WILLIAM E. HAIK, M.D., F.C.C.P.
DIPLOMATE TO THE BOARD OF PULMONARY MEDICINE
928-A MAR WALT DRIVE
FORT WALTON BEACH, FL 32547
PHONE (850) 862-4759

April 25, 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 twenty years, I believe your proposal is an excellent attempt to define severity of illness based on DRGs for the Medicare population.

However, I am highly perplexed you would propose to adopt the MS-DRGs for FY08 while the Rand Corporation is deciding this year between your methodology and five other vendors for subsequent adoption probably in FY09.

I am unsure if you realize this would create enormous cost for hospitals as they "educationally gear up" for the MS-DRGs and then potentially for another system one year later. I am aware of hospitals where the coding supervisors are already taking time out of their work days to study the proposed notice. Although this only amounts to a few hours, if multiplied by the number of hospitals in the country, it is a signficant loss of productivity.

Additionally, undoubtedly, hospitals will be bombarded by consultants (of which I am one) who will charge hospitals educational hours to get ready for a system which may only be in place for one year. As you know, hospitals commonly expend educational dollars attempting to legitimately optimize the current CMS-DRG Grouper.

In summary, although I applaud your methodology, I am opposed to any new system occurring in FY08, unless it is deemed to be the final system adopted from the ones which are currently being studied.

Thank you.

With kindest regards,

WILLIAM E. HAIK, M.D.

WEH/ddm

LEXINGTON MEMORIAL

April 26, 2007

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

Re: CMS 1533-P
"Redesignations" – Lugar Hospitals under1886(d)(8)
Lexington Memorial Hospital
Provider Number: 34-0096

Dear Sir/Madam:

We write on behalf of Lexington Memorial Hospital (Provider Number 34-0096) to inquire about Davidson County NC specifically as to why this county is not listed as a Lugar County on the Table of Lugar Counties in the proposed rule; and, therefore, why the hospitals located in the County are not reclassified.

Davidson County NC is located just south of the Greensboro-High Point, NC CBSA and the Winston-Salem, NC CBSA. Davidson County NC was formerly part of an MSA that included these adjacent areas (in addition to Alamance County NC which is now the Burlington, NC CBSA).

After the MSA split, Davidson County, NC became a "micropolitan" area and is currently subject to the three year hold harmless until September 30, 2007. Davidson County has a commuting exchange with both the Greensboro (Guilford and Randolph Counties) and Winston-Salem (Forsythe County, et al) CBSAs which indicates that the County would satisfy the outlying county criteria of 25% if commuting to both areas was considered (over 20% commuting to Greensboro and about 16% commuting to Winston). There are two hospitals located in Davidson County - Lexington Memorial (34-0096) and Thomasville Medical Center (34-0085). The County is not listed on the Lugar Table in the proposed rule and the hospitals are not listed as Lugar reclassifications on Table 9 A.

In the absence of a reason as to why Davidson County NC (and the hospitals therein) they are not a Lugar County and therefore the hospitals reclassified as Lugar to the Greensboro-High Point, NC CBSA, it appears that a change in the rule is necessary in order classify this county/hospitals appropriately. The County appears to satisfy the criteria and the hospitals should be reclassified as a Lugar.

See Attachment I attached for a more complete discussion of theses issues and feel free to contact me with any questions you may have.

Sincerely,

Danny Squires, Vice President/CFO, Lexington Memorial Hospital

Attachment I

Lexington Memorial Hospital
Analysis of Commuting Exchange with Adjacent Counties
And Medicare Payment Issues Related to Lugar County Status
April 2007

Introduction

Lexington Memorial Hospital (LMH) is located in Davidson County North Carolina. Davidson County was excluded from a CBSA/MSA (Core Based Statistical Area, formerly called Metropolitan Statistical Area) effective with FFY 2005. This had the effect of placing the hospital in the rural North Carolina wage area with a substantially lower Area Wage Index (AWI). The new CBSAs/MSAs were developed using county boundaries as the basic geographic area. The commuting rate of employed workers to adjacent areas is used to determine if an adjacent county meets the criteria for being an "outlying" county of a CBSA/MSA. Therefore, it is the commuting exchange that will determine if a county is deemed to be an "outlying" county of an adjacent CBSA/MSA.

The New CBSA/MSA

New MSA/CBSAs were established by the 2000 census data and subsequently used in the Medicare program for the wage adjustment (AWI) for FY 2005.

Prior to this change, Greensboro was the MSA for the hospital. The counties that were included in that MSA were Guilford, Randolph, Alamance, and Davidson. The changes implemented by Medicare using the new CBSAs resulted in the split of the CBSA/MSA. Guilford County and Randolph County were placed together in their own CBSA. Alamance County was placed into its own CBSA (Burlington), and Davidson County was considered micropolitan which under the new definitions is in rural North Carolina.

Davidson County is adjacent to the Winston-Salem CBSA which includes Forsythe County.

As stated previously, Davidson County is not currently included in a CBSA; it is a rural area. LMH, which resides in Davidson County, has therefore had its Medicare payments been significantly affected. The changes in the CBSAs/MSA have resulted in a large decrease in the area wage adjustment for LMH. Medicare recognized this fact and implemented a three year hold that expires September 30, 2007.

"Outlying" County Status

When discussing "outlying" counties, the December 27, 2000 Federal Register the Bureau of the Census states the following. "A county qualifies as an "outlying" county of a CBSA if it meets the following commuting requirements: (a) at least 25 percent of the employed residents of the county work in the central county or counties of the CBSA; or (b) at least 25 percent of the employment in the county is accounted for by workers who reside in the central county or counties of the CBSA." Initially, Davidson County did not meet either of these criteria to be considered an outlying county.

According to U.S. Census data of 2003, 20.4% of the employed workers who reside in Davidson County work in Guilford County, and 3.9% work in Randolph County. This suggests that 24.3% of Davidson County employed residents work in the Greensboro CBSA. More current data could indicate the Davidson County would meet the "outlying county" status.

It is equally important to note that Davidson County is also adjacent to Forsythe County (which is part of the Winston-Salem, NC CBSA) and that the percentage of employed Davidson County residents to that County is 16.1%. Therefore, taken together the degree of commuting to both Guilford County and Forsythe counties indicates that the commuting exchange is nearly 40%, well above the 'outlying county" criteria.

Lugar County Status

A provision for counties in just the same situation as Davidson is in statute and regulation - the Lugar County. This provision allows for a county to be considered to be part of a adjacent area if it meets the "outlying county" criteria using the commuting to two adjacent areas.

Given the commuting data, it appears that the major issue that contributed to the exclusion of Davidson from a CBSA was the fact that it is adjacent to 2 CBSAs – Winston-Salem and Greensboro. Because of this adjacency, the counties' employed workers commuting exchange is diluted between to two areas. Therefore, Davidson County does not meet the commuting exchange rate to be included in either CBSA. Had there been only adjacency to one of those areas, the county would have met the outlying county criteria. It does, however, meet the criteria for a Lugar County.

If one examines the commuting data above, one can see that if the commuting exchange to both adjacent CBSAs is taken together, the County would clearly meet the criteria of 25%, as the commuting exchange would be over 40.4% (Guilford County – 20.4% + Randolph – 3.9% + Forsythe 16.1% = 40.4%). This indicates that Davidson County meets the criteria as a Lugar County and should be reclassified under Section 1886(d)(8) to the adjacent CBSA to which the highest number of residents commute – Greensboro-High Point CBSA.

Addressing the Situation

CMS should examine the commuting data and the situation of Davidson County for reclassification as a Lugar County for FY 2008. Such inclusion is appropriate and would avert a short fall in payment for the hospital for FY 2008.

<u>The appropriate remedy for this situation is to classify Davidson County NC as a Lugar County and reclassify its hospitals to the Greensboro-High Point, North Carolina CBSA for payments beginning October 1, 2007.</u>

Essent Healthcare, Inc.
3100 West End Ave., Suite 900
Nashville, Tennessee 37203
615 312-5100
615 312-5101 Facsimile

MAY 10 2007

May 9, 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: File Code CMS-1533-P
Hospital Reclassifications and Redesignations
New England Deemed Counties

Dear Sirs/Madam:

We are writing to seek clarification of the proposed regulation to consider the Litchfield and Merrimack Counties as rural and the hospitals within them as being redesignated to urban CBSA 25540 Hartford-West Hartford-East Hartford, CT and urban CBSA 31700 Manchester-Nashua, NH, respectively. For the hospitals which have psychiatric units, would the PPS portion of the psychiatric payment be based on the rural wage of their respective State upon the finalization of the Federal Fiscal Year beginning on October 1, 2007? Because the regulations that govern psychiatric hospitals and units do not recognize wage index reclassifications, it would appear that the rural wage index would apply upon the effective date of this change.

We appreciate the opportunity to seek clarification of the application that this change may have on both the acute care and psychiatric services that these hospitals provide. If you have any question, please feel free to contact me at 615-312-5106.

Sincerely,

Judy S. Gibson

Judy S. Gibson
Vice President, Reimbursement

Baystate Mary Lane Hospital

85 South Street Ware, Massachusetts 01082 413-967-6211 baystatehealth.com/mlh

4-0 (3)

May 16, 2007

Centers for Medicare & Medicaid Services
Attn: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Subject: Comments on CMS-1533-P

We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates.

DRG Reform and Proposed MS-DRG

We urge CMS to eliminate the proposed 2.4% behavioral offset to the update factor from the final regulation. CMS would cut all operating and capital inpatient payments by 2.4% in each of FY2008 and FY2009 for coding changes that CMS believes might happen with the implementation of its proposed changes to the diagnosis-related groups (DRG) classification system.

We strongly disagree with CMS's conclusion that adoption of the MS-DRGs would create any increase in aggregate levels of payments as a result of increased documentation and coding. The underlying system of classifying patients for coding under the proposed MS-DRGs is the same as our current practice. Therefore, hospitals will have little ability to change their classification and coding practices.

Baystate Mary Lane Hospital and other inpatient PPS hospitals have been coding under the DRG System for over 20 years. We have been coding complications and co-morbidities (CCs) at high rates for many years. CMS's proposal incorrectly assumes that Baystate Mary Lane Hospital and other hospitals have the ability to use even more CCs, but this ability is, in fact, very low and an offset is unnecessary.

Capital Payment Rate

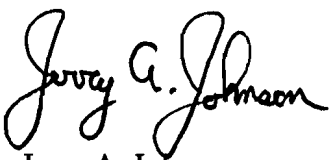
We urge CMS to continue annual capital rate updates for hospitals located in urban areas.

We strongly disagree with CMS proposed elimination of the annual update for hospitals in urban areas. Medicare is required by statute to pay for the capital-related cost of

inpatient hospital services to help fund Medicare's share of expenses for new facilities, renovations of existing facilities and purchase of needed equipment. Baystate Mary Lane Hospital's annual growth in capital-related cost have been and will continue to increase at a rate that greatly exceeds the annual update included in the Medicare capital payment rate. CMS should be proposing significant increases in capital to recognize past year underpayment rather than eliminating updates to urban hospitals to meet the Medicare statute.

If you have any questions, please contact me at 413-794-7924.

Sincerely,



Jerry A. Johnson
Director, Payment Systems

Baystate Franklin Medical Center

164 High Street Greenfield, MA 01301 Tel: (413) 773-0211 baystatehealth.com/fmc

4-1

May 16, 2007

Centers for Medicare & Medicaid Services
Attn: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Subject: Comments on CMS-1533-P

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If you have any questions, please contact me at 413-794-7924.

Sincerely,

Jerry A. Johnson

Jerry A. Johnson
Director, Payment Systems

Baystate
Medical Center
A Member of Baystate Health System
Springfield, Massachusetts 01199
413-794-0000

4-2

May 16, 2007

Centers for Medicare & Medicaid Services
Attn: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

Subject: Comments on CMS-1533-P

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IME Adjustment
Time Spent by Residents on Vacation or Sick Leave
And in Orientation

We urge CMS to abandon its proposal to exclude vacation and sick leave from the FTE resident count for purposes of both IME and direct GME payments.

CMS has developed a methodology for Medicare payment of the cost of direct medical education activities that includes a base year allowable cost per resident times current year resident FTE and Medicare utilization. The base year allowable cost per resident was determined by dividing direct medical education costs by resident FTE. The resident FTE included time spent by residents on vacation and sick leave. In order to have consistency between base year FTE used for development of cost per resident cap and current year FTE for purposes of direct GME payment, CMS needs to include vacation and sick leave in the FTE count.

Provider Reimbursement Manual (CMS - Pub 15-2) Section 3605.2 treats amounts paid for vacation and sick leave as part of wages and salaries. Therefore, the vacation and sick leave expense and related hours are included in line 1 of the hospital wage index information. In order to have consistency between the wage index reporting and resident FTE reporting, CMS needs to include vacation and sick leave time.

42 CFR Section 412.105 (f)(1)(iii)(A) states that full-time equivalent status is based on the total time necessary to fill a residency slot. Resident vacation and sick leave are components of the total time necessary to fill a residency slot and therefore needs to remain as part of resident FTE calculation.

If you have any questions, please contact me at 413-794-7924.

Sincerely,

Jerry A. Johnson
Director, Payment Systems

union HOSPITAL

1606 North Seventh Street
Terre Haute, IN 47804-2780
(812) 238-7000

5

WAYNE R. HUTSON
Sr. V. P. Finance, CFO

May 11, 2007

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

Dear Sir or Madam:

In response to the "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates" (72 FR 24680) we submit the following comments for your consideration.

RRCs (File Code CMS-1533-P):

Section 401 of Public Law 106-113 amended section 1886(d)(8) of the Act by adding subparagraph (E), which creates a mechanism, separate and apart from the MGCRB, permitting an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. The statute directs the Secretary to treat a qualifying hospital as being located in the rural area for purposes of provisions under section 1886(d) of the Act. In addition, one of the criteria under section 1886(d)(8)(E) of the Act is that the hospital would qualify as an SCH or rural referral center if it were located in a rural area.

At the time of enactment, the only benefit under section 1886(d) of the Act for an urban hospital to become a rural referral center was the waiver of the proximity requirements that are otherwise applicable under the MGCRB process as set forth in § 412.230(a)(3)(i). Although CMS has correctly indicated in the May 3, 2007, Proposed Rule that RRCs are not subject to the 12-percent cap on DSH payments, this provision of law was not enacted until the passing of Public Law 108-173.

The Conference Report accompanying Public Law 106-113, the language discussing the House bill (H.R. 3075, as passed) indicates that: "[H]ospitals qualifying under this section shall be eligible to qualify for all categories and designations available to rural hospitals, including sole community, Medicare dependent, critical access, and referral centers. Additionally, qualifying hospitals shall be eligible to apply to the Medicare Geographic Reclassification Review Board for geographic reclassification to another area."

In the August 1, 2000, Federal Register (65 FR 47089), CMS indicated their agreement "that Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(8)(E) of the Act in order to become RRCs so that the hospital would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area." CMS further stated, **"...we believe that the intent underlying this language (a description of**

the House bill) was to allow certain urban hospitals to become RRCs (upon reclassifying from urban to rural under section 1886(d)(8)(E) of the Act) and then reclassify under the MGCRB process (as RRCs, the hospitals would be exempt from the MGCRB's proximity requirements." [Emphasis added]. We note that the "certain urban hospitals" mentioned in CMS's quotation are specifically identified at section 1886(d)(8)(E) of the Act. The Act defines such hospitals as subsection (d) hospitals located in an urban area satisfying any of the following criteria:

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

We further acknowledge the CMS concern regarding the potential interface between rural reclassifications under section 401 and section 407(b)(2) of Public Law 106-113, which authorized a 30-percent expansion in a rural hospital's resident full-time equivalent count for purposes of Medicare payment for the indirect costs of medical education (IME) under section 1886(d)(5)(B) of the Act. Under the regulatory provisions at the time, an urban hospital could have potentially reclassified as rural under section 1886(d)(8)(E) of the Act for purposes of receiving the IME benefit while also reclassifying under the MGCRB process for purposes of a higher wage index. To prevent this situation from occurring, CMS revised the regulations governing MGCRB reclassifications by adding paragraph (a)(5)(iv) to section 412.230 stating that: "An urban hospital that has been granted redesignation as rural under Sec. 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status as long as such redesignation is in effect."

To accommodate Congressional intent, CMS decided to revisit their policy decision on section 4202(b) of Public Law 105-33. Specifically, in the August 1, 2000, Federal Register (65 FR 47089), CMS stated its revised policy decision as follows: **"Accordingly, in light of section 1886(d)(8)(E) of the Act and the language in the Conference Report, we have decided to revisit our policy decision on section 4202(b) of Public Law 105-33. Effective as of October 1, 2000, hospitals located in what is now an urban area, if they were ever an RRC, will be reinstated to RRC status under section 4202(b) of Public Law 105-33."** [Emphasis added]. CMS goes on to explain how this policy revision will allow OMB redesignated hospitals to regain their former RRC status; however, nowhere in the policy statement does CMS indicate that urban hospitals who were once RRCs under section 1886(d)(8)(E) of the Act are exempt from the revised policy. In fact, as indicated in the above quotation, CMS references section 1886(d)(8)(E) of the Act in the introduction to their revised policy decision.

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

Conclusion:

Based on the above discussion, we disagree with the assertion stated in May 3, 2007, Proposed Rule (72 FR 24812) indicating Medicare's policy has been that a hospital cannot continue to be an RRC once it cancels acquired rural status under § 412.103. The historical facts point to just the opposite as summarized below:

1) CMS acknowledged the Congressional intent behind section 401 of Public Law 106-113 was to allow "certain urban hospitals" to become RRCs and then reclassifying under the MGCRB process (as RRCs, the hospitals would be exempt from the MGCRB's proximity requirements). [65 FR 47089]

2) The phrase "certain urban hospitals" is specifically defined at section 1886(d)(8)(E) of the Act to include urban hospitals that would qualify as RRCs if located in a rural area.

3) The regulations at § 412.230 were amended to prevent reclassification under the MGCRB while simultaneously reclassified as rural under section 1886(d)(8)(E) of the Act. [65 FR 47108]

4) CMS made a policy revision allowing for retention of RRC status regardless of urban designation. [65 FR 47089]

5) CMS amended the RRC regulations at § 412.96 to eliminate all references to subsequent review of RRC status. [70 FR 47485]

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

1) Certain urban hospitals (as defined by section 1886(d)(8)(E) of the Act) are allowed to reclassify as rural under § 412.103 and obtain RRC status under § 412.96.

2) Rural hospitals under § 412.103 are allowed to reclassify under the MGCRB only if they first terminate their acquired rural designation.

3) Effective October 1, 2000, any hospital located in an urban area, if they were ever an RRC, will be allowed to maintain its RRC status.

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

In light of the Congressional intent surrounding Public Law 106-113, we do not believe the CMS proposal to remove RRC status once a hospital has terminated its acquired rural designation and/or to increase the minimum duration of acquired rural status under § 412.103 to be appropriate. CMS has expressed its concern that some IPPS hospitals are acquiring rural status solely to benefit from the MGCRB reclassification rules. However, in the August 1, 2000, Federal Register (65 FR 47089), CMS itself acknowledged that such was the intent of Congress in passing section 401 of Public Law 106-113.

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

- The urban hospital must be able to meet all remaining RRC criteria.
- The urban hospital's wage index would need to be at or very near the level of the State rural wage index to avoid a significant loss in reimbursement while designated rural under §412.103.
- The urban hospital's DSH payment percentage would need to be at or below 12%. Any higher and the hospital could lose significant reimbursement during the time between the effective date of rural designation and the effective date of RRC status (given the CMS Regional Office has 60 days to review the rural designation request, hospitals would likely file the request at least 60 days prior to the start of their next cost reporting period to ensure RRC status for the following fiscal year).
- The urban hospital must be situated in an area where it is beneficial to reclassify to the closest urban area.
- The urban hospital must meet the 82% test under § 412.230(d)(3)(ii) of the MGCRB process.

Taking these factors into consideration, there are very few hospitals that would qualify for or benefit financially from the process. Market research indicates approximately 15 to 20 hospitals nationwide in which this mechanism would make sense from a financial feasibility perspective. These hospitals fit the profile of other existing urban RRCs. Like their counterparts, these hospitals play a significant role in treating Medicare beneficiaries from surrounding rural areas. Many are located in an urban county sharing borders with multiple rural counties, counties containing a single critical access hospital, or counties containing no hospitals at all. The language in the Conference Report accompanying Public Law 106-113 was intended to address these hospitals as well.

Based on the foregoing we respectfully request CMS reconsider its proposed change in policy as described in the May 3, 2007, Proposed IPPS Rule (72 FR 24812).

Sincerely,

Wayne R. Hutson
Sr. Vice President & CFO

cc: Michael,Craig, David Doerr, Shantha Aaron

6

Eleanor A. McCain, M.D., P.A

Internal Medicine

918 MarWalt Drive
Ft. Walton Beach, FL 32547

(850) 863-8812

MAY 14 2007

May 8, 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 twenty years, I believe your proposal is an excellent attempt to define severity of illness based on DRGs for the Medicare population.

However, I am highly perplexed you would propose to adopt the MS-DRGs for FY08 while the Rand Corporation is deciding this year between your methodology and five other vendors for subsequent adoption probably in FY09.

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Additionally, undoubtedly, hospitals will be bombarded by consultants (of which I am one) who will charge hospitals educational hours to get ready for a system which may only be in place for one year. As you know, hospitals commonly expend educational dollars attempting to legitimately optimize the current CMS-DRG Grouper.

In summary, although I applaud your methodology, I am opposed to any new system occurring in FY08, unless it is deemed to be the final system adopted from the ones which are currently being studied.

Thank you.

With kindest regards,

Eleanor A. McCain, M.D.

EAM/wkb

7-0
(3)

T. J. Samson Community Hospital

1301 North Race Street
Glasgow, Kentucky 42141-3483
270-651-4444

BILL KINDRED
Interim Chief Executive Officer

May 8, 2007

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Proposed Inpatient Prospective Payment System Rule

Dear Ms. Norwalk:

We write to express our strong opposition regarding two provisions in the proposed Inpatient Prospective Payment System (IPPS) regulation which, if promulgated, would severely restrict beneficiary access to critical hospital services in both rural and urban areas, and thwart medical technology and capital investments that promote quality and reduce health care costs in urban areas.

As you are aware, the IPPS regulation adopts the Medicare Severity Diagnosis Related Groups (MS-DRGs), which bases hospital reimbursements on the complexity of medical diagnosis and services. The regulation, however, imposes a 2.4 percent cut to all inpatient hospital services for Medicare patients in FY08 and FY09 based on the assumption that hospitals will change coding practices, resulting in higher payments. MS-DRGs are simply a refinement of an existing classification system that hospitals have been using for 23 years. Hospitals are already expert in coding for payment; they have little ability to change their coding and classification practices. The proposed cut, also called a "behavioral offset" will result in a $24 billion cut in operating and capital payments to hospitals over the next five years.

CMS is not mandated by law to impose a behavioral offset in the IPPS regulation, yet has chosen to do so. There is no precedent in other payment systems for making prospective adjustment of this magnitude without any evidence of actual changes in coding. These

draconian cuts in reimbursements, which are based on conjecture, will impose an added burden on all hospitals. As a result, many hospitals in rural and urban areas, which operate on thin margins, may be forced to reduce their services, leaving patients without a sufficient level of access to hospital services. As you know, hospitals in underserved areas and oftentimes in rural communities form the cornerstone of the fragile health care delivery system. The reductions in this regulation could result in unmet needs of thousands, potentially millions of patients living in both rural and urban areas.

In addition, the proposed rule restricts beneficiary access to hospital services by freezing and/or altogether eliminating reimbursements to hospitals for capital-related costs of inpatient hospital services. As you area aware, for years, the Medicare program has paid for its share of the capital-related costs of inpatient hospital services. The proposed rule would freeze capital payments for all hospitals in urban areas and would eliminate additional capital payments made to large hospitals in urban areas. Taken together, these cuts would amount to nearly $1 billion over the next five years.

Payment reductions of this magnitude would make it difficult for hospitals to buy advanced technology and equipment and would slow clinical innovation in the hospitals most likely to conduct cutting edge research. Additionally, freezing capital payments would stall much-needed health information technology and the long-term commitments that hospitals have made to capital acquisitions. As you know, health care reform is predicated on our ability to increase quality care and efficiency through technological advances, including health information technology. We strongly urge CMS to take actions that foster healthy care innovation through technology.

The proposed rule will jeopardize beneficiary access to critical hospital services. In addition, the proposed rule will stifle hospital investment in technology that will increase patient quality and reduce health care costs. We therefore urge CMS to eliminate the behavioral offset and restore Medicare reimbursements to hospitals for capital investments in your final regulation.

Sincerely,

Bill Kindred, Chief Executive Officer
T.J. Samson Community Hospital

BK/pd

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Our Mission:
"To improve the health of those we serve in a spirit of love and compassion."

May 14, 2007

Ms. Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Proposed Inpatient Prospective Payment Rule

Dear Ms. Norwalk:

I write you to express my strong opposition to two provisions in the proposed Inpatient Prospective Payment Systems (IPPS) regulation. I respectfully request that these provisions be excluded from the final regulation.

The first provision would impose a 2.4 percent cut to all operating and capital payments for inpatient hospital services for Medicare patients based on the misguided premise of a so-called "behavior offset." This unwarranted proposal would result in payment reductions for hospital services in both FY08 and FY09, cutting $24 billion dollars in operating and capital payments over the next five years.

The second proposal would reduce payments to hospitals in urban areas for capital-related costs for inpatient hospital services, cutting payments by nearly $1 billion over the next five years. We urge you to eliminate both provisions when the final regulation is published.

Please allow me to further explain my strong objection to these changes:

1. Cuts due to a "Behavioral Offset." The suggestion to cut hospital operating capital payments is based on the suggested adoption of a classification system called Medicare Severity Diagnosis-Related Groups (MS-DRGs). This change is grounded on the belief that with the implementation of the MS-DRGs, hospitals would change coding practices, resulting in higher payments. Not even in the initial years of the IPPS was coding change found to be of the magnitude of CMS's proposed FY08 and FY09 cuts. MS-DRGs are simply a refinement of a classification system that hospitals have been using for 23 years. Hospitals are already experts in coding for payment; they have little ability to change their classification and coding practices.

The rationale for the reduction is also based on the transition of hospitals in Maryland to a completely new type coding system called All Patient Refined DRGs (APR-DRGs). I have concerns with the methodology of reaching this conclusion. Maryland's hospitals are paid under a state rate-setting system where an incentive to code accurately did not significantly affect what a hospital was paid. The classification system recently adopted by Maryland is much more complicated than what CMS is proposing and changed the coding incentive for Maryland hospitals. Generalizing the Maryland experience to the rest of the nation's hospitals is an "apples-to-oranges" comparison.

CMS is not mandated by law to impose a behavioral offset in the IPPS regulation, yet has chosen to do so. There is no precedent in other payment systems for making a prospective adjustment of this magnitude without any empirical evidence of actual and measurable changes in coding. While CMS has, on occasion, made adjustments for coding in implementing new payment systems, these changes generally have been made based on actual experience. When implementing a new physician fee schedule payment system in 1992, CMS (then the Health Care Financing Administration) imposed a behavioral offset on physician services, primarily to offset predicted increases in the volume of services. I later learned that the offset was much higher than was necessary, and the reduction was never returned to the physicians adversely affected by those cuts.

2. Cuts to Capital-Related Payments. For years, the Medicare program has paid for its share of the capital-related costs of inpatient hospital services. The proposed rule would freeze capital payments for all hospitals in urban areas and would eliminate additional capital payments made to large hospitals in urban areas. Taken together, these cuts would amount to nearly $1 billion over the next five years.

   These changes in capital payments would make it much more difficult for hospitals to purchase advanced technology and equipment and could have the effect of slowing clinical innovation in the hospitals most likely to conduct cutting edge research. Additionally, such a reduction could slow the adoption of much needed health information technology. Hospitals make long-term commitments to capital acquisitions. This proposal amounts to pulling the rug out from under their financial obligations to maintain and improve their physical facilities for patients.

Congress recently opposed a component of the administration's fiscal year 2008 budget proposal that would have significantly reduced hospital payments. As you know, both the FY08 House and Senate budget resolutions reinforced this sentiment by rejecting those cuts. The administration's attempt to achieve payment reductions of this magnitude through the regulatory process is equally unacceptable. I believe this action circumvents Congress' intent that hospital services for Medicare patients not be reduced.

In closing, I would like to reiterate my belief that CMS's decision could serve to jeopardize hospitals' ability to continue to care for patients. CMS's behavioral offset is unnecessary, and will result in devastating cuts to hospital services for our constituents. CMS's proposal to cut capital-related payments would create significant financial difficulties for many of our most

innovative hospitals. I strongly support the elimination of these provisions from your final regulation.

Both CMS and Members of Congress share the goal of serving the American public and helping those most in need. I hope that you will give strong consideration to the bipartisan concerns outlined in this letter.

Sincerely,

James A. Diegel, FACHE
President & CEO
Cascade Healthcare Community

cc: American Hospital Association
Oregon Association of Hospitals and Health Systems

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MAY 3 1 2007

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May 10, 2007

Ms. Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Proposed Inpatient Prospective Payment Rule

Dear Ms. Norwalk:

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2. **Cuts to Capital-Related Payments.** For years, the Medicare program has paid for its share of the capital-related costs of inpatient hospital services. The proposed rule would freeze capital payments for all hospitals in urban areas and would eliminate additional capital payments made to large hospitals in urban areas. Taken together, these cuts would amount to nearly $1 billion over the next five years.

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Both CMS and Members of Congress share the goal of serving the American public and helping those most in need. We hope that you will give strong consideration to the bipartisan concerns outlined in this letter.

Sincerely,

Gary Stokes, CEO

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JUN -1 2007

Carolyn B. Jackson
Chief Executive Officer
Lake Pointe Medical Center
6800 Scenic Drive
Rowlett, Texas 75088

May 31, 2007

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

RE: CMS Proposed Inpatient Prospective Payment Rule

Dear Ms. Norwalk:

We write to express our strong opposition to two provisions in the Inpatient Prospective Payment System (IPPS) regulation. We respectfully request that these provisions be excluded from the final regulation.

The first provision would impose a 2.4 percent cut to all operating and capital payments for inpatient hospital services for Medicare patients based on the misguided premise of a so-called "behavioral offset." This unwarranted proposal would result in payment reductions for hospital services in both FY08 and FY09, cutting $24 billion dollars in operating and capital payments over the next five years.

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In closing, we would like to reiterate our belief that CMS's decision could serve to jeopardize hospitals' ability to continue to care for patients. CMS's behavioral offset is unnecessary, and will result in devastating cuts to hospital services for our constituents. CMS's proposal to cut capital-related payments would create significant financial difficulties for many of our most innovative hospitals. We strongly support the elimination of these provisions from your final regulation.

Both CMS and the Members of Congress share the goal of serving the American public and helping those most in need. We hope that you will give strong consideration to the bipartisan concerns outlined in this letter.

Sincerely,

Carolyn B. Jackson

POCONO
MEDICAL CENTER

May 22, 2007

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Attention: CMS-1533-P.

Dear Sir or Madam:

By this letter, Pocono Medical Center, Medicare Provider No. 39-0201, hereby advises the Centers for Medicare and Medicaid Services that the proposed wage index assigned to the hospital on Table 2 of the proposed inpatient prospective payment system update for fiscal year 2008 is incorrect, and requests that the agency correct this error in the final rule and for purposes of Medicare payment systems utilized during fiscal year 2008.

PMC is located in Monroe County, Pennsylvania, which is located in Rural Pennsylvania for Medicare payment purposes. However, Monroe County and PMC qualify for an out-migration adjustment equal to 0.1091. *See* Table 4J, 72 *Fed. Reg.* at 24,958. As such, the hospital's applicable proposed wage index for fiscal year 2008 should be 0.9457, *i.e.*, the proposed wage index for Rural Pennsylvania (0.8366) plus the proposed out-migration adjustment (0.1091). Table 2 shows the proposed wage index assigned to PMC for fiscal year 2008 as 0.8366. *See* Table 2, 72 *Fed. Reg.* at 24,901.

PMC requests that CMS correct this error and assign the proper wage index in the final rule and for purposes of Medicare payment systems utilized during fiscal year 2008.

If you have any questions concerning this letter, please call me at (570) 476-3620.

Sincerely,

Edward Walsh

Edward Walsh
Chief Financial Officer

cc: John Cooper, BKD LLP
Eric Zimmerman, McDermott Will & Emery, LLP

10

PHYSICIAN HOSPITALS OF AMERICA
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Phone: 605-275-5349; Fax: 605-731-2575
Email: info@physicianhospitals.org Web: www.physicianhospitals.org

May 24, 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:

Physician Hospitals of America (PHA), representing the nation's physician owned hospitals, is pleased to offer comments on the proposed rule for the fiscal year 2008 inpatient prospective payment system (IPPS).

The key issues for our members are the adoption in fiscal year 2008 of severity adjusted DRGs; the proposed disclosure of physician ownership and 24/7 on-site physician coverage; and possible revision of regulatory standards for hospital personnel.

DRG Reclassifications

PHA has previously supported the recommendations of the Medicare Payment Advisory Commission (MedPAC) to revise the inpatient payment system to better align payments with true costs of care. In addition, PHA supported the previous CMS IPPS changes in 2007. PHA 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 a reasonable policy to make sure 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.

1090 Vermont Avenue NW, Suite 510, Washington D.C. 20005 ph 202 414 0140 | 800 962 9008

11

May 30, 2007

The Honorable Leslie V. 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

Subject: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates
72 *Fed. Reg.* 24680 *et seq.* (May 3, 2007) (CMS-1533-P)

IME Adjustment

Dear Administrator Norwalk:

On behalf of the nation's 59,000 osteopathic physicians and more than 12,000 osteopathic medical students, the AOA appreciates this opportunity to comment on proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates. Our comments focus on changes to the Medicare graduate medical education (GME) regulations, proposed in Section D, "Indirect Medical Education (IME) Adjustment." We firmly believe that these changes would adversely affect osteopathic GME programs and the interns, residents, physicians and teaching hospitals we represent.

Background

According to last year's Inpatient Prospective Payment System (IPPS) rule, certain activities are not allowable for IME and/or direct graduate medical education (DGME) payment purposes even though they are performed as part of an approved residency program.

For residents training in nonhospital settings, the time residents spend in nonpatient care activities, including didactic activities such as educational conferences, journal clubs, and seminars, may not be included in the hospital's FTE resident counts for DGME and IME purposes if they occur in nonhospital conference rooms, freestanding clinics, physician offices, or medical schools. In determining what constitutes "patient care activities" the agency states that it looks to the "plain meaning" of the term. That term was defined very narrowly, including

only "the care and treatment of particular patients or services for which a physician or other health care practitioner is allowed to bill." According to the agency, the term "patient care activities" "would certainly not encompass didactic activities." This restrictive reading is in direct conflict with the policy expressed in a 1999 letter on agency policy. In that letter CMS interpreted "patient care activities" as encompassing "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." (Letter of September 24, 1999, from Tzvi Hefter, Director of the Division of Acute Care to Scott McBride of Vinson & Elkins.) No rationale was provided for this dramatic change in agency policy.

According to CMS, the distinction between patient care and nonpatient care activities also is relevant in the hospital setting. Consequently, for IME purposes, a hospital may count only the time residents spend in patient care activities. Although this policy has no statutory basis, CMS apparently excludes time spent in didactic activities based on the assumption that because IME is an adjustment to the DRG system, it is related inherently to patient care. This flawed rationale creates a serious disincentive for establishing and maintaining high quality GME programs.

CMS correctly acknowledges that the distinction between patient care and nonpatient care is irrelevant for DGME purposes. Accordingly, resident time spent in "all areas of the hospital complex" may be counted so long as the resident is in an approved program.

The AOA firmly believes that didactic instruction is integral to physician training and inextricably tied to patient care, no matter where it occurs. In our view, nothing in the Medicare statute supports CMS' new-found dichotomy between "patient care" and "nonpatient care" activities, whether training takes place in the hospital or in ambulatory settings.

The Proposed Rule

The proposed rule is part of a continuing effort to whittle away GME payment in ways that are ill-conceived and counterproductive. If implemented, it would require teaching hospitals to deduct the time residents spend on vacation and sick leave from their full time equivalent (FTE) resident counts for both IME and DGME purposes.

As the rationale for the proposal, CMS states that questions have arisen about how resident vacation, sick leave, and orientation should be treated under agency policy as it has evolved over the last several years. In response to these questions, CMS suggests that vacation, sick leave and orientation are neither "patient care" nor "nonpatient care" activities, falling instead into a third category. Because orientation likely occurs at the beginning of a rotation and may be related to patient care, CMS proposes to follow existing policy, which allows time spent in orientation to be counted. Although vacation and sick leave have been treated in the same manner since 1991, the agency proposes mandating different treatment. CMS' rationale for this change is that vacation and sick leave are not related to patient care but are provided as a benefit of the resident's status as an employee. According to the agency, time spent in these activities thus should be deducted or removed from the hospital's FTE resident count.

At a time of increasing concern about whether the number of physicians will be adequate to address the health care needs of the population, the proposed change is misguided. CMS' continuing efforts to "clarify" its regulations, change definitions and pare payment create confusion and powerful disincentives for high quality medical education. Although this proposal may result in modest savings now, if implemented, it will imperil educational quality and exacerbate physician supply and distribution problems that could haunt the nation for decades to come.

As further justification for the proposed change, CMS notes that the ACGME does not impose a vacation or sick leave policy on the teaching programs it accredits. Unlike ACGME, the AOA, which accredits the nation's osteopathic postdoctoral training programs, has adopted an explicit policy on resident vacation and other leaves of absence. To protect residents and ameliorate stress and fatigue, this policy requires osteopathic programs to provide interns and residents a minimum of 10 business days of vacation time during each year of their training. *AOA Basic Documents for Postdoctoral Training Institutions and Postdoctoral Training Programs* at Section 2.52(a).

CMS' proposal to disregard resident needs for personal time away from the mental, physical and emotional demands of their programs is in direct conflict with recent efforts to establish reasonable limits on time spent in the training environment. These limits were established to protect the health, safety and well-being of residents and their patients.

For the reasons set forth in this letter, the AOA respectfully recommends that CMS rethink this ill-considered change in GME policy. We stand ready to assist the agency as it reevaluates its proposal to alter this longstanding policy. Thank you for your consideration of our concerns.

Sincerely,

John A. Strosnider DO.

John A. Strosnider, DO
President

Cc: Peter B. Ajluni, DO, President-Elect
Marcelino Oliva, DO, Chair, Bureau on Federal Health Programs
John B. Crosby, JD, Executive Director
Sydney Olson, Associate Executive Director
Shawn Martin, Director, Department of Government Relations
Margaret J. Hardy, JD, Director, Hospital and Medical Educator Affairs

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JUN - 5 2007

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www.lourdesnet.org

June1, 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" section contained in the FFY 2008 proposed IPPS rule published in the May 3, 2007 Federal Register.

Our Lady of Lourdes Medical Center (OLLMC) and Lourdes Medical Center of Burlington County (LMCBC) 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, OLLMC & LMCBC 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. OLLMC & LMCBC have significantly benefited over the past three years from the imputed rural floor legislation. Hospitals in New Jersey, are faced with increasing numbers of patients who are uninsured or underinsured. At the same time, hospital based physicians in New Jersey have repeatedly turned to hospitals for additional payments as they are faced with rapidly rising malpractice costs, inadequate reimbursements rates and uncompensated care. We've also been able to increase RN salaries while reducing agency cost. It has also enabled us to keep up with technology.

As noted above, the expiration of the imputed floor would have a detrimental impact on OLLMC and LMCBC. As such, OLLMC and LMCBC do not support the expiration of the imputed floor due (among other things) to the fact that the rationale for implementing the imputed floor three years ago has not changed since the inception of the imputed floor regulation. Therefore, we urge CMS to extend the imputed floor regulation.

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

Respectfully submitted,

Gwendolyn Burnett

Gwendolyn Burnett
Director of Reimbursement

12-1

JUN - 5 2007

Princeton HealthCare System

Redefining Care.

June 1, 2007

Ms. Leslie V. Norwalk, Esq.
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: File Code CMS-1533-P

Dear Ms. Norwalk:

Please note that the following comments correspond to the "Imputed Floor" section contained in the FFY 2008 proposed IPPS rule published in the May 3, 2007 Federal Register.

Princeton HealthCare System (PHCS) 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, PHCS 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.

University Medical Center at Princeton

Princeton House Behavioral Health

Merwick Rehab Hospital & Nursing Care

Princeton HomeCare Services

Princeton Surgical Center

Princeton Fitness & Wellness Center

Princeton HealthCare System Foundation

253 Witherspoon Street | Princeton, NJ 08540 | Tel: 609.497.4000
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- 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 negative impact on the future plans of PHCS. We have recently received State approval to build a new hospital and several months away from commencing construction. Any change in reimbursement of this magnitude would have an unfavorable impact on this major project.

As noted above, the expiration of the imputed floor would have a detrimental impact on PHCS. As such, PHCS does not support the expiration of the imputed floor due (among other things) to the fact that the rationale for implementing the imputed floor three years ago has not changed since the inception of the imputed floor regulation. Therefore, we urge CMS to extend the imputed floor regulation.

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

Respectfully submitted,

Bruce Traub
Chief Financial Officer

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RML
SPECIALTY HOSPITAL

JUN - 5 2007

June 1, 2007

Ms. Leslie V. Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8011
Attn: CMS – 1533-P
Baltimore, Maryland 21244-8015

RE: CMS – 1533-P

Dear Ms. Norwalk:

By way of background, RML is a freestanding hospital licensed in the State of Illinois and is a Medicare pre-October 1997 LTCH facility. RML is a 501(c)(3) not-for-profit limited partnership, whose owners are Rush University Medical Center and the Loyola University Medical Center. RML's programmatic focus is on ventilator weaning (respiratory), complex medical, and complex wound services. RML has one of the highest case mix levels of any LTCH nationally, and we pride ourselves on having some of the best outcomes of any program in the country. RML Specialty Hospital is also one of the highest volume, single institution ventilator programs in the country (if not the largest.)

The purpose for this letter is to comment on the proposed rule that would impact long term acute care hospitals by reducing their standardized amount by 2.4% each year for FY'08 and FY'09. It is indicated in the proposed rule that this reduction is being done to eliminate the effective changes in coding or classification of discharges that do not reflect real changes in case mix. My opposition to this 2.4% reduction is centered around an erroneous assumption used by CMS in their explanation, which states that "LTACH's will have a significantly increased opportunity to better code for these patients under the proposed MS-LTC-DRG system." The new MS-DRG severity system stratifies the current DRG system into potentially one, two, or three new DRGs. My concern focuses on two specific high volume DRGs utilized in the long term acute care environment (which are currently DRG-565 and DRG-566) that convert into the proposed MS-DRG 207 and 208. These two new DRGs cannot be "up coded." There is a one-to-one DRG conversion between the existing DRG system and the proposed MS-DRG system, so the statement that assumes a 2.4% DRG creep within the overall structure cannot be valid, because there is no possibility of up coding these two high volume DRGs to a higher MCC or CC category. If these two DRGs account for a significant portion of the discharges within the LTACH environment, then the 2.4% "coding creep" offset should be lowered because there is no ability to have DRG creep within these two DRGs.

5601 South County Line Road • Hinsdale, Illinois 60521 • *telephone*: 630-286-4000

EMTALA – The clarification of the EMTALA regulations is helpful, but I believe further clarification is necessary. In the long term acute care hospital environment, many facilities and organizations do not provide on-site, 24-hour physician coverage. Is it currently expected by CMS for all LTACHs (including hospitals-within-hospitals, satellites, and free standings) to have 24-hour physician on-site services? If this is CMS' interpretation, then it should be clearly translated into Medicare's Conditions of Participation. Clarification of this specific issue would be most helpful.

As always, if there is any additional information I can provide, please don't hesitate to call upon me. I can be reached at 630-286-4120.

Sincerely,

James R. Prister, FACHE
President/CEO
JRP/dmg

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JUN - 5 2007

May 23, 2007

Dept. Of Health and Human Services
Attn: Center for CMS-1533-P
P. O. Box 8011
Baltimore, Md., 21244 - 1850

To Whom It May Concern:

I am writing in response to an article I read that Medicare might no longer pay for mistakes made by hospitals. I strongly disagree with two of the items on the list of thirteen.

The first one I disagree with is about bed sores. As a retired R.N. I know the difficulty associated with bed sores. None of us want that to happen; however the physical condition of the patient prior to hospitalization contributes a great deal to a bed sore forming. If a patient is in poor condition and is no longer taking adequate nutrition orally and is being fed by IV or Hyperal , it is difficult to prevent sores from forming even using the latest in mattresses, frequent turning, and relieving pressure points.

The second one is C-difficile-associated disease. From experience with my husband, he acquired C-difficile at home after being administered a new oral antibiotic for an upper respiratory infection. I can see the same thing happening in the hospital setting if the patient cannot tolerate the antibiotic and that would be no fault of the hospital staff.

I believe these two conditions should be omitted from the list and possibly be evaluated on an individual basis.

Thank you.

Barbara Jones

Barbara Jones
8326 Alan Drive
Camby, In. 46113

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JUN - 6 2007

June 5, 2007

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

To Whom It May Concern:

The purpose of this letter is to register my opposition to the IPPS updates that the Centers for Medicare and Medicaid services has proposed for hospitals. While I commend the attempt to better classify the various diseases and conditions under the current DRG system, I have some concerns about portions of your plan.

In short, the plan to move from DRG's to MS-DRG's will result in a projected reduction in reimbursement to Community Memorials Healthcenter of approximately $168,000. For a rural institution like ours, that is a significant decrease. The cost of treating Medicare patients doesn't go down each year. Quite the contrary! Pressures created by increasing costs for labor and medical supplies are placing a great strain on the financial health of institutions. I must admit that I don't see your logic in this calculation.

Furthermore, I cannot understand your plan to implement a "behavioral adjustment" to Medicare reimbursement because you think hospitals will better utilize the coding systems that you have created. If, in fact, the new system is designed to better recognize the resources needed to treat the various DRG conditions, then the argument can be made that CMS has been underpaying our institutions for over 20 years if you feel the cost of healthcare is going to rise by over $24 billion over the next 5 years after your new plan is in place. As planned, this "behavioral adjustment" is estimated to result in another $369,000 reduction in reimbursement to our institution! It appears to me that this is just a budget-cutting tactic to which some vague nomenclature has been attached as a guise for its true purpose. Over 55% of the patients that Community Memorial Healthcenter treats are Medicare patients. Proper and adequate payment for our services is essential for our long-term survival.

Also, I am concerned that there are proposed cuts to capital payments through the program. Maintaining state-of-the-art facilities is very difficult for rural providers. Any reduction in payment for capital expenditures and facility improvements will place greater hardships on those of us with a heavy Medicare patient population.

I request that you withdraw your plan and or modify it to more adequately reimburse healthcare providers for the services they render. Your consideration of my request is appreciated.

Sincerely,

W. Scott Burnette, FACHE
President/CEO

WSB/crp

Cc: Congressman Virgil H. Goode, Jr.
Congressman J. Randy Forbes
Senator John W. Warner
Senator Jim Webb

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JUN - 6 2007

Arizona Hospital and Healthcare Association

June 5, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20510

Dear Ms. Norwalk:

On behalf of the Arizona Hospital and Healthcare Association (AzHHA), thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) fiscal year (FY) 2008 proposed rule for the hospital inpatient prospective payment system (PPS). AzHHA is very concerned about the proposed rule and the adverse effect it will have on our members. We are particularly concerned about the 2.4 percent "behavioral offset" and cuts related to capital payments, under which Arizona hospitals could lose a combined total of $378.3 million over the next five years. Accordingly, we request that CMS reconsider the proposed rule and revise it to address these concerns.

Background

Arizona is the nation's fastest growing state, with total population growth expected to increase 64.8 percent from 2000-20, according to the U.S. Census Bureau. This population explosion has placed considerable demand on healthcare services, as is demonstrated by the18 percent increase in hospital admissions from 2001 to 2005. To meet this demand, Arizona's hospitals plan to add 2,900 inpatient beds over the next five years. This additional capacity is imperative, as Arizona ranks 47th in the nation in the number of hospital beds per capita. Having said this, Arizona's hospitals cannot be expected to support this additional capacity without adequate payor reimbursement. In Arizona, Medicare is the single largest payor of inpatient services, accounting for 30 percent of all patient days in 2006. As such, it is vital that Medicare pay its fair share.

"Behavioral Offset"

The FY 2008 inpatient PPS rule proposes implementation of a new severity-adjusted DRG system by replacing the existing 538 DRGs with 745 new DRGs that reflect different levels of complications and co-morbidities. It includes a 2.4 percent cut to hospital operating and capital payments in each of FY 2008 and FY 2009 in anticipation of coding changes that CMS believes hospitals *might* implement under the new system. This "behavioral offset" would cut payments to Arizona hospitals by $35.6 million in FY 2008 and $332.8 million over five years.

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www.azhha.org

This proposal appears to be based upon a misinformed assumption that hospitals would change their coding practices in response to the severity-adjusted DRG system, when there is no relevant data to support this. Hospitals in Arizona have been coding under the DRG system for over 20 years, and there are numerous incentives currently built into the system to encourage hospitals to code as carefully and as accurately as possible. Moreover, according to the American Hospital Association, an analysis of claims from 2001 to 2005 shows that more than 70 percent of claims already include complications and co-morbidities (CCs), and a majority include more than nine CCs – the maximum accepted by Medicare's computer program for grouping cases into appropriate DRGs. The type of "behavioral offset" CMS proposes inappropriately assumes that hospitals have the ability to use even more CCs, but this ability is extremely low and the offset is unwarranted.

We respectfully request that CMS eliminate this arbitrary and unnecessary "behavioral offset" from the final regulation.

Capital-Related Payment Cuts

Medicare is required to pay for capital-related costs of inpatient services to help fund Medicare's share of expenses for new facilities, renovations, expensive clinical information systems and hi-tech equipment. Because the PPS for inpatient capital costs uses DRGs in the payment formula, the 2.4 percent "behavioral offset" already reduces payments for urban and rural hospitals. In addition, CMS is proposing to freeze capital payments to all urban hospitals for FY 2008 (a 0.8 percent cut) and to eliminate additional capital payments to large urban hospitals (an additional 3 percent cut). Under these two proposals, Arizona hospitals stand to lose $6 million for FY 2008 and $45.5 million over five years.

The proposed cuts in capital-related payments will disrupt the ability of urban hospitals to meet their existing long-term financing obligations and make it increasingly difficult to support facility expansions that are so vital to the healthcare infrastructure in a fast-growing state like Arizona. The cuts may also slow clinical innovation, as Arizona's hospitals struggle to fund the advanced technology, equipment and clinical information systems our patients have come to expect. Arizona's hospitals have committed to making capital improvements under the expectation that Medicare would pay its fair share of costs and remain a stable source of funding. Reducing capital payments at this time creates a significant financial burden and, quite frankly, is unfair.

We respectfully request that CMS eliminate the capital-related payment cuts from the final regulation.

Conclusion

In short, there is no rationale for the cuts that would be implemented as a result of the proposed FY 2008 inpatient PPS rule. They are unwarranted, and neither

mandated nor supported by Congress. Furthermore, they come at a time when the Medicare Payment Advisory Commission is estimating the lowest overall Medicare margins in 10 years – a negative 5.4 percent in 2007. In an under-funded system, with increasing demand, CMS should take this opportunity to shore up Medicare for the millions of patients who rely on it – rather than weaken it.

We appreciate the opportunity to comment on the proposed rule. If you have any questions or would like further information regarding our comments, please call me.

Sincerely,

John R. Rivers, FACHE
President and Chief Executive Officer

/gmh

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Ball Memorial Hospital, Inc.

JUN - 5 2007

June 4, 2007

VIA FEDERAL EXPRESS
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: **Hospital Reclassifications and Redesignations**

Dear Sir or Madam:

This letter responds to your request for comments under section III.I (Revisions to the Proposed Wage Index Based on Hospital Redesignations).

Ball Memorial Hospital (provider number 15-0089) is a 402 bed community hospital serving Muncie and the surrounding areas of East Central Indiana. BMH is the only hospital in Delaware County, and therefore the only hospital in the Muncie, IN MSA (34620). Because Ball is alone in the Muncie MSA, it cannot qualify for wage index reclassification.

A. Ball Cannot Qualify for Reclassification

Ball satisfies two of the three tests required for wage index reclassification. Ball is located 10.2 miles from the Madison County line, which presently is part of the Anderson, IN MSA. As such, Ball is proximate to the Anderson County MSA. Ball also satisfies the 84 percent test to the Anderson, IN MSA. Ball's three-year average hourly wage for fiscal years 2006 through 2008 ($24.8594) is nearly 96 percent of the AHW of hospitals in the Anderson, IN MSA ($26.0238).

However, Ball cannot satisfy the 108 percent test, because the test mathematically cannot work when there is only one hospital in the MSA. CMS has provided no mechanism for a hospital that is alone in its MSA to satisfy this wage comparison test, and to therefore qualify for reclassification. Moreover, Ball cannot qualify for reclassification as a hospital group, because the Muncie MSA is not part of the Indianapolis Combined Statistical Area ("CSA").

B. CMS Should Revise the Reclassification Regulations to Allow Hospitals in Single-Hospital MSAs to Qualify for Reclassification

For the following reasons, CMS should revise the reclassification regulations in a manner that would allow Ball and other hospitals that are in single hospital MSAs to qualify for wage index reclassification.

The purpose of the reclassification process is not being fulfilled for these hospitals because of the way CMS has set up the 108 percent test. Envision two hospitals, identical in terms of size and services offered, and located across the street from one another. However, running down the street that separates the two hospitals is a county line and MSA boundary. As such, the two hospitals are located in distinct MSAs. Like gas stations located on opposite street corners that match gas prices, these hospitals could have exactly the same AHW, because they compete with one another for hospital employees. It is undeniable that these hospitals would be in the same labor market. Yet, they could be assigned very different wage indexes because they are assigned to distinct MSAs.

Congress established the reclassification process to address exactly this type of scenario. However, if one of the hospitals is the only hospital in that MSA, it could not qualify for reclassification to the neighboring MSA. In this instance, the reclassification process would not be functioning as it should for this hospital. This scenario is essentially the situation faced by Ball.

The notion that hospitals that are alone in their MSA should not need to reclassify, because they determine their own wage index, denies the purpose of reclassification. Conceding for argument sake that a hospital in a single-hospital area is adequately compensated because it determines its own wage index, these hospitals still should be eligible for geographic reclassification. Whether or not a hospital unilaterally determines its wage index says nothing about whether that hospital competes with hospitals on the other side of an MSA boundary, whether the applicant is in the same labor market as those other hospitals, or whether the wage index assigned to that hospital is appropriate.

Additionally, it is disputable whether determining one's own wage index necessarily means the hospital is compensated adequately. Just because payments to a hospital may be determined using a hospital-specific wage index does not mean that the hospital is adequately compensated for its labor costs, or even that it is appropriately positioned to fairly compete with other hospitals in its labor market. Because of the way CMS uses MSAs to define labor markets, huge wage index disparities and reimbursement differentials can exist among hospitals in the same labor market, if they are assigned to different MSAs.

The situation confronting Ball illustrates this point. The two hospitals closest to Ball are St. Johns Health System (15-0088) and Community Hospital (15-0113). Ball undeniably competes with both for hospital labor. Ball, St. Johns and Community all have very comparable average hourly wages: $24.8594, $26.6296 and $25.2152, respectively. Yet, St. Johns and Community receive a significantly higher wage index. Both St. Johns and Community are in the Anderson, IN, MSA, and both qualify for wage index reclassification to the Indianapolis, IN MSA. Both Saint Johns and Community have a proposed wage index of 0.9723 for FY 2008, while the wage index applicable to Ball will be 0.8599. The fact that Ball sets its own wage index is of little consolation in this instance, and is completely irrelevant to the question of whether Ball is able to compete fairly with the hospitals in its labor market. If Ball, St. Johns and Community compete in the same labor market for hospital employees, Ball should have the opportunity to reclassify, so that it can compete on a level playing field with those other providers.

Furthermore, the notion that hospitals that are in single-hospital areas can rectify their situation by increasing labor compensation, and thereby increasing the prevailing wage index ignores several fundamental characteristics of the functionality of the wage index in Medicare reimbursement. First, the wage index does not provide a dollar-for-dollar return to hospitals for their labor cost investments. While hospitals in single-hospital areas can unilaterally determine their wage index, they cannot affect the portion of the payment that is adjusted by the wage index. CMS does not use a hospital-specific labor share adjustment to determine the portion of the standardized amount modified by the wage index. Rather, CMS uses a national labor-share adjustment. To the extent that labor cost as a percentage of total cost is less than the applicable labor share adjustment, these hospitals could not hope to recoup their full investment, even though their wage index would increase.

Moreover, because the wage index is determined using labor cost data from three years prior, it would take Ball at least three years before it began to realize any return on its investment in hospital labor. Ball operates on a thin margin, and cannot afford to carry inflated labor costs for three years in the hope that it will get some return on that investment in the future.

Finally, a closer look at the facts and circumstances shows a pattern that demonstrates that Ball is at a disadvantage. For all practical purposes (other than Wage Index Classification), Ball is part of "metropolitan Indianapolis." Frequently, individuals who live in the Muncie MSA choose to not commute – but in fact move – to the Indianapolis MSA – sometimes after first being trained and even working in the Muncie MSA for a period of time. Ball in fact has to compete with hospitals in the Anderson and Indianapolis MSAs – despite the disparities in reimbursement.

CMS has previously said, "We believe that geographic reclassifications should be limited to those hospitals which are disadvantaged by their current geographic classification because they compete with the hospitals that are located in the geographic area to which they seek to be reclassified."[1] Ball is disadvantaged by its current geographic classification because it competes with hospitals that are located in nearby MSAs. Yet, Ball is barred from even applying for reclassification. Ball should be able to avail itself of the reclassification process.

C. Proposed Solutions

Following are two ways CMS could revise the reclassification rules to resolve the problems confronted by Ball and other similarly situated hospitals.

1. Exempt hospitals in single-hospital areas from the 108 percent test.

CMS could resolve the problem confronted by hospitals in single-hospital areas by exempting them from the 108 percent test. The purpose underlying the 108 percent test is for the applicant to demonstrate that its wage costs are disproportionately high compared to its neighbors. Where the applicant has no neighbors in its MSA, a meaningful average area wage cannot be determined, and the 108 percent test is not an appropriate comparison. CMS exempted hospital groups from a local wage comparability test for this very reason. CMS recognized there would be no way for these hospitals to satisfy such a test. CMS can adequately evaluate whether the applicant is disadvantaged by its geographic classification by requiring it to demonstrate

[1] 56 *Fed. Reg.* 25,458, 25,469 (June 4, 1991).

wage comparability with, and proximity to a neighboring area, much like it does for hospital groups.

2. Combine single-hospital areas with neighboring MSAs

CMS could partially resolve the problem for hospitals in single-hospital areas by combining the MSA in which the hospital is located with another MSA. This proposal would address CMS's concerns with single-hospital labor markets. According to CMS, single-hospital labor markets "create instability in the wage index from year to year for a large number of hospitals."[2] CMS further noted that single-hospital labor markets "reduce the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals."[3]

CMS cited these reasons as the basis for rejecting Micropolitan Areas for purposes of defining labor markets. CMS could further address concerns with single-hospital labor markets by combining these areas with neighboring MSAs to form larger labor markets with more hospitals for purposes of determining the wage index. CMS could implement this change in a variety of ways. For example, CMS could merge a single-hospital MSA only when it is adjacent to another MSA. Where the single hospital MSA is adjacent to two or more other MSAs, CMS could base the merger determination on commuting patterns, and merge the single-hospital MSA with the MSA with which it shares the highest commuting pattern interchange. In many ways, this would be similar to Lugar reclassifications made pursuant to § 1886(d)(8)(B). There are 49 MSAs with only one hospital. Not all of these MSAs are adjacent to another MSA. As such, this proposed change would affect fewer than 49 hospitals.

* * * * *

Ball is proposing two solutions that would enable the hospital to qualify for reclassification, and to receive a somewhat higher wage index. However, it is important to note that neither solution would be a complete remedy. As previously noted, Ball competes for labor most directly with the two hospitals in Madison County; Ball also competes for labor with hospitals in surrounding rural areas, including those in Grant, Blackford, Jay, Randolph and Henry counties. There are two general acute care hospitals (and several critical access hospitals) located in these surrounding counties: Henry County Memorial Hospital and Marion General Hospital. Both Henry County and Marion General qualify for wage index reclassification into the Indianapolis MSA. Consequently, the four hospitals in closest proximity to Ball – Saint Johns, Community, Henry County and Marion General – all will have a wage index of approximately 0.9732 during FY 2008.

If CMS makes one of the changes recommended above, and Ball is able to qualify for reclassification into the Anderson MSA, it still will be severely disadvantaged vis-à-vis its competitors. Of the 33 hospitals in closest proximity to the hospital, Ball is paid at the second lowest rate. Only Fayette Memorial Hospital is paid less, and it is located in Rural Indiana. Ball's wage index is more than 11 points lower than the hospitals physically located in Indianapolis and the hospitals that reclassify into Indianapolis. As such, enabling Ball to qualify

[2] 69 *Fed. Reg.* at 28,251.
[3] *Id.*

for reclassification would hardly level the playing field, as it should be. Nonetheless, such a change would be a step in the right direction, and a significant help to the hospital.

We appreciate your consideration of our situation and these comments. Please call me at 765-747-3251, if you have any questions concerning these comments.

Sincerely,

Brent L. Batman, President

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JUN - 5 2007

COVENANT
HealthCare

May 31, 2007

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

RE: Comments to the Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates [CMS-1533-P]

Dear Sir or Madam:

Covenant HealthCare ("Covenant") is pleased to submit these comments on the *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates* (the "Proposed Rule").[1] Like the Centers for Medicare and Medicaid Services ("CMS"), Covenant is committed to ensuring access to high quality health care for Medicare beneficiaries. Covenant also shares the agency's priority of efficiency in service provision. Accordingly, Covenant appreciates this opportunity to respond to CMS' requests for comments on the Proposed Rule.

As one of the largest, most comprehensive health care facilities north of metro Detroit, Covenant provides a complete range of medical services to 15 counties in east central Michigan. With 643 beds and more than 20 inpatient and outpatient facilities, Covenant offers a broad spectrum of programs and services, ranging from obstetrics, neonatal and pediatric care, to acute care including cardiology, oncology, surgery, and many other services on the leading edge of medicine. Covenant also provides the highest amount of indigent care in the region.

I. Introduction

Our comments relate to issues raised in the "Hospital Reclassifications and Redesignations" section of the Proposed Rule. In the subsection entitled "Other Issues," CMS described a situation in which one hospital's reclassification had adversely affected

[1] 72 *Fed. Reg.* 24680 (May 3, 2007).

another hospital's opportunity for reclassification.[2] In fact, CMS acknowledged that "[t]here are no options under our current regulations that would allow this hospital to reclassify."[3] In order to gather information on the situation and to consider the policy issues at stake, CMS solicited comments on "this or similar situations."[4] In addition, the agency indicated that it would welcome public comments that directly addressed the situation described as well as comments that raised issues that the agency had not considered in relation to this situation.

In response to this request, we would first like to highlight the inequity in the situation described. *Without modification of the regulations, CMS will fail to afford any regulatory relief to a hospital that has been economically disadvantaged, through no fault of its own, by the actions of another hospital in the region.* Although this particular instance of inequity arose in the group reclassification context, inequity exists – sometimes to a greater degree – in other contexts. The rest of our comments focus on a unique scenario in which the issue of inequity arises.

II. Inequity Among Hospitals in Saginaw, Michigan

Like the scenario outlined in the Proposed Rule, our inequitable situation features a hospital – Covenant – that has been unfairly disadvantaged by an unjustified reclassification of another area hospital – St. Mary's of Michigan ("St. Mary's"). Covenant and St. Mary's are located within 1.4 miles of each other and have been located in the same statistical area (Saginaw) for area wage index ("AWI") calculations since FY 2000. Covenant HealthCare comprises 57.2 percent of the area's wages and St. Mary's comprises 42 percent. The remaining 0.8 percent of Saginaw's wages belongs to HealthSource Saginaw, a hospital that provides mostly psychiatric and rehabilitation services.

According to data published annually in the Federal Register, the average hourly wages of Covenant and St. Mary's have been consistent for several years. From 2000 to 2003, for example, the difference in their wage rates ranged from $0.062 to $1.43.[5] However, from FY 2003 to FY 2004, St. Mary's average hourly wage jumped from $22.68 to $29.20 – a spread of $6.52, or four-and-a-half times the spread in previous years.[6] In August 2004, Covenant found these anomalous data and brought them to the attention of St. Mary's.

According to St. Mary's, the anomaly was attributed to the improper inclusion in its filed cost reports of certain wage-related costs that should not have been included, combined with the subsequent failure to remove these costs upon audit. After further conversations between the two hospitals, St. Mary's told Covenant that St. Mary's had retained an outside auditor to review its wage information. Based on the results of this

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[2] *Id.* at 24798.
[3] *Id.*
[4] *Id.*
[5] 66 *Fed. Reg.* 39828 (August 1, 2001), 39954 *et seq.* (Table 2); 69 *Fed. Reg.* 48916 (August 11, 2004), 49295 *et seq.* (Table 2).
[6] 69 *Fed. Reg.* 48916, 49295 *et seq.* (Table 2).

review, St. Mary's expressed to Covenant that it had incorrectly reported its wage index information and that it intended to contact CMS.

The data were not, however, corrected. Moreover, based on these incorrect data, St. Mary's received approval from the Medicare Geographic Classification Review Board ("MGCRB") in early 2005 for reclassification into the Flint core based statistical area ("CBSA") and for an individual urban hospital redesignation in FYs 2006, 2007, and 2008. Covenant, on the other hand, was not successful in its reclassification application in 2005.

Overnight, the change in area wage indices created a substantial disparity between the two hospitals. The reclassification created a spread in the area wage index between the hospitals of 16.35 percent in FY 2006, 16.67 percent in FY 2007, and 20.25 percent for Proposed FY 2008. As the purpose of the wage index is to measure differences in hospital wage rates among labor markets, CMS surely did not intend such a sizeable differential between hospitals that compete literally for the same labor pool.

The improper reclassification of St. Mary's has had a variety of significant effects on the Saginaw hospitals. The payment for procedures now gives St. Mary's a considerable competitive advantage over Covenant. For example, payment for a cardiac defibrillator implant (DRG 535) is now $37,343 at Covenant and $41,101 at St. Mary's. Similarly, payment for heart failure (DRG 127) is $5,312 at Covenant and $5,847 at St. Mary's. The overall DRG payment differential between the two hospitals is more than 10 percent per discharge.[7]

The overall economic impact of the reclassification is demonstrated in the following tables. Using the Occupation Mix Adjusted area wage indices for both providers, St. Mary's will be advantaged by $27 million over the three-year period.

Table 1: Economic Impact of the Decreases in the AWI on Covenant[8]

Fiscal Year	Total Annual Impact	Cumulative Impact
FY 2006	($3,717,509)	($3,717,509)
FY 2007*	$362,559	($3,354.950)
FY 2008 proposed	($929,377)	($4,284,327)

*Note: The slight increase in payments in FY 2007 is related to the benefit from the Occupational Mix Adjustment.

[7] 70 *Fed. Reg.* 47278 (August 12, 2005), 47580 *et seq.* (Tables 4A and 4C); 71 *Fed. Reg.* 47870 (August 18, 2006) (Tables 4A and 4C).

[8] *Economic impact analysis for both hospitals was prepared by RSM McGlardey, Inc., Davenport, Iowa and are calculated based on Occupational Mix Adjusted AWI's for both providers.* 70 *Fed. Reg.* 47278 (August 12, 2005), 47580 *et seq.* (Tables 4A and 4C); 71 *Fed. Reg.* 47870 (August 18, 2006) (Tables 4A and 4C).

Table 2: Economic Impact of the Reclassification of the AWI on St. Mary's[9]

Fiscal Year	Total Annual Impact	Cumulative Impact
FY 2006	$6,636,379	$6,636,379
FY 2007	$6,988,042	$13,624,421
FY 2008 proposed	$8,949,865	$22,574,286

As shown in Tables 1 and 2, over the three-year period during which St. Mary's has been improperly reclassified, Covenant has experienced real declines in payment from Medicare related to AWI, while St. Mary's has benefited greatly from being classified into the Flint CBSA.

III. Need for CMS to Resolve the Inequitable Situation

As evidenced by the comparative payment data, the reclassification of St. Mary's has led to significant economic disparities between St. Mary's and Covenant. But for St. Mary's data reporting error, the two Saginaw hospitals would almost certainly still be reporting similar average hourly wages and, thus, receiving comparable reimbursements from Medicare. Because the reclassification and attendant economic disadvantage to Covenant occurred on account of St. Mary's mistake and through no fault of Covenant, there is a glaring inequity in the hospitals' situation.

However, under the existing regulatory framework, Covenant does not have the opportunity to correct the error. The wage index data correction process allows a hospital to request a correction of an error in its own data but does not afford redress for a data error that it did not cause but that harms the hospital.[10] We believe that CMS should take responsibility for the ways its regulations and review process have failed Covenant. To ignore the inequity experienced by Covenant is to shirk the agency's duties to base Medicare payments on accurate information and to treat providers in the same market fairly.

Furthermore, the unfairness in Covenant's situation is compounded by the structure of the reclassification system. Under this system, a hospital that has once been reclassified can essentially guarantee its continued success in reclassification applications based on the way it spends the additional money received from the higher wage index payments, i.e., by using its increased revenue to raise employees' wages. Because reclassification decisions are based on the difference between the applicant hospital's wages and the wages paid by other hospitals in the default CBSA, the increased spread between the wages paid by the applicant hospital and by the hospitals in its former CBSA helps the applicant continue to meet this criterion for reclassification.

As a result, aberrant wage data and consequential payment differentials can be indefinitely entrenched into the health care labor market. In Covenant's situation, these differentials are the direct result of an improper reclassification produced by a data error – an error that occurred through no fault of Covenant. Moreover, the current regulatory system will allow the improper reclassification and attendant payment differentials to be

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[9] *Id.*

[10] 72 *Fed. Reg.* 24680, 24801.

perpetuated year after year. The inequity of such a situation can be neither denied nor permitted to stand. We strongly urge the agency to take swift action to provide relief to Covenant and to modify its regulations to break the cycle of entrenchment.

The rationale for such action is, at core, the need to remedy an inequity, even mid-year through a three-year reclassification cycle. CMS indicated its willingness to consider this very type of mid-year action in the FY 2008 IPPS proposed rule by seeking comments on a similar situation.[11] In the scenario addressed in this year's Proposed Rule, the afflicted hospital is seeking either reclassification or application of a blended wage index for the remaining year of the three-year reclassification cycle. Covenant, likewise, is seeking mid-cycle relief from an inequitable wage index. Thus, as CMS considers what form of relief to afford the hospital discussed in the Proposed Rule, the agency should also address Covenant's similarly inequitable situation and afford a mid-year remedy.

Another cause that has motivated the agency in the past – avoidance of competitive disadvantage – also demands that the agency address Covenant's situation. In the FY 2007 IPPS proposed rule, CMS sought to remedy "competitive disadvantage" in more than one situation. One of these situations involved the agency's decisions to allow newly constructed hospitals to join group reclassifications and to require all hospitals in an urban county to apply for redesignation as a group. CMS explained its decisions as intended to avoid a result that "would be . . . unfair to new hospitals because it would put them at a competitive disadvantage with other hospitals in the county."[12] According to CMS, its chosen policy would protect a new hospital from "hav[ing] to accept a lower wage index than all other hospitals in the county with which it competes for labor for up to 3 years."[13] CMS later confirmed this policy and rationale in the FY 2007 IPPS final rule.[14]

Covenant finds itself in the same situation as the new hospitals with which CMS was concerned when addressing this group reclassification policy. Because Covenant competes with St. Mary's for nursing and other skilled labor, Covenant suffers competitive disadvantage as a result of St. Mary's improper reclassification, which allows St. Mary's to pay higher wages relative to Covenant. In addition, because St. Mary's is almost certain to be approved for another 3-year reclassification (for the reasons discussed above regarding the structure of the reclassification system), Covenant is at significant risk for another three years of competitive disadvantage. We request that CMS act to avoid this unfair competitive disadvantage as it has in the past.

IV. Proposed Solution to the Inequity Experienced by Covenant

In light of the inequity experienced by Covenant as well as the potential for such inequity to become ingrained in Saginaw's health care market, CMS should, in fairness to Covenant, address the situation. We believe that an appropriate solution would entail the following: (1) implementation of a blended wage index rate for both Covenant and St.

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[11] *Id.* at 24798.

[12] *Id.* at 24110.

[13] *Id.*

[14] 71 *Fed. Reg.* 47870 (August 18, 2006), 48069.

Mary's for the last year of this 3-year cycle; (2) regulatory changes that would allow for midyear corrections to wage index data in a situation like Covenant's; (3) adoption of a review process to mitigate the negative impacts of improper reclassifications.

The first component of our proposed solution is specific to Covenant. As the comparative payment data provided in Section II of these comments show, Covenant has suffered economic disadvantage in comparison to St. Mary's ever since the improper reclassification occurred. Because St. Mary's current 3-year reclassification cycle runs through FY 2008, Covenant will continue to experience this inequity through September 30, 2008. To spare Covenant from further inequitable treatment, CMS should make a wage index correction for FY 2008. In keeping with its prospective-only change policy, CMS could make this correction in one of three ways.

First, CMS could reclassify Covenant to the Flint CBSA and thereby raise Covenant's wage index. Second, CMS could reduce St. Mary's wage index to the same non-reclassified rate as Covenant. Third, CMS could create a blended wage index for both hospitals, thus increasing Covenant's rate and decreasing St. Mary's rate to some extent. While we would support any of these three options, applying a blended wage index to both Covenant and St. Mary's would treat both hospitals fairly in the period before St. Mary's improper reclassification expires.

Because this implementation of a one-year blended wage index would require CMS to make a midyear correction to wage index data, CMS should modify its regulations to specifically account for this situation. Currently, under § 412.64(k)(1), CMS makes such midyear corrections "only if a hospital can show that: (1) The fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the year."[15] This regulation, as written, would not afford any relief to a hospital that is harmed by the effects of errors in another hospital's wage data.

Thus, the second component of our proposed solution would be for CMS to explicitly modify the set of situations in which it will make midyear corrections to an area's wage index. The regulation found at § 412.64(k)(1) should be revised to allow CMS to make a midyear correction if the requesting hospital can demonstrate significant direct market competition with another hospital in the same MSA and can show a mistake in the submitted data of that hospital resulted in an improper reclassification which generated an AWI differential greater than 0.1 between the hospitals. Modifying the regulation to account for this unique situation would enable CMS to respond appropriately to truly inequitable situations without simultaneously opening the door to hospitals seeking to reduce other hospitals' wage indices without having first suffered harm because of another hospital's unjustified reclassification.

Finally, the third component of our proposed solution would be a procedural change intended to prevent the perpetuation of the harmful effects of improper reclassifications. To this end, we urge CMS to create a policy going forward in which it systematically monitors the impact of aberrant data that create a percentage differential in

[15] 72 *Fed. Reg.* 24680, 24801.

the health care market through the three-year cycle of reclassification. Should the error perpetuate an inequitable situation or further prevent a faultless hospital from reclassification, CMS should review this unique scenario with special consideration and redress. Such a review process would ensure that the effects of improper reclassifications are minimized and are revisited if necessary to ensure equity to hospitals harmed by unjustified reclassifications.

We urge CMS to make these regulatory and subregulatory changes in order to provide fair treatment to hospitals that are harmed through no fault of their own by other hospitals' erroneous data submissions. Not to address this situation is to remain idle in the face of clear inequity. CMS can and should take action to remedy the injustice.

* * *

Thank you for the opportunity to submit these comments. Covenant looks forward to working with CMS while these provisions of the Proposed Rule are being finalized. Please do not hesitate to contact us if you have questions or concerns.

Sincerely,

Spencer T. Maidlow
President/CEO

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Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

JUN - 6 2007

BARD

June 1, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. 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: Comments on *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates*

Dear Ms. Norwalk:

On behalf of C. R. Bard, Inc., I am pleased to offer the following comments on the May 3, 2007 proposed rule for the Medicare hospital inpatient prospective payment system (*Federal Register*, Vol. 72, No. 85). This rule proposes a number of significant refinements to the Medicare diagnosis-related group (DRG) payment system, including a payment adjustment for cases where a hospital-acquired condition (not present on admission to the hospital) would result in an increased payment.

Last year, in response to the FY 2007 proposed rule, we commented on this particular DRG refinement, which was mandated by section 5001(c) of the *Deficit Reduction Act of 2005*. This provision encourages hospitals to avoid preventable complications by not allowing them to benefit from higher payment associated with infections acquired during a hospital stay. This payment adjustment is scheduled to become effective for at least two conditions in FY 2008. Hospitals will not receive additional payment for cases in which the selected conditions were not present on admission.

In our comments on the FY 2007 proposed rule, we stated our support for this approach, and we suggested its application to nosocomial infections, particularly urinary tract infections (UTIs). We re-affirm in these comments our support for inclusion of UTIs among the hospital-acquired conditions for which there will be a payment adjustment in FY 2008, and we suggest that ventilator-associated pneumonia (VAP) be considered when additional conditions are added to this initial list.

For more than 95 years, C. R. Bard, Inc. has committed its resources to creating innovative products and services that meet the needs of healthcare providers and patients. Today, Bard is a leading multinational developer, manufacturer, and marketer of innovative, life-enhancing

medical technologies in the fields of vascular, urology, oncology and surgical specialty products. Bard is committed to advancing the technology of diagnosis and intervention to help reduce healthcare costs and improve patient outcomes. Founded in 1907, C. R. Bard has facilities in eight U. S. locations and in 20 other countries around the world, and employs more than 8,100 people.

DRGs: Hospital-Acquired Conditions

Proposed Selection of Catheter-Associated Urinary Tract Infections (UTIs)

Bard believes that the emphasis Congress has placed on preventing hospital-acquired infections is long overdue. The facts speak for themselves: According to the Centers for Disease Control and Infection, these conditions account for an estimated 2 million infections, 90,000 deaths, and $4.5 billion in excess health care costs annually in this country. And much of the financial burden resulting from hospital-acquired infections is borne by public programs like Medicare and Medicaid.

We at Bard believe that the incentives provided by section 5001(c) will spur hospitals to take long-overdue action—in the training they provide care-givers, and in the technologies they use to reduce the rate of hospital-acquired urinary tract infections (UTIs). We agree with CMS that Catheter-Associated UTI meets each of the specified criteria for selection as one of the initial hospital-acquired conditions, and we are pleased that CMS has ranked this condition at the top of its list of conditions being considered for selection under section 5001(c).

There are, however, difficult issues associated with the implementation of this condition under section 5001(c), many of which are addressed in the Preamble to the proposed FY 2008 rules (on pages 24719-24720). For example, we noted in our 2007 comments the secondary diagnosis codes for UTI (e.g., ICD-9-CM codes 599.0, *urinary tract infection*, and 996.64, *infection and inflammatory reaction due to indwelling urinary catheter*), and we suggested that these codes not be used to identify a complication or a co-morbidity (CC) not present on admission that would result in the assignment of cases to higher-cost DRGs. We are pleased that you take this approach in the Preamble discussion (on page 24719) to the proposed FY 2008 rules.

In addition, the Preamble to the proposed FY 2008 rules identifies a series of additional ICD-9-CM codes that would not be used to identify a CC if they are developed after admission, and it states that CMS did not include codes, such as code 590.00, *chronic pyelonephritis, without lesion or renal medullary necrosis*, because these codes could be considered chronic urinary conditions not acquired during the hospital stay. We generally support this coding approach, but think it deserves close monitoring to ensure that clinician opinion does not cloud coding.

Clinically, any UTI that occurs 48 hours after a patient is admitted to the hospital should be considered to be healthcare-associated, and coded appropriately. Although some clinicians may suggest that the signs of infection can be somewhat ambiguous (and not recognized on admission), we do not believe this to be the case with UTIs. Patients entering the hospital typically receive a thorough history and physical (H&P) upon admission. Their vital signs are

monitored and a series of screening questions are asked. The symptoms of UTI are typically obvious (fever, frequency, urgency, dysuria, foul urine) and should be easily identified during the H&P process. If a UTI is suspected, a urine culture and/or urinalysis will be ordered. Based on the physical and laboratory findings, the physician will determine if a UTI is present on admission. All of this information should be clearly documented in the patient's medical record, allowing for easy identification of UTI that is present on admission.

In addition, it should be noted that it is possible that a patient may be admitted with a Foley catheter (e.g., from a nursing home). In these instances, it may be more difficult to identify the symptoms of infection. However, in most hospitals, it is standard practice to change the Foley catheter in a patient admitted with one. When the catheter is changed, it is customary to perform a urine culture and/or a urinalysis. These baseline tests, which should be clearly documented in the patient's medical record, will allow the physician to identify if a UTI is present on admission.

Non-Inclusion of Ventilator Associated Pneumonia (VAP)

While UTIs represent the most common type of hospital-acquired condition, ventilator associated pneumonia (VAP) appears to represent the most costly (and deadly). The data cited in the Preamble (on page 24722) to the proposed FY 2008 rules is sobering: CDC reports that there are over 250,000 VAPs per year; CMS analysis finds that there were over 90,000 Medicare patients in FY 2006 with pneumonia as a secondary diagnosis—with average charges in excess of $88,000 per year; and a recent article in *Critical Care Medicine* found that patients with VAP have longer intensive care lengths of stay than those who do not.

Mechanical ventilation is used for both short-term (a few hours) and long-term (up to several weeks) management of patients. While there are several methods for ventilation, most ventilated patients will have an endotracheal tube (a tube passed through the mouth into the airway). Since it bypasses many of the body's natural defense mechanisms, the endotracheal tube allows bacteria to pass along the tube surface into the lungs.

Pneumonia is the leading cause of death from healthcare-associated infection, with a mortality rate as high as 50%. Available data suggests that pneumonia occurs at a rate of between 5 and 10 patients per 1,000 hospital admissions, with the incidence increasing by as much as 20-fold in mechanically ventilated patients. For critically-ill patients, pneumonia accounts for up to 25% of all infections and more than 50% of the antibiotics prescribed.

In theory, VAP will never be present on admission—unless the patient is transferred from another healthcare facility. Diagnosis is documented based on a combination of physical signs and symptoms, X-Ray results, and laboratory findings. Physicians will definitely document the presence of VAP, and we believe that identification of the condition for coding purposed should be straight forward.

We believe that VAP should be included among the hospital-acquired conditions selected under section 5001(c) as soon as practicable. While we recognize that currently there is no unique ICD-9-CM code that identifies VAP (which prevents it from meeting the statutory criteria for

being selected), our view is that this condition should be identified by a new ICD-9-CM code this year, and should be included among the section 5001(c) conditions when additional hospital-acquired conditions are added to the initial list that will be used for FY 2008.

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Thank you for considering Bard's comments and recommendations. If you have any questions, do not hesitate to contact me (770-784-6101) or David Parr, Vice President of Reimbursement (908-277-8170 or david.parr@crbard.com) at your convenience.

Sincerely,

Sharon Alterio
President
Bard Medical Division

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JUN - 5 2007

AMERICAN ASSOCIATION FOR RESPIRATORY CARE
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June 1, 2007

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

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

To Whom It May Concern:

On behalf of the American Association for Respiratory Care (AARC), we are pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Changes to the Hospital Inpatient Prospective Payment Systems - Fiscal Year 2008.

The AARC is the national professional association representing over 43,000 respiratory therapists who, under medical direction, prevent, identify and treat high-risk patients with acute and chronic cardiopulmonary diseases and conditions.

Section II.F.6.(g) "Hospital-Acquired Conditions"
Ventilator Associated Pneumonia

Comment: The AARC's Clinical Practical Guideline (CPG) on Ventilator Associated Pneumonia may be of assistance to CMS in its effort to establish a unique code for this complicated diagnosis.

Respiratory therapists, by virtue of their education and competency are involved in all aspects of ventilator management, from the initial placement of the patient on the ventilator, to where clinically feasible, the weaning of

the patient off the ventilator. Respiratory therapists are extremely cognizant of the need to adopt procedures that will eliminate or diminish patients developing ventilator associated pneumonia.

We bring to the attention of CMS an evidence based peer-reviewed AARC Clinical Practice Guideline (CPG) on strategies that should be disseminated and available to hospitals for the prevention of ventilator associated pneumonia. The CPG can be found at:
http://www.rcjournal.com/cpgs/09.03.0869.html

The CPG acknowledges that more research needs to be conducted on this complex area. The CPG does clearly address procedures to be followed regarding ventilator circuit changes, passive humidifiers and the use of closed suction catheters as it pertains to reducing ventilator associated pneumonia.

The AARC recognizes the need for further study and analysis before CMS can accurately create an ICD-9-CM code that identifies ventilator-associated pneumonia. We support that effort and support the eventual inclusion of an ICD-9-CM code as a quality measure.

Section IV.A. "Hospital Quality Data"

Comment: The AARC encourages CMS to continue to add quality measures and the reporting of data to ensure the highest quality care for Medicare beneficiaries.

The AARC supports the initiative that provides hospitals the opportunity to submit quality data. The data collected not only provides valuable information to the Medicare program but also serves as a source of public information about hospital quality to the community at large. We continue to support the reportable measures under the pneumonia topic, in particular the provision of adult smoking cessation counseling services, a clinical intervention in which respiratory therapists are acknowledged experts.

Section IV.F.2. "Patient Safety Measures

Comment: To provide additional assurances for patient safety, CMS should encourage hospitals, regardless of their size, to have an

organized Respiratory Therapy Department and a designated Medical Emergency or Rapid Response Team.

The proposed regulation expresses concerns regarding patient safety measures. The proposed regulation notes adverse incidents occurring at certain hospitals where there are inadequate qualified physicians and/or qualified health personnel available to respond to emergencies such as patients in respiratory arrest. We support the efforts of CMS to recognize and address this growing patient safety concern.

The AARC applauds the release of the April 26th 2007 Guidance Document on Hospital Emergency Services Requirements applicable to nearly all US hospitals. Affected hospitals must be able to evaluate persons with emergencies, provide initial treatment, and refer or transfer these individuals when appropriate.

We believe that any organization that holds itself out as a hospital should have the capability to identify and respond to life-threatening situations.

Recommendation 1:
We recognize that not all accredited hospitals have formal organized respiratory therapy departments. This tends to be the case for hospitals with few beds. However, we believe CMS should encourage all hospitals, whatever the bed size, to have an organized respiratory therapy department staffed with credentialed respiratory therapists who are readily and immediately available to assist in patient emergencies.

Respiratory therapists, by virtue of their formal education and documented competency in all aspects of cardio-respiratory care, are key members of a hospital's staff.

Respiratory therapists have the clinical skills necessary to respond to emergent events such as patients in respiratory arrest. It is standard for respiratory therapists to be members of Rapid Response Teams, air emergency transport teams, and intensive and neonatal care units, and they are the experts in ventilator management.

Recommendation 2:
We recommend that CMS require all hospitals participating in Medicare to have a designated and organized Medical Emergency or Rapid Response

Team available at all times. All the health care professionals on this Team must be required to be certified in Advanced Cardiac Life Support (ACLS). Certification in ACLS provides necessary skill sets to respond to an array of clinical emergencies.

A Medical Emergency or Rapid Response Team is trained to stabilize patients before either transferring them to the appropriate department in the facility or to another hospital which can administer appropriate services. Using these types of Teams not only saves lives (the ultimate goal) but can reduce the number of hospital days, thus providing cost savings to the health care system.

A 2003 prospective before-and-after trial of a medical emergency team reported in the Medical Journal of Australia[1] concluded that the "incidence of in-hospital cardiac arrest and death following cardiac arrest, bed occupancy related to cardiac arrest, and overall in-hospital mortality decreased after introducing an intensive care-based medical emergency team. The patient outcomes are indicated below

Rapid Response Team (RRT) Results

Measure	Before RRT	After RRT	Relative Risk Reduction
No. cardiac arrests	63	22	65% (p=001)
Deaths from cardiac arrest	37	16	56% (p=.005)
No. days in ICU post arrest	163	33	80% (p=.001)
No. days in hospital post arrest	1,363	159	88% (p=.001)
Inpatient Deaths	302	222	25% (p=.004)

Another prospective controlled trial conducted by Bellomo, et al, in 2004[2] of the effect of a medical emergency team on postoperative morbidity and mortality rates concluded that the "introduction of an intensive care unit-based medical emergency team in a teaching hospital was associated with a reduced incidence of postoperative adverse outcomes, postoperative mortality rate, and mean duration of hospital stay.

[1] Table adapted from Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. *Medical Journal of Australia.* 2003;179(6):283-287.

[2] Bellomo, R, Goldsmith D., Uchino S, et al. Prospective controlled trial of effect of medical emergency team on postoperative morbidity and mortality rates. *Crit Care Med.* 2004;32(4):916-921.

Many hospitals have added designated Emergency Medical or Rapid Response Teams; thus, we believe a Medicare requirement for all hospitals to add such an important measure would not be overly burdensome to these facilities. Hospitals that have yet to implement this patient safety and ultimate cost saving staffing concept must do so.

Thank you for your time and consideration.

Sincerely,

Toni Rodriguez, EdD, RRT
President

MIDDLESEX
HOSPITAL

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JUN - 6 2007

June 5, 2007

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

Subject: Comment – IPPS Proposed Rule 1533-P – Out-Migration Adjustment

Dear Sir or Madam:

Middlesex Hospital (Provider 07-0020) has reviewed the FFY 2008 Proposed Rule published April 13, 2007. As stated in the proposed rule (display copy) pg.444, CMS is reconsidering its policy regarding the calculation of the out-migration adjustment from basing eligibility for the adjustment on pre-reclassified wage indexes to basing eligibility for the adjustment on post-reclassified wage indexes.

We respectfully request that CMS not implement this change to an established methodology which has been consistently applied for federal fiscal years 2005-2007. This change will negatively impact many smaller providers which receive the out-migration adjustment under the current pre-reclassified wage index measuring point. Should this change be implemented, Middlesex Hospital will suffer an estimated $105,000 decrease in Medicare reimbursement due to its loss of the out-migration adjustment. We believe that this proposed change, to an established reimbursement methodology, only servers to decrease reimbursement to those smaller hospitals that most need enhanced Medicare payments in order to survive.

We thank you for your consideration of these matters.

Sincerely.

Vincent G. Capece, Jr.

Sr. VP, Finance & Operations

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May 23, 2007

Dear Sir or Madam:

This correspondence is in response to your request for comments regarding CMS-1533-P, Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates. In agreement with previous commenters who have noted that the death, injury, and cost of hospital-acquired infections are too high to limit this provision to two conditions, I would propose that it include Legionnaires' Disease (LD). A recognized illness complicating hospital stays at high cost, both financially and in terms of serious morbidity and mortality, LD meets each of the three criteria set forth in Section 5001(c) of Pub. L. 109-171.

Burden (High Cost/High Volume):

According to CDC, an estimated 8,000-18,000 cases of LD occur each year in the United States. This is particularly striking as the agency also notes that only a fraction of LD cases are reported. LD is a reportable condition in most states; however, because of under-diagnosis and under-reporting only 2%-10% of estimated cases are reported.[1]

Most LD cases are sporadic; 23% are nosocomial and 10%-20% can be linked to outbreaks. Death occurs in 10%-15% of LD cases, and a substantially higher proportion of fatal cases occur during nosocomial outbreaks. Disease is often attributed to inhalation of contaminated aerosols from devices such as cooling towers, showers, and faucets, and aspiration of contaminated water. Importantly Medicare beneficiaries, including the elderly, cigarette smokers, persons with chronic lung or immunocompromising disease, and persons receiving immunosuppressive drugs are at particularly high risk.[1]

Prevention Guidelines:

CDC guidelines for the prevention of LD have been available and widely distributed for years. They may be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm .

Coding/CC:

ICD-9-CM code 482.84 defines cases of LD.[2]

In summary, on the basis of high disease burden, widely available, evidence-based prevention guidelines, and a distinct identifying ICD-9-CM coding that would result in higher payment to institutions not taking all necessary preventive measures, I strongly recommend that CMS include LD as a complication under CMS-1533-P.

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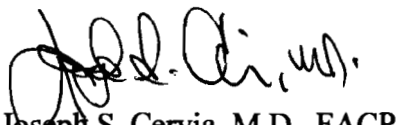
[1] http://www.cdc.gov/ncidod/dbmd/diseaseinfo/legionellosis_t.htm
[2] http://icd9cm.chrisendres.com/index.php?action=child&recordid=4666

Sincerely,



Joseph S. Cervia, M.D., FACP, FAAP, FIDSA
Clinical Professor of Medicine and Pediatrics
Albert Einstein College of Medicine
Medical Director and Senior Vice-President
Pall Medical

nile's pr ject Celebrate Life.
"We pledge daily deeds of kindness"

JUN - 7 2007 23

June 4, 2007

The Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Attention: Marc Hartstein

RE: Inpatient Prospective Payment System (IPPS) Proposed Rule

Dear Acting Administrator Norwalk:

As an American who has been deeply impacted at a very personal level by the dangers of MRSA, I am writing to urge that you take action to correct a flaw in a recently released proposed rule and help ensure that our healthcare providers take this grave threat seriously. It is simply beyond reason how MRSA could be left off an initial list of infections contained in the proposed rule.

We are not a corporation, but we hope these words from private citizens about our many times of being in the hospital help in some way. Remo, my husband, has had 3 back operations and a heart attack. I have had 3 hip replacement operations. We could have been victims of HAIs as well as any other patient, but we weren't.

Our hearts go out to the victims of HAIs and their families, because we know these infections could have been avoided and this is scary. We truly believe that healthcare providers should be made to answer for their lack of caring about what happens to the lives of their patients who fully trust them to do their best for them.

The threat posed by MRSA is continuing to become more serious every passing day. Public Health Officials with the Centers for Disease Control and Prevention (CDC) and other organizations have recognized this threat by developing and communicating evidence-based guidance healthcare professionals can use to dramatically reduce instances of MRSA. Thankfully, we have seen success stories throughout the country in which vigilant doctors and hospitals have taken comprehensive action and have dramatically reduced instances of MRSA and other Hospital Acquired Infections.

To ensure more hospitals take similar measures, I am urging that you include MRSA on the list of reasonably preventable conditions that your agency is to release by the start of the next fiscal year. By taking this meaningful step forward, Medicare will say loudly and clearly that it is simply unacceptable for hospitals and other

healthcare providers to fail to take action to prevent and reduces instances of MRSA.

It seems clear to me and many other individuals who have been impacted by MRSA that taking this action is in line with the wishes of Congress when it enacted this law last year. While I applaud you for including some other HAIs on the list of conditions scheduled for initial implementation, excluding MRSA - **the single most common hospital acquired infection (HAI) that occurs across a broad spectrum of diagnoses** - is extremely problematic and must be fixed.

In addition to the fact that MRSA results in the lion's share of all deaths linked to HAIs, perhaps Medicare should keep in mind the associated costs - more than $3 billion in annual Medicare charges - that result from the current situation. These costs can, should, and are already being avoided or sharply reduced through the application of evidence-based guidelines developed and promoted by the CDC, Society for Healthcare Epidemiology of America (SHEA), and similarly focused organizations.

Administrator Norwalk, please don't continue to place the lives of countless Medicare beneficiaries at risk of serious injury, lengthy hospital stays, and even death from a condition that is highly preventable. Our Medicare beneficiaries deserve this level of protection.

Thank you for your attention to this most important matter.

Sincerely,

Remo and Alice Moscatelli
3605 Poseidon Street
Kitty Hawk, NC 27949

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Patient Financial Services

Kettering Medical Center Network℠

May 30, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20510

Dear Ms. Norwalk:

We, the undersigned hospital organization, write to urge you to eliminate two 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 for 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 two proposals that cut, by $25 billion over the next five years, Medicare payments for hospital services provided to America's seniors and disabled. The first 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. The second proposal would reduce capital payments to hospitals located in urban areas. We strongly urge you to eliminate both provisions from the final regulation.

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.

There are no relevant data or experiences to support a prospective 2.4 percent cut for anticipated behavioral changes in each of the next two years. Not even in the initial years of the inpatient PPS was coding change found to be of the magnitude of CMS' proposed cuts for FY 2008 and FY 2009. This type of behavioral offset is unprecedented and unnecessary. CMS' rationale for the 2.4 percent cut stems from the recent transition of Maryland hospitals, which are excluded from Medicare's inpatient PPS, to a completely new type of classification and coding system called All Patient Refined DRGs (APRDRGs). MS-DRGs and APR-DRGs are two completely different systems for classifying patients, and generalizing from one to the other is completely inappropriate.

Inpatient PPS hospitals have been coding under the DRG system since 1983. That's more than 20 years of experience with coding under today's system. The vast majority of

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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.

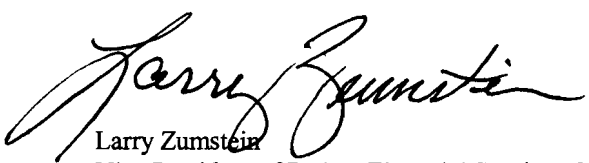
Capital-related Payment Cuts = $1 billion over the next 5 years

Medicare is required to pay for the capital-related costs of inpatient hospital services to help fund Medicare's share of expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (such as MRIs and CAT scanners). Since the PPS for inpatient capital costs uses DRGs in its payment formula, the 2.4 percent cut already reduces payments for urban and rural hospitals. In addition, CMS' proposed rule would eliminate the annual update for capital payments for all hospitals in urban areas, and would eliminate additional capital payments made to large hospitals in urban areas. These proposed cuts to capital payments would make it more difficult to purchase the advanced technology, equipment and clinical information systems that consumers have come to expect, and could have the effect of slowing clinical innovation. Capital cuts of this magnitude will disrupt the ability of urban hospitals to meet their existing long-term financing obligations. Hospitals have committed to these improvements under the expectation that Medicare's PPS for capital-related costs would remain a stable source of income. Reducing capital payments creates significant financial difficulties for our nation's most innovative and cutting edge hospitals.

CMS has chosen a path that is in direct opposition to policy makers on Capitol Hill. In fact, 223 representatives and 43 senators recently signed letters clearly stating their opposition to any effort to cut Medicare and Medicaid funding. Hospitals cannot sustain additional cuts in an already under-funded system. In fact, according to the Medicare Payment Advisory Commission, the independent commission that advises Congress on Medicare payment policy, overall Medicare margins will reach a ten-year low in 2007 at negative 5.4 percent.

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 regulation. Today's—and tomorrow's—patients deserve better.

Sincerely,



Larry Zumstein
Vice President of Patient Financial Services & Contract Management
Kettering Medical Center Network
2110 Leiter Rd
Miamisburg, OH 45342

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June 4, 2007

The Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Attention: Marc Hartstein

Dear Acting Administrator Norwalk,

I write to bring your attention to a sweeping epidemic that is responsible for nearly 100,000 deaths a year - Hospital Acquired Infections - and to urge the Centers for Medicare and Medicaid Services (CMS) to take action and address the most common form of HAIs-Methicillin-resistant Staphylococcus Aureus (MRSA).

In a single year, thousands of patients die in hospitals due to HAIs that are preventable and avoidable. In addition to the health dangers associated with MRSA and other HAIs, the cost associated with treatment is in the billions. Medicare claims data shows that MRSA infections alone cost approximately $3 billion in related hospital charges in 2006.

Recognizing this danger and the associated government spending, Congress last year passed the Deficit Reduction Act that directed CMS in Section 5001 (c) to ensure that healthcare providers are not rewarded by being paid additional - and even larger reimbursements - to care for patients who develop preventable infections after being admitted to the hospital. CMS has since released an Inpatient Prospective Payment System (IPPS) proposed rule that fails to include a number of major HAIs such as MRSA, Vascular-Catheter Associated Infections, surgical site infections, and Ventilator-Associated Pneumonia (VAP) on the list of conditions slated for initial implementation. I find it of grave concern that these dangerous HAIs, especially MRSA, are not given greater priority, and I believe healthcare providers need to be held accountable since MRSA in particular can be reasonably prevented through application of evidence-based guidelines.

Thankfully, it is not too late to make a difference, and I urge CMS to include MRSA as a condition scheduled for initial implementation under the IPPS rule. Thank you for your attention to this matter. I look forward to hearing from you soon. Please do not hesitate to contact me should you have any questions.

Sincerely,

Denise Moscatelli
7609 Lake Glen Drive
Glenn Dale, MD 20769
dlmoscat@bechtel.com

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Kathie Butts - Original Designs
28701 Springfield Dr.
Laguna Niguel, CA. 92677
Phone 949/363-1505 Fax 949/363-1501 kathiebutts@cox.net

The Honorable Leslie Norwalk, Acting Administrator June 3, 2007
Attention: Marc Hartstein
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Dear Acting Administrator Norwalk,

Having lost a close young friend recently who succombed to the deadly MRSA infection, and having heard many, many stories of others who have contacted hospital acquired infections, I write to bring your attention to this sweeping epidemic that is responsible for nearly 100,000 deaths a year, Hospital Acquired Infections. I urge the Centers for Medicare and Medicaid Services (CMS) to take action and address the most common form of HAI, Methicillin-resistant Staphylococcus Aureus (MRSA).

In a single year, thousands of patients die in hospitals due to HAIs that are preventable and avoidable. In addition to the health dangers associated with MRSA and other HAIs, the cost associated with treatment is in the billions. Medicare claims data shows that MRSA infections alone cost approximately $3 billion in related hospital charges in 2006.

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Thankfully, it is not too late to make a difference, and I urge CMS to include MRSA as a condition scheduled for initial implementation under the IPPS rule. Thank you for your attention to this matter. I look forward to hearing from you soon. Please do not hesitate to contact me should you have any questions.

Sincerely, Kathie Butts

Kathie Butts

THORATEC
CORPORATION

THORATEC
CORPORATION

May 24, 2007

Centers for Medicare and Medicaid Services (CMS)
Marc Hartstein
7500 Security Blvd.
Mail-Stop C4-08-06
Baltimore, MD 21244-1850

Dear Mr. Hartstein:

I am writing on behalf of Thoratec Corporation, a world leader in providing left ventricular assist devices (LVAD) to treat cardiovascular disease. Our Thoratec® VAD and HeartMate® have been implanted in more than 10,000 patients suffering from heart failure, and the HeartMate is the only left ventricular assist system approved by the FDA for use in both bridge-to-transplant and destination therapy indications. Thoratec works closely with the physician and hospital communities that implanting VADs to advance health care standards in support of high quality LVAD services.

First, we would like to thank the Center for Medicare and Medicaid Services (CMS) for modifying what was earlier proposed in the Hospital Inpatient Payment System (HIPPS) by appropriately grouping implanted ventricular assist devices with heart transplantation in the CMS Hospital Inpatient Proposed Payment System (HIPPS) for fiscal year (FY) 2008 and creating a new Medicare severity (MS) Diagnosis Related Groups (DRG) MS DRG 1 Heart Transplant or Implanted Assist Device with Major Complications or Comorbidities (MCC) and MS DRG 2 Heart Transplant or Implanted Assist Device without MCC.

Secondarily, this letter serves to provide background information and justification supporting the CMS HIPPS proposed rule for FY 2008 rule. We understand CMS is looking at refining the current DRG system to better recognize severity of illness and has proposed utilization of a MS- DRG which would replace the current DRG system to better recognize complications among the Medicare population. We seek to provide additional data and to recommend updates of this system as it pertains to left ventricular assist devices.

Summary of Recommended Modifications to Proposed Rule

CMS has correctly observed that hospital resources expended vary based upon patient complications as is demonstrated in the creation of MS DRG 1 Heart Transplant or Implanted Assist Device with Major Complications or Comorbidities (MCC) and MS DRG 2 Heart Transplant or Implanted Assist Device without MCC. We would ask CMS maintain consistency in the new MS DRG system by creating another MS DRG 215 (b) Other Heart Assist implant with major complications and modify and change the wording of MS DRG 215 (a) to Other Heart Assist implant without major complications. By capturing severity of the patient under ICD 37.65 Implant of external heart assist system, hospitals will be more appropriately reimbursed and CMS will be consistent in its policy.

Background

CMS expanded coverage in 2003 to recognize "destination therapy" as well as providing a technical correction to DRG 525 in 2004. CMS moved ICD-9 procedure code 37.62 from DRG 525 to DRGs 104/105. Non-FDA approved axial flow pumps were initially described by ICD-9 procedure code 37.62 but were then defined by ICD-9 procedure code 37.66 for 2004.

CMS has proposed a new MS DRG system to reimburse for inpatient hospital cases. The MS-DRG system is the first major change to the DRG system since it was originally implemented in 1983, and incorporates type of complication into the DRG classification system.

The primary Thoratec ICD-9-CM procedure codes describing LVAD placement and the DRGs to which these cases would be assigned are:

Thoratec Product(s)	**ICD-9-CM Procedure Code**
PVAD	**37.65** Implant of external VAD
IVAD, HM XVE	**37.66** Implant of internal VAD

Issues Related to CMS' Proposal to Implement MS-DRGs

CMS is now suggesting changing the DRG system with CMS-DRG 103 cross walking to the new MS DRG 1 Heart Transplant or Implanted Assist Device with MCC and MS DRG 2 Heart Transplant or Implanted Assist Device without MCC. ICD-9 procedure code 37.66 (Insertion of implantable heart assist system) would now track to these new MS DRGs. This change seems to appropriately capture severity of illness based upon mean length of stay (LOS) days and charges the associated with implantable LVADs as long as hospitals accurately capture and document complications.

Since Thoratec works closely with the physician and hospital communities, we have a strong interest in ensuring that the HIPPS continues to reimburse fairly and efficiently. We believe that the cross walk of DRG 525 to MS-DRG 215 without breaking out by complication classifying code distorts MS-DRG 215 creating a windfall for those cases that report ICD-9 procedure code 37.65 without complications. The proposed MS-DRG system has been created to group patients by severity of illness. Without MS-DRG 215 having a distinction between complications, CMS could be over reimbursing for the less severe cases and underpaying for those with major complications.

The Medicare 2005 MEDPAR data reflects the significant differences between length of stay days and charges with the ICD Code 37.65. It also reports the variability in patients with or without complications. For example, cases with MCCs within the proposed MS-DRG 215 have average charges in excess of $74,000 compared to those without MCCs, and the average LOS of cases with MCCs is higher by 53%.

Table 1. Breakout of MS-DRG 215 cases in MEDPAR 2005 by MCC and non-MCC

Status	*Number of Discharges*	*Average LOS*	*Average Total Charges*
MCC	154	14.8	$253,544.99
non-MCC	51	9.6	$179,400.96
Total	205	13.5	$235,099.40

* * * * *

To summarize, Thoratec supports CMS' decision to align procedures described by ICD-9 procedure code 37.66 with heart transplant procedures under the proposed MS-DRG system. However, we also strongly recommend that the proposed MS-DRG 215 be broken out by MCC and non-MCC subgroups, similar to MS-DRGs 1 and 2.

If you should have any questions, please do not hesitate to contact me at 603-598-0422. We look forward to working with CMS to resolve this issue.

Thank you for your consideration in this matter.

Sincerely,

Robin Bostic
Vice President of Reimbursement
Thoratec Corporation