reporting infection rates leaves it to hospitals to use whatever process measures and other strategies they feel appropriate to achieve a low infection outcome. Curbing HAI takes a comprehensive approach and infection rates will reveal which hospitals are taking such an approach. The notice refers to a desire to "balance the competing goals of assuring the development of a comprehensive yet parsimonious set of quality measures while reducing reporting burden on hospitals." Then, focus on outcomes. It is impractical for the CMS Hospital Compare system to keep adding process measures each year. Further, process measures do not always translate into improved outcomes.

Generally, we urge CMS to turn its focus on outcome measures relating to issues other than hospital-acquired infections. Thus, we support the other outcome measures listed for inclusion and possible inclusion, such as readmissions and AHRQ quality and patient safety indicators.

With respect to validation of data being submitted by hospitals, we understand that in FY 2008 CMS will not be applying the validation requirement to 3 SCIP anti-infection measures (Infection 2, VTE 1 and 2). Since this data comes from the hospitals and it can impact their business, it is imperative to include validation processes to assure the public that the information is accurate. We appreciate the Agency making it clear that they will be subject to validation in FY 2009 and, since they trigger Federal payments, we believe they may already be subject to the False Claims Act.

With respect to public reporting, combining data across multiple campuses hides from consumers serious quality problems at a single facility. The notice states that 5-10% of hospitals report in this manner, which could have an impact on many consumers. As long as this grouping is in place, the public must be informed as to which facilities are falling

⁷ 100,000 deaths each year divided by 365 days, then by 24 hours, or 11.4 infections per hour.

into these groups. But it is ultimately more important to address the underlying problem that is preventing CMS from reporting the performance of each individual hospital. We urge CMS to report the quality measures for each specific hospital campus.

One more issue we would like to raise that is not addressed in the notice is coordination with the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), the successor of the agency's National Nosocomial Infection Surveillance System. Many of the states passing infection reporting laws will be using the NHSN to analyze hospital data; one major state, New York, has already begun reporting through this network and eventually well over a thousand hospitals will do the same. As CMS considers reporting infection rates, it should ensure coordination with CDC to avoid duplication of efforts by hospitals that are complying with state laws, but also want to be eligible for the full market basket updates. We urge CMS to begin working on this immediately.

IMPACT STATEMENT

We seriously challenge the conclusion in the Impact Statement relating to Hospital-Acquired Conditions, including infections, found in section VII. A of the CMS document suggesting the expected savings from this proposal will be minor. While the direct savings based on non-payment may be minimal, the savings resulting from preventing HAI and other events could be significant. For example, if every hospital began systematically following CDC guidelines on urinary catheters in an attempt to prevent non-payment for patients who get a urinary tract infection (UTI), the cost savings to Medicare (as well as other payers) from preventing high volume/high cost UTIs could be quite substantial. The threat of non-payment will be a big motivator for hospitals to be more diligent in complying with CDC guidelines that have been published for many years. We believe the number of deaths from HAI and the additional costs have been well documented in a number of studies. Reducing the rate of infection will be a money saver to payers, but more importantly, it is a life saver, and therefore justifies more urgency and action in stopping HAIs.

Thank you for your consideration of these comments.

Sincerely,



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June 11, 2007

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

Re: File Code CMS-1533-P

Dear Ms. Norwalk:

Please note that the following comments correspond to the “Imputed Floor” and “Section 508 Reclassification” contained in the FFY 2008 proposed IPPS rule published in the May 3, 2007 Federal Register.

Warren Hospital continues to support the Centers for Medicare and Medicaid Services (CMS) proposal related to “Special Circumstances of Hospitals in All-Urban States” set forth in the FFY 2005 proposed Inpatient Prospective Payment System (IPPS) rule published in the May 18, 2004 Federal Register. Conversely, Warren Hospital objects to the proposed expiration of the imputed floor for the following reasons:

- CMS does not give any substantive rationale as to the reason the imputed floor should expire. For comparative purposes, please note the following quote from CMS in the FFY 2005 final rule:

We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or “floor”, from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period.

- CMS does not provide in the FFY 2008 proposed rule any change in either the existence or effect of the aforementioned “anomaly”; therefore, CMS does not provide any substantive support for the elimination of the imputed floor.
- We believe that it would be improper for CMS to include in the final rule any empirical analysis regarding the imputed floor, as that would constitute avoidance of public commentary.

- CMS has contradicted itself by stating in the FFY 2008 proposed rule that “we believe the policy should apply only when required by statute.” However, in the FFY 2005 final rule, CMS responded to commenters’ contention at that time that “any special provision for urban-only States should be subject to legislative action.” Citing Social Security Act (SSA) section 1886(d)(3)(E) as the authoritative basis for establishing the imputed floor, CMS correctly noted that the agency “does have the discretion to adopt a policy that would adjust wage areas” in the manner established by CMS at that time; that is, the policy reflected in the imputed floor regulation.
- In addition, in the past CMS has repeatedly utilized SSA section 1886 (d)(5)(I)(i) to implement wage index adjustments absent specific statutory authority. Furthermore, CMS is currently relying on this section of the SSA for another proposed wage index matter in these proposed regulations.
- CMS notes in the proposed rule that “Urban providers in ... the Mid-Atlantic Region (NJ) will experience a decrease ... by 0.2 percent ... from the imputed rural floor no longer being applied” in New Jersey. We respectfully request that CMS provide the public, during the public comment period, with the rationale that supports the agency’s conclusion in this regard. We request that the agency furnish this information during the public comment period so that interested parties will have due opportunity to review the rationale and comment, as they deem appropriate.
- On an individual hospital level the reduction in funds under the expiration of the imputed floor would have the following impact on our hospital. Warren Hospital will experience a reduction of approximately \$2,239,000 per year in Medicare reimbursement without the imputed floor. Such reduced revenues will lead to significant patient care changes, such as potential closure of our Alcohol and Drug Rehab Program as well as our Inpatient and Outpatient Psychiatric services.
- On an individual hospital level the reduction in funds under the expiration of the Section 508 Reclassification would have the following impact on our hospital. Warren Hospital will experience an overall decrease of \$5,201,000/year going from the NYC wage index to the Allentown-Bethlehem-Easton Pennsylvania “Core- based Statistical Area”, effective October 1, 2007. Such reclassification will result in a 12% decrease to our Medicare rates/revenues which will be one of the largest decreases in Medicare reimbursement of any hospital in the entire country! Such reduced revenues will lead not only to the significant patient care changes noted above but in addition we will have to implement material layoffs of our workforce and given the fact Warren Hospital is the second largest employer in Warren County this will be devastating to the local economy.

Ms. Norwalk
6/11/2007
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As noted above, the expiration of the "imputed floor" and "Section 508 Reclassification" would have a detrimental impact on Warren Hospital. As such, Warren Hospital does not support the expiration of the imputed floor/section 508 due (among other things) to the fact that the rationale for implementing such criteria three years ago has not changed. Therefore, we urge CMS to extend the imputed floor regulation and Section 508 reclassification.

Thank you for considering these important comments and we look forward to your response.

Respectfully submitted,



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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 1 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.

(4) Adjustments to other aspects of LTACH PPS

CMS provides few details in the proposed regulation as to how the MS-LTC-DRG system would interact with other aspects of the LTACH PPS. For example, the high-cost outlier (HCO) fixed loss amount is set so that expected HCO payments will equal 8 percent of total payments to LTACHs. The relative weight changes that CMS proposes in this regulation may very well affect those calculations. It is reasonable to expect that HCO patients will be found more commonly in the higher severity weighted MS-LTC-DRG categories. With changes in which patients get distributed into the categories, more HCO patients could have a harder time qualifying for the additional payment. This is because the total threshold to qualify for an outlier payment is the new MS-LTC-DRG-weighted payment plus the fixed loss amount. CMS has not made adjustments for the possibility that fewer cases will qualify as HCO and if so CMS will not meet the requirement that 8 percent of payments be related to HCOs.

In recent years, CMS has tied more of LTACHs' payments to the inpatient PPS, including payments to LTACHs for certain short-stay outliers (SSOs) and for patients admitted from an acute hospital in excess of a certain threshold. The CMS policy, finalized for July 1, to implement "IPPS Thresholds" for SSO cases has not yet been implemented, and CMS is already asking LTACHs to incorporate different threshold levels into their operations systems. These threshold levels are based on a yet-to-be implemented MS-DRG system, but could have a profound impact on LTACH revenues. ALTHA believes more study needs to be done in order to verify the accuracy of these thresholds, and to understand their impact on LTACH revenues.

ALTHA recommends CMS study the interaction of the proposed MS-DRG system on expected LTACH revenues and publish more information which would allow LTACHs to provide meaningful comments on this system. ALTHA would prefer additional time to conduct its own analyses. For this reason, and others described above, ALTHA recommends delaying implementation of the proposed system with modifications until FY 2009.

We recognize that the current regulatory cycle makes it difficult for CMS to fully account for changes in the IPPS rule (i.e. DRG reweighting) to other aspects of the LTACH PPS, however, this does not negate the impact of the interaction of the two regulatory cycles on LTACH providers. ALTHA believes that CMS should explicitly address these effects whenever these changes are proposed and finalized in the IPPS rule. We recommend that CMS consider all interactive effects of each regulation, and to make sure the interactive effects are published, and incorporated fully into any impact analysis before implementation is undertaken. In addition, ALTHA recommends CMS delay or transition (smooth out) the effects to provide more regulatory stability for LTACHs. ALTHA would support the transition to a single rulemaking cycle for LTACHs as a means of addressing these issues.

In summary, ALTHA recommends that one and only one severity-adjusted DRG system be implemented and that such system should be the MS-LTC-DRG system. All necessary information should be made available for public comment before implementation. Since all the necessary information is not available, ALTHA recommends delaying implementation until such information has been made available and providers have had the opportunity to provide meaningful comments. A sufficient

timeframe should be allowed for implementation commencing October 1, 2008. Implementation should occur under a three-year transition period to minimize the detrimental impact of payment changes on LTACHs and allow a considered and supportable approach to any adjustments necessary to maintain budget neutrality. ALTHA looks forward to working with CMS to implement the proposed system, with the modifications described above, in the near future.

Sincerely,

A handwritten signature in black ink that reads "William Walters". The signature is written in a cursive style with a large, prominent "W" at the beginning.

William Walters
Chief Executive Officer
Acute Long Term Hospital Association

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June 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

JUN 06 2007

REF: CMS-1533-P

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

On behalf of Providence Health & Services, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to the hospital Inpatient Prospective Payment System (IPPS). CMS published these changes as part of its Notice of Proposed Rule Making (NPRM) in the *Federal Register* on May 3, 2007. Providence Health & Services is a faith-based, non-profit health system that includes 26 hospitals, more than 34 non-acute facilities, physician clinics, a health plan, a liberal arts university, a high school, approximately 45,000 employees and numerous other health, housing and educational services in Alaska, Washington, Montana, Oregon, and California.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit comments on several areas related to the proposed changes to the DRG classification system which were published in the *Federal Register* (Vol. 72, No. 85, pages 24680-25135) on May 3, 2007. Our comments on other aspects of the proposed rule for the hospital IPPS will be submitted under separate cover.

DRG Reclassifications

In FY 2007, CMS began the process of reforming the DRG system by adopting cost-based weights over a three year transition period and making interim changes to the DRGs. Moving towards a DRG system that recognizes the severity of illness and resource usage of patients is a goal shared by CMS, MedPAC and Providence Health & Services. The adoption of severity-weighted cardiac DRGs in FY 2006 has proven to more completely reflect the care and resources used by these patients and led to more accurate payment rates in the IPPS. Through these changes, and the creation of additional severity-based DRGs in FY 2007, CMS has taken the initial steps to reform the current system.

For FY 2008, CMS is proposing comprehensive changes to the DRG system to better account for the severity of illness and resource usage of patients. The magnitude of these changes is on the level of the original implementation of the DRGs.

CMS has explored DRG reform through two initiatives – engaging the RAND Corporation as a contractor to evaluate alternative DRG systems and reviewing ICD-9-CM diagnosis codes to further refine the current CMS DRGs. Providence Health & Services believes both avenues of exploration are crucial, but cautions CMS to allow the completion of this work before implementing sweeping, and potentially transitory, changes. Refinements to the current CMS DRG system to improve payment accuracy and reduce financial incentives to create specialty hospitals are needed, however, Providence Health & Services urges CMS to implement such changes in a careful, incremental manner to allow for the evaluation of unintended consequences. Upon evaluation, CMS will then be able to make adjustments to the system in a deliberate fashion based on established evidence rather than conjecture.

DRG Reform and Proposed MS-DRGs

Evaluation of Alternative DRG Systems

CMS engaged the RAND Corporation to evaluate alternative DRG systems that may better recognize patients' severity of illness than the current CMS DRGs. Five commercially available software systems are currently being analyzed by RAND. Although a preliminary report on their findings is available, RAND has not yet completed its final evaluation. Because the analysis is currently incomplete, CMS is not proposing to use any of these proprietary DRG products for FY 2008. RAND is scheduled to deliver its final report by September 1, 2007 at which time CMS will evaluate whether to adopt one of the five alternative DRG systems for purposes of the IPPS.

In spite of this established evaluation process with RAND, CMS is proposing to adopt the MS-DRG system for FY 2008. CMS has created the MS-DRG system by modifying the current CMS DRGs to better account for severity of illness of patients and, without analysis by RAND, is proposing to implement this system beginning October 1, 2007. Although CMS has instructed RAND to evaluate the proposed MS-DRGs using the same criteria that it is applying to the other five DRG systems, CMS is planning to move forward with the implementation of this system without the benefit of a final RAND analysis.

Furthermore, CMS acknowledges that a comprehensive evaluation of each severity-based DRG system, including the MS-DRGs, is necessary to determine the next steps in the reform of the IPPS. This suggests that CMS, while moving forward with the implementation of the MS-DRGs for FY 2008, may, in fact, determine that an alternate severity-based DRG system is appropriate for FY 2009 and beyond. By instituting the MS-DRG system for FY 2008 without allowing the evaluation process by RAND time to complete, CMS is jumping ahead of itself. Although Providence Health & Services applauds CMS in the development of a non-proprietary severity-based DRG system, we are concerned about the adoption of such system prior to thorough and careful analysis by RAND as part of the already-established process. After RAND's final report,

CMS may determine that the MS-DRG system is the most viable option to meet the goals of the agency and will be the best system to capture the severity of illness of patients; however, another system may be better suited for those purposes. It seems counterintuitive to move forward with the implementation of the MS-DRG system in FY 2008 when, in fact, CMS may choose another system in FY 2009.

Recommendation:

Providence Health & Services would like to commend CMS on the development of the MS-DRG system to more accurately capture patients' severity of illness and use of resources. However, we urge CMS to allow RAND to complete their evaluation of all five proprietary severity-based DRG systems and the new MS-DRG system prior to moving forward with the implementation of a severity-based DRG system. Only after careful analysis of RAND's final report should CMS make decisions regarding further reform of the IPPS, including the determination of *which* severity-based DRG system to implement.

Payment Accuracy and Case-Mix Impact

As part of RAND's comprehensive analysis, the potential changes in coding patterns or behaviors which may increase a hospital's case mix index (CMI) and subsequent payments will be evaluated. While some increase in CMI due to improved documentation and coding is to be expected with the implementation of any severity-based DRG system, different levels of risk can be associated with different systems. In their final report, RAND will include a comparison of the anticipated CMI increase attributed to improved coding and documentation changes between the five proprietary severity-based DRG systems and the MS-DRG system.

In the Proposed Rule, CMS has analyzed the changes in CMI that occurred in the State of Maryland after the introduction of APR DRGs and has attributed a significant increase in CMI to improved documentation and coding practices. While recognizing that some increase in CMI is actual real change in the type of patients being cared for, the analysis performed by CMS of Maryland's experience with a severity-adjusted DRG system contains several mistaken assumptions and conclusions. Drawing direct comparisons from Maryland's implementation of the APR DRG system with a nationwide implementation of the proposed MS-DRG system should not be done. Not only are the systems different, but they are being implemented on a different scale, during a different time-frame, and with very different levels of preparation. Additionally, when calculating the CMI changes in Maryland, CMS compared the CMI increases experienced in the early transition teaching hospitals to national rates of real changes in CMI; however the comparison was not done using the same time period (early transition hospitals using CY 2000 to FY 2003; national CMI changes using FY 2004-2006).

By using the State of Maryland's experience with the implementation of the APR DRG system as a means to anticipate the effects of a national implementation of the MS-DRG system, CMS has wrongfully concluded that CMI would increase

due to coding and documentation practices, as opposed to real case mix change, at a rate of 4.8% over the next two years. Thus, CMS has proposed to “adjust” the base DRGs to compensate for this behavioral change. Providence Health & Services strongly opposes this dramatic, prospective adjustment because it is based upon a faulty comparison. Such an unsubstantiated behavioral offset, which effectively negates the market basket update, threatens the ability of the nation’s hospitals to provide comprehensive and effective care.

Recommendation

Providence Health & Services urges CMS to allow RAND to complete their final analysis of all five proprietary severity-adjusted DRG systems and the proposed MS-DRG system, including a comparison of the CMI impact of all the systems. Such an analysis is necessary to assist CMS with determining not only the appropriate severity-adjusted DRG system to propose for FY 2009, but is also required to evaluate how much, if any, adjustment to the base DRGs should be undertaken to account for behavioral changes in coding and documentation practices. Until such analysis is complete, we urge CMS to refrain from any type of behavioral offset to the base DRGs.

Comprehensive Review of the CC List

As part of the development of the MS-DRG system, CMS undertook a comprehensive review of the complication and comorbidity (CC) list. This list, other than incorporating new ICD-9-CM diagnoses, has been virtually unchanged since 1980. Obviously, there have been dramatic changes not only in the accuracy and completeness of the coding of secondary diagnoses, but also in the characteristics of patients admitted to hospitals as well as practice patterns within hospitals. By revising the CC list, CMS intended to better distinguish cases that are likely to result in increased hospital resource use based on secondary diagnoses. Having a revised CC list comprised of significant acute disease, acute exacerbations of significant chronic diseases, advanced or end stage chronic diseases and chronic diseases associated with extensive debility will require the secondary diagnosis to have a consistently greater impact on hospital resources compared to the current CC list.

Recommendation

CMS recognizes that the review and comprehensive update to the CC list could lead to significant improvements in the ability of the current CMS DRGs to recognize severity of illness. Providence Health & Services urges CMS to consider adopting the revised CC list as an interim step in the IPPS reform process. By implementing the revised CC list in FY 2008, CMS could move forward in their goal of utilizing a system that more accurately recognizes the severity of illness of patients. This would allow a more accurate DRG system to be in place while CMS is evaluating the final RAND report, once available, to determine which severity-based DRG system to propose for implementation in FY 2009.

Providence Health & Services supports CMS in their efforts to reform and improve the existing DRG system to better recognize severity of illness and use of resources by patients.

We are also supportive of CMS' development of a severity-based DRG system that has no proprietary constraints. We look forward to working with CMS to institute a severity-based system, but urge CMS to move forward with implementation only after a thorough evaluation by RAND of *all* potential candidates, including the MS-DRGs. Once the RAND evaluation is complete, CMS will have the necessary information in which to base future reforms to the IPPS.

In closing, thank you for the opportunity to review and comment on the Medicare Program Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates NPRM. Please contact Beth Schultz, System Manager, Regulatory Affairs, at (206) 464-4738 or via e-mail at Elizabeth.Schultz@providence.org if you have questions about any of the material in this letter.

Sincerely,

A handwritten signature in black ink that reads "John Koster MD". The signature is written in a cursive, flowing style.

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

SynCardia Systems, Inc.
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Rec'd
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June 11, 2007

BY HAND DELIVERY

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

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

Dear Administrator Norwalk:

SynCardia Systems Inc. ("SynCardia") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule related to the fiscal year 2008 inpatient hospital prospective payment system ("Proposed Rule").¹ As the developer of biomechanical cardiac replacement and assist devices that are utilized for hospital inpatients, the inpatient hospital prospective payment system ("IPPS") impacts the reimbursement of our product by many payers, not solely Medicare. As such, we offer comments on the treatment of heart transplants under the Proposed Rule.²

We do not have a particular view as to whether the IPPS unit of payment should be the diagnosis related groups ("DRGs") or the Medicare Severity DRGs ("MS-DRGs"). Rather, we want to ensure that, under whatever scheme is used, hospitals that utilize our cardiac replacement device are adequately compensated under IPPS. Based on the Proposed Rule, that can only be assured if cases in which our device is used are assigned to MS-DRG 1.

¹ 72 Fed. Reg. 24680 (May 3, 2007).

² As such, all of the comments contained herein are pertinent to the caption "DRG Reform and Proposed MS-DRGs" which the agency asks that commenters identify early in the comment letter.

BACKGROUND

SynCardia manufactures the CardioWest™ temporary Total Artificial Heart (“TAH-t”). This medical device is the modern version of the Jarvik 7 artificial heart first implanted in 1982. The TAH-t is the only Food and Drug Administration (“FDA”) approved temporary artificial heart. It is used as a bridge-to-heart transplant device for transplant eligible patients dying from end stage biventricular failure.

To save the lives of these morbidly ill patients, the diseased heart is removed and the TAH-t is implanted. All implants are done in carefully chosen institutions that must be on the Medicare approved list of adult heart transplant centers and destination therapy for ventricular assist devices. The TAH-t pumps more blood, up to 9.5 liters per minute, than any ventricular assist device. This higher level of perfusion helps patients regain their strength, making them better heart transplant candidates. Currently, the TAH-t is powered by an external pneumatic driver and the size of the driver dictates that the patient remain in the hospital while awaiting a transplant. SynCardia is working with the FDA towards approval of a new driver that is much smaller and would allow patients to be discharged from the hospital while awaiting a transplant. We hope to obtain approval from the FDA for a Category B investigational device exemption (“IDE”) this summer.

We recognize that Medicare has a national noncoverage decision in place for artificial hearts. Nonetheless, we believe it is important for CMS to consider the appropriate assignment of cases in which a temporary artificial heart is utilized under IPPS for a number of reasons. Foremost, we will shortly be submitting a request to reconsider the national coverage decision (“NCD”) on artificial hearts to authorize coverage for artificial hearts when used as a bridge to transplant. As you know, with the statutory timeframes on the NCD process, a final decision, which we hope will authorize coverage, likely would become effective during fiscal year 2008. Further, given that many private insurers currently cover an artificial heart as a bridge to transplant for their insureds (e.g., CIGNA, Unicare, Empire Blue Cross Blue Shield, Anthem, and Aetna) and that many insurers utilize IPPS for reimbursing hospitals, proper assignment of cases in which an artificial heart is transplant is important.

DISCUSSION

I. Cases in Which an Artificial Heart is Implanted Must be Assigned to the Same DRG(s) as Heart Transplant Cases

Currently, cases in which a temporary artificial heart is implanted are assigned to DRG 525, with reimbursement at levels that are significantly lower than DRG 103, where heart transplant cases are assigned. Under the proposed MS-DRGs, heart transplant cases now in DRG 103 would be assigned to one of two MS-DRGs: MS-DRG 1 (Heart transplant or implant of heart assist system with major complication or comorbidity (“MCC”)) or MS-DRG 2 (Heart transplant or implant of heart assist system with complication or comorbidity (“CC”)). Cases now assigned to DRG 525 would be assigned to MS-DRG 215 (Other heart assist implant). Based on the listed relative

Leslie Norwalk, Acting Administrator

June 11, 2007

Page 3

weights in the Proposed Rule, the payments for cases assigned to MS-DRG 2 and MS-DRG 215 would be about the same, and would be close to, if not a little less than, the current payment for DRG 525. Payments under proposed MS-DRG 1 would be above the current amount paid for cases in DRG 103.

In this scheme, in which cases are assigned to DRGs or MS-DRGs based on relative resources used, there can be no question that cases in which the TAH-t is used must be assigned to MS-DRG (or the equivalent if CMS does not finalize its use of MS-DRGs). The cost to the hospital of the TAH-t alone exceeds the proposed national rate for MS-DRG 2 and MS-DRG 215. Placement of cases in which the TAH-t is implanted into MS-DRG 2 or MS-DRG 215 would result in a lack of resource coherence for cases in either of those MS-DRGs and likely would severely curtail, if not block, access to this technology. This would apply regardless of whether the recipient of the TAH-t is discharged from the hospital or not.³ Accordingly, we urge CMS to assign all cases in which an artificial heart is transplanted into MS-DRG 1.

In our view, the proper case assignment could be accomplished by moving diagnosis code V4322 (organ or tissue replaced by other means, fully implantable artificial heart) from the CC list in Table 6K of the Proposed Rule to the MCC list in Table 6J. Given that patients who receive the TAH-t are in biventricular failure and are at imminent risk of death, these cases involve a major complication and comorbidity. SynCardia asks that CMS make this change in the final rule.

CONCLUSION

Again, SynCardia appreciates the opportunity to comment on the important issues raised by the Proposed Rule. As detailed above, we urge CMS to ensure that cases in which the TAH-t is implanted are assigned to the DRG or MS-DRG for heart transplants. If the agency moves to the proposed MS-DRGs, it should assign such cases to the MS-DRG that includes cases with major complications or comorbidities.

If you have questions concerning this letter, please do not hesitate to contact me at (520) 545-1234. Thank you for your consideration.

Sincerely,



David Mackstaller
VP, Sales and Marketing

³ As noted earlier, under SynCardia's current approval for the TAH-t patients remain in the hospital until they receive a transplant or expire. However, the IDE trial that we are pursuing has the potential to allow patients to be discharged to the home while awaiting a transplant.



95-0
(2)

June 1, 2007

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

RE: DRG reform and proposed MS-DRGs

Dear Sir or Madam:

Thank you for requesting comments on the issue of DRG reform and proposed MS-DRGs. After reading your proposed methodology and having worked with the DRG system for 20 years, I believe your proposal is an excellent attempt to define severity of illness based on DRGs for the Medicare population.

However, I am perplexed by your proposal to adopt the MS-DRGs for fiscal year (FY) 2008 while the RAND Corporation is deciding this year between your methodology and five other vendors for subsequent adoption, which will take place probably in FY 2009.

I am unsure if you realize that this would create potentially enormous costs for hospitals as they "educationally gear up" for the MS-DRGs and then for another system one year later. Additionally – and undoubtedly – hospitals will be bombarded by consultants who will charge them for educational hours to get ready for a system that may be in place for only one year. As you know, hospitals commonly expend educational dollars attempting to legitimately understand and optimize the current CMS-DRG grouper.

In summary, although I applaud your methodology, I am opposed to any new system occurring in FY 2008 unless it is the final system selected from those that are currently being studied.

Thank you.
With kindest regards,



LANIER
HEALTH SERVICES

95-1

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

RE: DRG Reform and Proposed MS-DRGs

Dear Sir or Madam:

This letter has been written in response to the request for comments on the issue of "DRG Reform and Proposed MS-DRGs." After reading your proposed methodology and having worked with the DRG system, we believe your proposal is an excellent attempt to define severity of illness based on DRGs for the Medicare population. However, it is not clear why you would propose to adopt the MS-DRGs for FY 08 while the Rand Corporation is deciding this year between your methodology and five other vendors for subsequent adoption probably in FY 09.

I am unsure if you realize this would create enormous costs for hospitals as they "educationally gear up" for the MS-DRGs and then potentially for another system one year later.

In summary, although I applaud your methodology, I am opposed to any new system occurring in FY 08, due to the unreasonable burden it will place on institutions like our hospital. This objection would not apply in the event that a final system is adopted from the proposals that are currently being studied and there will be no additional modifications in FY 2009 or 2010.

Sincerely,

Reba Sanders, RHIA
Health Information Manager
Lanier Health Services
Valley, AL

Hard Copy

97

~~CMS-15517-1~~

**Prospective Payment System for Inpatient Rehabilitation Facilities
for FY 2008**

Submitter : Mr. Larry Ragel

Date & Time: 05/17/2007

Organization : Passavant Area Hospital

Category : Hospital

Issue Areas/Comments

**Proposed FY 2008 IRF PPS
Federal Prospective Payment
Rates**

Proposed FY 2008 IRF PPS Federal Prospective Payment Rates

IRF PPS

In the proposed rule it is acknowledged that rural referral centers have experienced declining operating margins with the average capital margin since 1997 of .26% overall and yet the impact of the proposed rule will further erode payments to rural hospitals. I am writing to express my strong objection to the rules as proposed. Specifically the "behavioral offset" of 2.4% to account for upcoding as well as the reduction in capital payments for rural hospitals. This results in an overall reduction in payments to rural hospitals at a time when additional reporting requirements for quality indicators and new reporting requirements for "present on admission" are being imposed. Our inpatient Medicare payor mix is more than 70% and increasing. It is difficult for hospitals invest in new equipment and technology to continue to provide adequate services to the communities we serve in an environment of escalating costs and reduced reimbursement. Perhaps the behavioral offset could be applied to urban/teaching hospitals where the tendency to upcode may be more pronounced based on the complexity and volume of services provided.

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



Dear Madam/Sir:

I, as a member of Kalispell Regional Medical Center leadership team, a not for profit community hospital, writing to urge you to eliminate provisions in the proposed rule for the FY 2008 hospital inpatient prospective payment system (PPS). At a time when increasing numbers of people rely on the Medicare program for their health care, it is necessary to strengthen the ability of hospitals to care for patients. Yet, inexplicably, the Centers of Medicare & Medicaid Services (CMS) has chosen a different course, one that would weaken hospitals' ability to provide needed services. In its proposed rule, CMS offers proposals that cut, by \$25 billion over the next five years, Medicare payments for hospital services provided to America's seniors and disabled. The proposal would cut all operating and capital inpatient payments by 2.4 percent in each of FY 2008 and FY 2009 for coding changes that CMS believes "might" happen with the implementation of its proposed changes to the diagnosis-related groups (DRG) classification system.

2.4 Percent Cut for Coding Changes = \$24 billion over the next 5 years

CMS bases its proposal to cut hospital operating and capital payments on its misinformed concerns that hospitals would change their coding practices in response to a CMS proposal to modify the existing DRGs to account better for patients' severity of illness. CMS' proposal would reconfigure the existing 538 DRGs into 745 refined Medicare Severity DRGs (MS_DRGs). The underlying system of classifying patients and "rules of thumb" for coding under the proposed MS-DRGs is generally the same as current practice. Therefore, hospitals will have little ability to change their classification and coding practices.

Inpatient PPS hospitals have been coding under the DRG system since 1983. That's more than 20 years of experience with coding today's system. The vast majority of hospitals already are 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 and co-morbidities (CCs) at high rates for many years. More than 70 percent of claims already include CCs. Most Medicare claims not only include CCs but also include more than 9 CCs, the maximum number accepted by Medicare's computer program for grouping cases into appropriate DRGs. CMS' proposal incorrectly assumes that hospitals have the ability to use even more CCs, but this ability is, in fact, very low and an offset is unnecessary.

One area of particular concern is the issue of reducing payment for hospital acquired infections, and medical errors. Our industry has grappled with a non-punitive

environment to help address and improve medical error discovery and the ability to address these. Now the government comes up with a punitive response and impacts payment. This is not based on clinical logic and evidence-based practice.

My comments regarding the proposed Medicare reimbursement changes as outlined in the aforementioned document are delineated in the following paragraphs.

1. Catheter-associated urinary tract infections.

It is well recognized that Catheter-associated urinary tract infections are commonly encountered hospital associated infections. The literature is replete with data addressing various methods to decrease the frequency of this problem. The utilization of medication and metal coated catheters, closed drainage systems and the intravesical instillation of antimicrobial solutions have been effective in decreasing but not eliminating this problem. There are data that suggest that genetic factors, not controllable by modern medicine, select for specific HLA types making some individuals more susceptible. Although healthcare providers can utilize a variety of techniques to minimize the number of infections per number of catheter days it is unrealistic to believe that this problem can be entirely eliminated. Hence, I do not believe that it is fair to penalize the healthcare system for not preventing something that is beyond their control.

2. Bed Sores

Bed sores are a preventable problem. Although they can occur, even in the presence of good nursing care, there is currently technology that can be employed to prevent them. It is my opinion that bed sores are a preventable problem. I have no argument against payment being withheld for therapy of this condition if it was not preexisting prior to the hospitalization in question.

3. Objects left in after surgery

Irrespective of how careful a surgical team is in their accounting for sponges, instruments and other objects that are used in the course of surgery foreign objects are still left in after surgery from time to time. There are many techniques that are employed to eliminate this complication. It is my opinion that remuneration should not be withheld for the primary surgery that resulted in the leaving in of a foreign object, but should be withheld for any procedure that is employed to retrieve and remove the object.

4. Air embolism, or bubbles, in bloodstream from injection.

Although I have heard of this complication, I have to wonder if it is just an urban myth. Outside of the intentional injection of air into an intravenous line, which I would presume to be a malicious act, I have to question if this is a real entity. Hence,

if there is documentation of this event actually occurring, I would have no objection to payment being withheld for the treatment of this complication.

5. Patients given incompatible blood type

Transfusion reactions from individuals receiving an incompatible blood type do occur. However, I feel that when this happens one should consider the circumstances. It is not an uncommon practice for an individual, in the time of a life-threatening emergency secondary to hemorrhage, to receive Type Specific or Type O, Rh negative blood without benefit of a full blood crossmatch. This can result in a transfusion reaction. The resultant reaction needs to be treated. It is my opinion that payment for the blood transfusion and the treatment of a transfusion reaction, if necessary, should not be withheld if it occurs under life saving emergency circumstances.

6. Bloodstream staph infection

Each and every one of us is colonized on our skin, in our genital tract, and in our gastrointestinal tract with a myriad of microorganisms including but certainly not limited to Staphylococci. Bloodstream infections emanating from this colonization do occur. The employment of aseptic techniques and barrier precautions in procedures such as the instillation of intravascular catheters and others can minimize but not totally eliminate this problem. Even under optimal circumstances the number of bloodstream infections per catheter days is not zero. In addition, the brushing and/or flossing of ones teeth have also been associated with bloodstream infections with microorganisms. Furthermore, since the reference is to Staphylococcal bloodstream infections, can one assume that bloodstream infections with streptococci, enterococci, the enterobacteraciae and the nonfermenters is acceptable? I do not think that it is reasonable or realistic to penalize the healthcare profession for caring for patients that acquire staphylococcal blood stream infections. (vide supra)

7. Ventilator-associated pneumonia

This complication, associated with significant morbidity, mortality and hospital expenses is very difficult to prevent. Although there are many technical and process advances that can be utilized to decrease the frequency of ventilator associated pneumonias, to totally eliminate them with current tools is not feasible. Patient's mouths and upper airways are colonized with numerous microorganisms. Even though precautions can be taken to try to minimize the organisms from these sites from reaching the lower respiratory tract they are not 100% effective. Leakage of secretions around the most well designed and efficient endotracheal tubes still occurs. Hence, it is impossible to totally prevent this complication, and therefore there should continue to be reimbursement for caring for these individuals.

8. Vascular-catheter-associated infection

Vascular catheter associated infections are most commonly caused by the indigenous flora of the patient. Even in the face of aseptic technique and barrier precautions in placing these devices, the formation of the biofilm that becomes adherent to them and subsequently colonized by the patient's skin flora cannot be totally prevented with our current technology. This colonized biofilm is the source of these infections, and hence, is beyond the control of the healthcare provider. There should not be a penalty for providing care for a condition that cannot be prevented.

9. Clostridium difficile-associated disease (gastrointestinal infections)

Clostridium difficile is part of the normal flora of the gastrointestinal tract of many persons. It becomes a clinical problem as a gastrointestinal infection when it becomes dominant flora and is toxin producing. The employment of a myriad of antibiotic agents to treat all types of infections including dental, surgical, traumatic and others have been associated with clostridium difficile associated disease. The only way to prevent this disease is to never employ antibiotics to treat infections. This is unrealistic. Hence, to penalize the healthcare system for treating a condition which they cannot predict or prevent should not be done.

10. Drug-resistant staph infection

It is estimated that every one of us from time to time is harboring a microorganism in our indigenous flora that is resistant to an antimicrobial agent. This includes Staphylococci as well and many others. It is well established that although organisms can be transmitted from person to person many of those that cause infections in an individual are harbored by the infected person as part of their indigenous flora. This most often occurs when an individual receives a broad spectrum antibiotic to treat an existing condition. This treatment can, by decreasing the numbers of drug sensitive organisms, select for the resistant organisms. The healthcare system can only try to minimize, but cannot prevent infections caused by drug resistant organisms that are harbored by an individual as part of their flora. They should not be penalized for treating these infections once they occur.

11. Surgical site infections

Surgical site infections have been extensively studied for many decades dating back to Lister in the 1850s. In recent times the most extensive work in this area has been by Dr. Peter Cruse at the Foothills Hospital in Calgary, Alberta, Canada. His extensive work in closely evaluating over 40,000 patients that underwent surgery has given us not only definitions of risk for surgical site infections but guidelines on how to minimize them. Surgical site infections are influenced by multiple factors and can be minimized. However, even with our current technology we can never totally

eliminate the risk of a surgical site infection. Once it occurs it has to be treated. One should not be penalized for providing care for a condition that they cannot control.

12. Wrong surgery

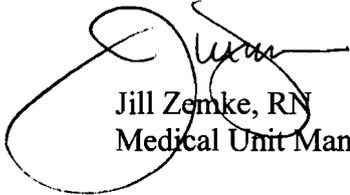
If what is meant by wrong surgery is amputating the right leg when the left leg is the one that is diseased, this is a blatant error. It is my opinion that the least of the worries of individuals that have performed wrong surgery is not being reimbursed for the procedure. If, however, something else is meant by the ambiguous term wrong surgery it needs to be more clearly and objectively defined. To withhold a provider's reimbursement based on someone's opinion of what is right and what is wrong is irresponsible.

13. Falls

Falls occur in hospital settings. Although they can be minimized they cannot be totally eliminated. Patient's are people like everyone else and just like you cannot eliminate the likelihood that you will ever fall you cannot do so for patients. The only possible solution to totally eliminate falls is to never admit a patient. Hence, to withhold payment for the treatment of an individual that was injured by something that could not be prevented is not reasonable.

In short, there is no rationale behind imposing such dramatic cuts to hospital payments for the services that millions of our Medicare patients rely on. They are not mandated; they are not supported by Congress and they are unnecessary. At a time when Medicare should be strengthened to meet rising demand, CMS must eliminate this arbitrary and unwise provision from the final regulations. Today's-and tomorrow's- patients deserve better.

Respectfully submitted,



Jill Zemke, RN
Medical Unit Manager

99 JUN 12 2007

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June 11, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1533-P; Multicampus Hospitals

Dear Sir or Madam:

We are filing these comments on behalf of Evanston Northwestern Healthcare ("ENH"). ENH appreciates the opportunity to submit comments regarding the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24680 (May 3, 2007) (the "Proposed Rule").

ENH is a multicampus hospital with three campuses, previously located in a single core-based statistical area ("CBSA"). As a result of the new labor market areas implemented in October 2004, two of the campuses remain in the original CBSA but a third is located in another CBSA. ENH welcomes the efforts by the Centers for Medicare and Medicaid Services ("CMS") to reduce the confusion and potential unfairness that arises when a multicampus hospital's data is reported into a single CBSA.

ENH strongly supports the proposal to allocate wage data for multicampus hospitals located in more than one CBSA among the CBSAs where the campuses are located. Further, ENH agrees that apportioning the wages and hours for each campus based on the full-time equivalent staff located at each campus is the most sensible approach to apportioning the data.

ENH does, however, suggest one clarification of the proposal that would enable multicampus hospitals to more efficiently and appropriately report the number of full-time equivalent staff. Certain executives and other employees of a multicampus hospital provide services to all the campuses and are not assigned to any one campus. In an integrated system it is

Centers for Medicare and Medicaid Services

June 11, 2007

Page 2

difficult to apportion accurately among the campuses the wages and hours of these personnel based on hours worked. Therefore, ENH recommends that for wage index purposes, the wage and hour data for personnel that are not allocated by the multicampus hospital to any particular campus should be allocated among the campuses in proportion to the full-time equivalent staff assigned to each campus. Thus, if 60% of employed personnel are assigned to Campus 1, 25% to Campus 2 and 15% to Campus 3, then 60% of the unassigned personnel would be allocated to Campus 1, 25% to Campus 2 and 15% to Campus 3. We believe that this would represent the most accurate allocation of the wages and hours of the unassigned personnel.

With this clarification, ENH believes that the proposed rule is the fairest and most appropriate method for apportioning wage data among the campuses of a multicampus hospital. Pursuant to the Proposed Rule at page 24784, ENH has submitted the requested 2004 cost report data to Ms. Kathy Ellingson.

ENH again thanks CMS for the opportunity to file these comments. Please do not hesitate to contact me if you need any further information or explanation.

Sincerely,

A handwritten signature in black ink, appearing to read "Marion Kristal Goldberg", with a long horizontal flourish extending to the right.

Marion Kristal Goldberg

THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

100

Health System Finance
Budget, Reimbursement,
Cost Accounting & Revenue Cycle

June 4, 2007

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

Re: Proposed Changes to the Hospital IP Prospective Payment Systems & FFY 2008 Rates

Dear Sir or Madam:

The University of Kansas Hospital (UKH) appreciates the opportunity to comment on CMS's proposed FFY 2007 inpatient PPS rule. We are a 508-bed teaching hospital with approximately 437 residents.

Summary of Comments

UKH does not support the omission of one of two diagnoses for congestive heart failure as a co-morbid (CC) or major co-morbid (MCC) condition. ICD9 428.0 Congestive heart failure unspecified and 428.9 Heart failure, unspecified were eliminated from the list of co-morbid conditions by CMS because they were considered to be chronic conditions and not reflective of an acute disease process.

UKH does not support the budget neutrality adjustment for the "paper" inflation of care levels derived from improved coding. We do not believe that the adoption of the MS-DRGs "would create a risk of increased aggregate levels of payment as a result of more comprehensive documentation and coding."

Congestive Heart Failure

ICD9 428.0 Congestive heart failure unspecified and 428.9 Heart failure, unspecified were eliminated from the list of co-morbid conditions by CMS because they were considered to be "chronic" conditions and not reflective of an acute disease process. When CMS determined what diagnoses made the cardiovascular patients sicker in the revision of DRGs for 2006, these diagnosis codes were part of the major

cardiovascular conditions (MCV). Now in 2008, CMS eliminated them from even the lower co-morbid classification (CC) without demonstrating that the diagnoses did not impact the cost of care.

Examination of FY2005 Medicare data (provided by American Hospital Directory) show 428.0 Congestive Heart Failure, NOS was the #1 diagnosis coded in the Medicare inpatient population. 6% of the over 12 million inpatients received that diagnosis.

In the preliminary 2006 data (also provided by American Hospital Directory), 45% of the claims that grouped to the highest severity category of the 2006 Cardiac DRGs (with MCV or CC), are proposed to group to the lowest severity DRGs in the proposed FY2008 grouper. Most likely this shift is due to the elimination of 428.0 Congestive Heart Failure as a CC or MCV.

Under 428.0 in the code book, there is no mention of the word chronic. It appears that this is the most appropriate diagnosis for congestive heart failure, a condition in which the heart fails and fluid collects in the lungs and other parts of the body. Acute pulmonary edema, a medical emergency correctly coded as 428.1 was only assigned a CC condition of lesser severity of illness than pneumonia. Most clinicians would disagree that pneumonia is more resource intensive than pulmonary edema.

Most facilities know physicians do not specifically document heart failure types despite the education hospitals provide to them, thus 428.0 will continue to be the #1 diagnosis for patients who present with congestive heart failure. CMS needs to demonstrate that diagnosis code 428.0 clearly does not command more intense resources before eliminating it from the CC list. In fact, all of the heart failure codes should be tested to see if they do not cause higher costs.

UKH is requesting that you do not eliminate ICD 428.0 from the co-morbidity list.

Budget Neutrality Adjustment

CMS has proposed a budget neutrality adjustment in the belief that the adoption of the MS-DRGs it is proposing “would create a risk of increased aggregate levels of payment as a result of more comprehensive documentation and coding.”

The Medicare Actuary has estimated that an adjustment of 4.8 percent over two years will be necessary to maintain budget neutrality for the transition to the MS-DRGs. The plan, therefore, is to reduce the IPPS standardized amounts by 2.4 percent each year for FY08 and FY09. UKH does not believe that our coding practices will change significantly due to the adoption of the MS-DRGs.

UKH is requesting that CMS delay the budget neutrality adjustment until FFY 2009, when six months of FFY 2008 data will be available for analyses. If analyses show that coding practices changed significantly due to the adoption of the MS-DRGs, then it would be appropriate to institute a budget neutrality adjustment in FFY 2009.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Sally Enevoldson". The signature is written in black ink and is positioned above the printed name and title.

Sally Enevoldson
Director of Reimbursement