

CMS-1533-P-201 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mr. Michael Snyder

Date & Time: 06/08/2007

Organization : Carolinas HealthCare System

Category : Hospital

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

CMS has proposed to freeze capital payments and eliminate the large urban add-on. The analysis that demonstrates hospitals have experienced significant positive margins on Medicare capital payments deserves further review. By reviewing the Medicare margins by region, it appears the large margins occur in the New England, Middle Atlantic and Pacific Regions. These regions have margins in excess of 10%. These regions also possess a significant number of large, teaching DSH facilities. All these categories also have margins in excess of 10%. We recommend a further review of whether these margins are more of a regional phenomenon as opposed to a national, large hospital issue. Reducing capital payments for all large hospitals does not make sense since it appears that some of these facilities are located in regions with modest or negative margins. Medicare beneficiary access to care may be compromised in these regions if hospitals do not receive at least their capital costs from the program.

Update Factors

Update Factors

1. The 2.4% reduction to standardized amounts as a result of arguably more complete coding:

CMS proposes to reduce the 3.3% update by 2.4% to account for case-mix increases not caused by intensity of service. Arguing that that hospitals will code more completely and accurately, causing an artificial increase to their case mix without a corresponding rise in the intensity of services, CMS points to the Maryland experience as support for the 2.4% reduction. The Maryland experience is not applicable to the rest of the nation currently on IP PPS. Maryland hospitals were exempt from IP PPS and were paid based upon an all-payor system where coding and documentation had no direct relationship to the case-mix or the amount paid. They were then thrust into a system where payment was totally dependent upon the coding and supporting documentation. Clinical and medical records staff received training on the APR-DRG system, causing an increase in case-mix as a result of increased and better coding and documentation. Hospitals currently on IP PPS are currently paid based on DRGs which are assigned based upon coding and documentation. The transition from the current DRG system to the proposed MS-DRG system will not entail a significant paradigm shift similar to what occurred in Maryland. There, payments are now based on coding and documentation where previously they were not. As a result, we believe there will not be a significant CMI change due to movement to the MS-DRG system as a result of coding.

CMS-1533-P-202

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

Submitter : Mrs. Akankshi Arora

Date & Time: 06/08/2007

Organization : University of California, Irvine

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

June 8, 2007

Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

File Code: CMS-1533-P
Re: Payment for Direct Graduate Medical Education

Dear Ms. Norwalk:

I write regarding the proposal for removing vacation and sick leave in the FTE resident count for purposes payment for direct graduate medical education. I would like to bring to your attention the increased administrative burden that compliance with your proposal would cause for residency and fellowship programs.

There are over 120 residents in the internal medicine residency/fellowship program at University of California, Irvine. To track their time on an hour by hour basis will cost the program thousands of dollars per month for the program. This is not a negligible effect. CMS must consider the local effect before it proposes these rules. I encourage CMS to finalize a rule that eliminates the local costs of complying with yet another regulation.

Sincerely,
Akankshi Aashi Arora

**CMS-1533-P-203 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Deborah Connors

Date & Time: 06/08/2007

Organization : CentraState Medical Center

Category : Hospital

Issue Areas/Comments

Imputed Floor

Imputed Floor

See Attachment

CMS-1533-P-203-Attach-1.DOC

- 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.
- Each year, CentraState provides uncompensated support to its community population through financial subsidies of the uninsured and charity patient care services, community programs which include education of students in our Health Awareness Center, support of our Family Practice Program, (which aims to add much needed primary care physicians to our market area and provide healthcare services to the underserved population of our market area; giving patients an alternative to unnecessary usage of Emergency Services). In 2006, these subsidies provided by CentraState were in excess of \$14.2 million dollars. On an individual hospital level, the reduction in funds under the expiration of the imputed floor could jeopardize the continuation of some of these programs and services.

As noted above, the expiration of the imputed floor would have a detrimental impact on CentraState Medical Center. As such, CentraState does not support the expiration of the imputed floor due (among other things) to the fact that the rationale for implementing the

Ms. Norwalk

6/11/2007

Page 3 of 3

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,

Deborah Connors
AVP of Budget/Reimbursement & Managed Care
CentraState Medical Center

**CMS-1533-P-204 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. J. Kevin Kinsella

Date & Time: 06/08/2007

Organization : Hartford Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#204

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

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

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

CMS-1533-P-205 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Harold Yang

Date & Time: 06/08/2007

Organization : PinnacleHealth at Harrisburg

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

There is no doubt that the use of DCD donors increases the in hospital costs for kidney transplantation. If CMS wishes to increase the use of these kidneys, I believe there should be an adjustment to the current DRG for kidney transplantation.

**CMS-1533-P-206 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Richard Brvenik

Date & Time: 06/08/2007

Organization : Windham Community Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter

CMS-1533-P-206-Attach-1.DOC

June 8, 2007

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

Re: Comment – IPPS Proposed Rule 1533-P, New England Deemed Counties

Dear Ms. Norwalk:

I am writing on behalf of Windham Community Memorial Hospital in Willimantic, Connecticut to express our opposition to the proposed changes to New England deemed counties. Further, I write to express that as the changes go forward by your agency that it be made clear that these changes will have no effect on the published rural floor value of 1.2439.

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

For about a quarter of a century, hospitals in Litchfield County, Connecticut have been deemed urban as required by statute and treated as urban for reclassification purposes. Over half of the acute care hospitals in Connecticut have a wage index established based on the Connecticut rural floor. As such, negative changes to the rural floor wage index value can have an enormous impact on the state of Connecticut and the ability of Connecticut hospitals to deliver high quality care.

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

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

Our organization appreciates the opportunity to offer these comments and urges your close consideration of them. Thank you very much.

Sincerely,

Richard A. Brvenik
President and CEO

**CMS-1533-P-207 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Colleen Scanlon

Date & Time: 06/08/2007

Organization : Catholic Health Initiatives

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letter from Catholic Health Initiatives

CMS-1533-P-207-Attach-1.DOC

June 11, 2007

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

REF: CMS-1533-P

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates; Proposed Rule, May 3, 2007

Dear Ms. Norwalk:

Catholic Health Initiatives appreciates the opportunity to comment on the proposed rule CMS-1533 -P. Catholic Health Initiatives is a faith-based, mission-driven health system that includes 72 hospitals, 42 long-term care, assisted-living and residential units, and two community health service organizations in 19 states.

Our national hospital associations will be providing you with more extensive comments on the proposed rule that reflect many common concerns. Catholic Health Initiatives would like to offer input on the following selected issues:

DRG REFORM AND PROPOSED MS-DRGS:

Severity of Illness

For Fiscal Year (FY) 2008, the Centers for Medicare and Medicaid Services (CMS) proposes refinement of the current DRG system by implementing Medicare-Severity Diagnosis Related Groups (MS-DRGS), increasing the number of DRGs from 538 to 745.

CMS also proposes revision of the current complication and comorbidity (CC) list with up to three tiers of payment for each DRG based on the presence of a major complication or comorbidity, a complication or comorbidity, or no complication or comorbidity.

Catholic Health Initiatives supports the adoption of a new or revised DRG classification system to better account for differences in patient severity and resource consumption.

The proposed MS-DRG system may be a substantial improvement over the current system. However, the proposed changes have not been reviewed by the RAND Corporation, the company retained by CMS to evaluate alternative classification systems. We believe an independent review and evaluation of the MS-DRGs should be undertaken before the new system is implemented to make sure this is the best approach.

Hospitals should not be subjected to the administrative burdens and financial consequences of changing to a new DRG system only to have it change again if the system is found to be flawed. Hospitals need stability and predictability in their payments to respond to the health care needs of their communities. When a new severity DRG is implemented, hospitals will also need an adequate transition period to prepare for the significant redistribution of payments that will occur with the changes.

Catholic Health Initiatives urges CMS to delay implementation of the MS-DRGs for one year to allow independent review of the proposal's ability to differentiate cases based on severity of illness and resource consumption. When and if a new severity DRG system is implemented, CMS should provide an adequate transition period to allow hospitals time to prepare for and adjust to significant redistribution of payments that will occur as a result of these changes.

Behavioral Offset

The proposed rule includes a 2.4% cut in Medicare payments to hospitals in FY 2008 and 2009 to eliminate what CMS claims will be the effect of coding or classification changes under the revised DRG system that do not reflect real changes in case-mix. CMS proposes this "behavioral offset" based on assumptions that we believe are not supported by data or experience.

This behavioral offset would cause significant and unjustified financial harm to Catholic Health Initiatives hospitals. The behavioral offset appears to be a back-door attempt to budget cut rather than a valid regulatory proposal.

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a refinement of the existing system; the underlying classification of patients and "rules of thumb" for coding would be the same.

There is no evidence that an adjustment of 4.8 percent over two years is warranted when studies by RAND, looking at claims between 1986 and 1987 at the beginning of the inpatient prospective payment system (PPS), showed only a 0.8% growth in case mix due to coding. Even moving from the original cost-based system to a new patient classification-based PPS did not generate the type of coding changes CMS contends will occur under the MS-DRGs.

Once MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment beforehand and should not do so without an understanding of whether there will even be coding changes in the first few

years of a refined system. CMS can always correct for additional payments made as a result of coding change in a later year if there is sufficient evidence to warrant an adjustment.

Catholic Health Initiatives urges CMS to remove the 2.4 percent behavioral offset for FY 2008 and FY 2009.

CAPITAL IPPS:

For FY 2008 and FY 2009, CMS proposes no capital update for urban hospitals (a 0.8 percent cut) and a 0.8% update for rural hospitals. For FY 2008 and beyond, CMS proposes elimination of the large urban hospital add-on (an additional 3 percent cut). CMS is considering discontinuing the IME and DSH adjustments to capital payments.

CMS also proposes applying the same 2.4 percent cut to capital payments that it proposes applying to operating payments as a behavioral offset in anticipation of the new MS-DRGs.

These cuts are unnecessary and inappropriate. CMS justifies the capital cuts based on an analysis that purports to show that hospitals are experiencing substantial positive margins under the capital payment framework. This analysis was based on a snapshot of capital margins rather than the full capital cycle of 15-20 years. Hospitals have capital expenditure cycles that involve a period of replacing/accumulating capital reserves and another period of making substantive capital expenditures. This cycle runs over the course of years, not annually.

The Medicare Payment Advisory Commission (MedPAC) has determined that overall Medicare margins will reach a 10-year low in 2007 at negative 5.4 percent. Whether or not hospitals experience a narrow positive margin for their capital payments is of small consequence to a hospital losing money, on average, every time it treats a Medicare beneficiary.

Capital cuts of the magnitude proposed by CMS would disrupt hospitals' abilities to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reduced capital payments would make buying the advanced technology and equipment that patients expect much more difficult for our hospitals and could slow clinical innovation. In addition, investments in information technology will become even more challenging.

Catholic Health Initiatives urges CMS to provide a full update in FY 2008 for urban and rural capital payments; maintain the large urban hospital capital add-on; eliminate the -2.4 percent behavioral offset for capital payments; and continue indirect medical education and disproportionate share hospital adjustments to capital payments.

HOSPITAL ACQUIRED CONDITIONS:

The Deficit Reduction Act of 2005 required the selection, by October 1, 2007, of at least two conditions that are: high cost or high volume or both; result in the assignment of a case to a DRG that has a higher payment when present as a second diagnosis; and could reasonably have been prevented through the application of evidence-based guidelines. Beginning October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. CMS has identified 13 conditions it is considering and proposes six conditions for implementation in FY 2009.

Catholic Health Initiatives supports implementation of this policy but believes CMS should start with a small number of conditions because there are significant challenges to correctly identifying cases that meet the criteria laid out by Congress. The use of secondary diagnoses to identify these conditions may not accurately identify hospital-acquired conditions as well as they should, particularly with regard to infections. Once the policy is implemented, CMS should study the first 6 months' experience with a validation process to make sure that hospital-acquired conditions are actually being identified.

CMS should start with the three conditions for FY 2009 that are identified by discrete ICD-9 codes and that can be coded by hospitals. Appropriate conditions to include for FY 2009 are: object left in during surgery; air embolism; and blood incompatibility. These are events that can cause great harm to patients and for which there are known methods of prevention. Catholic Health Initiatives is committed to patient safety and strives to ensure that these events do not happen in our hospitals.

The remaining three of the six proposed conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – are serious concerns but these conditions are not ready for inclusion in FY 2009. The correct identification of all three of these conditions will rely on the correct identification and coding of conditions that are present on admission. CMS implementation of present-on-admission coding has been pushed back to January 1, 2008 due to technical difficulties. Implementing a present-on-admission coding indicator will be a major challenge for hospitals and it will take time and intense educational efforts to achieve reliable data.

Catholic Health Initiatives urges CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections, and staphylococcus aureus until the necessary steps are taken to permit accurate identification of the relevant cases.

HOSPITAL QUALITY DATA:

In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included in the FY 2009 annual payment determination. To

receive a full market basket update, hospitals must to pledge to submit data on these five new measures, as well as the 27 existing quality measures, for patients discharged on or after January 1, 2008.

Catholic Health Initiatives appreciates this early notice on measures that hospitals will be required to report to receive their full FY 2009 inpatient payments. Significant lead time is needed to make arrangements with vendors and establish abstracting procedures for new quality measures. We encourage CMS to continue this practice.

We also appreciate that CMS has proposed adding measures that have already been adopted by the Hospital Quality Alliance (HQA) and agreed not to adopt any measures for FY 2009 that have not also been endorsed by the National Quality Forum (NQF) by the time of publication of the final rule.

Catholic Health Initiatives urges CMS to continue to provide hospitals with advance notice of quality measures for the next fiscal year and to only require reporting of measures that are NQF-endorsed and HQA-adopted.

RURAL FLOOR:

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008.

We have no objection to this approach but CMS should remove the compounding effect of erroneously applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998. The rural floor budget-neutrality adjustment was repeatedly applied without first reversing the prior year's adjustment as is done with the outlier calculation each year.

CMS should remove the effects of the adjustments made from 1999 through 2006 by increasing the positive budget-neutrality adjustment proposed for the standardized amount to reverse the 2007 adjustment. None of these changes should limit the rights of affected hospitals to appeal for appropriate relief from the understated standardized amounts.

Catholic Health Initiatives urges CMS to remove the compounding effect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998.

IME ADJUSTMENT:

CMS proposes removing vacation and sick leave from the total time considered to constitute a full time equivalent (FTE) resident for purposes of indirect medical education (IME) and graduate medical education (GME) payments, effective for FY 2008. CMS will continue to count time spent by residents in orientation activities for both IME and GME payments.

The proposal is not operationally practical. Hospitals would not only have to keep track of the leave for each resident but would also have to somehow apportion the leave to each of the hospitals the residents rotate through.

Catholic Health Initiatives urges CMS to treat vacation and sick leave in the same manner as orientation time and include them as part of the FTE count.

Thank you for the opportunity to review and comment on the proposed IPPS rule for Fiscal Year 2008. If you have any questions, please feel free to contact me at 303-383-2693.

Sincerely,

Colleen Scanlon, RN, JD
Senior Vice President – Advocacy

CMS-1533-P-208 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Michael Atwood

Date & Time: 06/08/2007

Organization : Stormont-Vail HealthCare

Category : Physician

Issue Areas/Comments

Impact--Capital IPPS

Impact--Capital IPPS

June 5, 2007

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

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

Dear Ms. Norwalk:

I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' proposed rule for the fiscal year 2008 hospital inpatient prospective payment system (PPS).

While my colleagues and I support many of the proposed rule's provisions, we oppose the proposed behavioral offset cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

We also believe that the 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 (\$24 billion over five years) will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoiding uninsured Medicaid and other low income patients.

We also oppose the elimination of the capital payment updates for all urban hospitals and the large urban hospital capital payment add-on which contains an additional 3 percent cut). These changes would result in a payment cut of \$880 million over five years to urban hospitals. These unnecessary cuts ignore how vital capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology.

We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any further cuts or adjustments to the capital PPS.

These cuts will further deplete scarce resources, ultimately making the mission of hospitals to care for patients even more challenging.

We support the position taken by the American Hospital Association and urge your consideration of this position to help ensure the viability of the community hospital.

Sincerely,

Michael Atwood, MD
Stormont-Vail HealthCare

**CMS-1533-P-209 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Daniel Landon

Date & Time: 06/08/2007

Organization : Missouri Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#209

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

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

CMS-1533-P-210 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Goran Klintmalm

Date & Time: 06/08/2007

Organization : American Society of Transplant Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

See attached

CMS-1533-P-210-Attach-1.DOC

CMS-1533-P-210-Attach-2.PDF

CMS-1533-P-210-Attach-3.PDF



American Society of Transplant Surgeons

June 8, 2007

Submitted electronically to
<http://www.cms.hhs.gov/eRulemaking>

Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

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

Dear Ms. Norwalk:

The American Society of Transplant Surgeons (ASTS) is pleased to have this opportunity to comment on the proposed Inpatient Prospective Payment Rule for FY 2008, as published in the May 3, 2007 Federal Register. ASTS is an organization comprised of over 1000 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

ASTS appreciates the agency's efforts to develop severity-based DRGs. We believe the MS-DRGs are generally a step in the right direction and a significant improvement over the APR-DRGs proposed for FY 2007. However, we have serious concerns about the proposal to create severity-adjusted DRGs for heart and liver transplants. Our concerns about this and a number of other issues are set forth below.

A. CMS should defer implementation of severity-based DRGs for heart and liver transplants pending further study.

Under the current DRG system, transplants procedures are each assigned to a single DRG, with the assignment being driven entirely by the procedure and not the patient's diagnosis.¹ Under the proposed rule, CMS would split the DRGs for

¹ Some combined transplant procedures are assigned to single organ DRGs. For example, a combined liver/kidney transplant or a liver/intestinal transplant are assigned to the liver transplant DRG.

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National Office

2461 South Clark Street
Suite 640
Arlington, VA 22202
Phone: 703 414-7870
Fax: 703 414-7874
Email: asts@asts.org
www.asts.org

President

Goran B. Klintmalm, MD, PhD
Baylor Regional Transplant Inst.
3500 Gaston Avenue
Dallas, TX 75246
Phone: 214 820-2050
Fax: 214 820-4527
Email: gorank@baylorhealth.edu

President-Elect

John P. Roberts, MD
Univ. of California San Francisco
Division of Transplantation
505 Parnassus Ave
Box 0780, Room M896
San Francisco, CA 94143-0780
Phone: 415 353-1888
Fax: 415 353-8709
Email: robertsj@surgery.ucsf.edu

Secretary

Robert M. Merion, MD
University of Michigan
315 West Huron, Suite 240
Ann Arbor, MI 48103-4262
Phone: 734 936-7336
Fax: 734 998-6620
Email: merionb@umich.edu

Treasurer

Michael M. Abecassis, MD, MBA
Northwestern University
Division of Transplantation
675 N. St. Clair Street, #17-200
Chicago, IL 60611
Phone: 312 695-0359
Fax: 312 695-9194
Email: mabecass@nmb.org

Immediate Past President

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Robert L. Kormos, MD
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Richard B. Freeman, Jr., MD
Dixon B. Kaufman, MD, PhD

Executive Director

Katrina Crist, MBA
Email: katrina.crist@asts.org

liver and heart transplants into two separate DRGs for each procedure; one in which the patient has a diagnosis on the major complicating condition (MCC) list and one in which the patient does not have a MCC. Thus, DRGs 1 and 2 would describe heart transplants with and without an MCC and would have of 24.4652 and 11.2998 and standardized DRG payment amounts of \$133,735 and \$63,897, respectively. Similarly, liver transplants would be described by DRGs 5 and 6 (with and without an MCC) with weights of 10.3032 and 4.7075 and standardized payments of \$58,284 and \$26,291, respectively. Thus, in both cases, the lower paying DRG is less than half of the higher paying DRG for the same transplant procedure.

Although ASTS generally agrees with the agency's goal of developing more refined DRGs that better capture the actual costs of a specific hospital admission, we do not believe that the proposed heart and liver transplant DRGs achieve this goal. Further, we believe that the payment for the "uncomplicated" procedures is much too low, resulting in financial instability for many centers and the creation of inappropriate patient selection incentives.

1. The MS-DRGs for heart and liver transplants would have a significant and destabilizing impact on Medicare-approved transplant centers

ASTS obtained the services of a consultant to review the impact of the new MS-DRGs for liver and heart transplants on Medicare-approved transplant centers. Based on the consultant's analysis, over 50% of heart and liver transplant centers reviewed would experience a reduction in DRG reimbursement for heart or liver transplants under the proposed methodology. What is more alarming, however, is that of the 52 liver transplant centers for whom data was available, 11 (19%) would experience reductions of more than 10 percent, with many experiencing reductions of over 20%. Of the 37 heart transplant centers for which data was available, 10 (27%) would undergo DRG payment reductions of more than 10 percent.² Small centers – those with volumes below 10 Medicare transplants per year – were excluded from the analysis. However, we believe it is reasonable to assume that the negative impact of the proposed MS-DRGs for heart and liver transplants would be even more severe for smaller centers. We are very concerned that reductions of this magnitude would cause significant economic instability at these centers, resulting in negative consequences both for patients undergoing transplantation at these centers and those on these centers' waiting lists.

Moreover, the relatively low volume of these procedures makes these DRGs more vulnerable to fluctuations, as DRG weights are annually revised to reflect the most recent available hospital cost data. Splitting these already low volume procedures into two separate DRGs compounds this effect. We also note that transplant centers would be expected to absorb the impact of a new DRG payment system at the same time that they are expected to comply with new transplant center conditions of participation.

In addition, as noted above, there is a significant differential between "with MCC" and non-MCC payment amounts for heart and liver transplants, and ASTS is extremely concerned about the impact of the proposal on transplant centers that perform a substantial number of heart or liver transplants that fall into the non-MCC category. The weights for the non-MCC DRGs are extremely low – less than half the weight assigned to the "with MCC" procedures. We estimate that the average payment under DRG 6, a "low complexity" liver transplant with an average LOS of 10.5 days would be \$26,243. We do not

² Because of patient privacy rules, the consultant was unable to provide an analysis of transplant centers performing fewer than 10 Medicare transplants; consequently many of the small transplant centers are not included in this analysis.

believe there are many, if any, transplant centers that could perform a liver transplant for this amount, even if the LOS was 4 or 5 days.

Similarly, payment under DRG 2 for a “low complexity” heart transplant with an average LOS of 22.7 days would be approximately \$63,897. Again, ASTS is not aware of any heart transplant centers that could perform a heart transplant for this amount.

Thus, we do not believe that the DRG weights for the “non-MCC” heart and liver transplants appropriately reflect the costs of these procedures. Under these circumstances, the adoption of the MS-DRGs as proposed may result in considerable financial hardship for transplant centers that perform a significant number of non-MCC transplants.

2. The MS-DRGs for heart and liver transplants do not take into consideration the most significant factors affecting costs of transplant procedures.

Preliminarily, we question the basic premise that there is, in fact, such a thing as an “uncomplicated” transplant patient. While the concept of dividing DRGs based on severity is conceptually sound in the context of admissions for many medical conditions and perhaps for certain surgical admissions, transplantation as a whole is an extremely complex process that generally involves patients with life threatening conditions. Under these circumstances, the concept of severity-adjusted DRGs may have significantly less application in the context of transplantation.

Moreover, the presence or absence of a condition on the MCC list is not a good predictor of inpatient hospital costs for liver and heart transplants. Absence of a condition on the MCC list does not, in our view, equate with low complexity or low cost. In fact, based on our review of the MCC list, we believe there are many patients with complicated and, consequently, high cost hospital stays whose admissions would not fall into the higher “w/MCC” DRG. Moreover, and more importantly, the factors that do have a positive correlation with complexity and cost were not included in the development of the MS-DRGs for transplants.

a. Donor Risk Index

One factor that influences hospital costs and lengths of stay is the characteristics of the donor organ. Liver transplantations involving a high donor risk index (DRI) have been associated with longer lengths of stay (LOS) and increased costs, regardless of the condition of the recipient.³ In one study, in comparable recipients, the use of organs with high donor risk index (DRI) was associated with an increase in LOS of 10.6 days, with incremental costs of \$47,986. *Id.* (Although this study involved both Medicare and non-Medicare patients, we have no reason to believe the data for Medicare patients alone would be any different.) Given the increasing demand for transplantable organs and large number of individuals on waiting lists around the country, use of marginal organs is increasing, consistent with the stated objectives of the Health Resources and Services Administration (HRSA) and the Breakthrough Collaborative. Therefore, it is important that any severity index for transplant DRGs take these factors into consideration.

³ Axelrod D, et. al., *The Economic Impact of the Utilization of Liver Allograft with High Donor Risk Index*, Am. J. of Trans. 2007; 7:990-997 (Attachment 1).

Currently, the MS-DRG methodology is not able to take donor risk into account because DRI is not captured in the MedPAR data base. ASTS would like to work with CMS to refine the IPPS system so that factors such as the DRI can be included in determining DRG assignment either through the development of diagnostic ICD-9 “V” codes or some other mechanism. However, until such refinements can be implemented, we do not believe CMS should implement severity-based DRGs for transplant procedures.

b. MELD Status for Liver Transplants

The model for end-stage liver disease (MELD) system, adopted in February of 2002, prioritizes patients awaiting liver transplants by severity of illness. Use of the MELD system has led to a reduction in mortality, especially among the sickest patients – those with the highest MELD score. Patients with high MELD scores have longer hospital stays and incur substantially higher hospital costs. Moreover, many patients with high MELD scores have renal failure and thus require a combined liver/kidney transplant. In one study, increasing MELD score was associated with higher costs of \$4309 per MELD point.⁴ Any severity-based DRG system for liver transplants should take into consideration the patient’s MELD score. Currently, however, this information is not captured in the MedPAR data base; consequently, the proposed MS-DRGs for liver transplants do not take this into consideration.

B. CMS should re-consider the establishment of a separate DRG for liver/kidney transplants.

Liver/kidney transplants are currently assigned to the DRG for liver transplants and liver/kidney transplants would continue to be assigned to one of the liver transplant MS-DRGs under the proposed rule. It appears that ICD-9 codes that describe some form of kidney involvement are among the most common “triggers” that result in the classification of liver transplant cases into the “with MCC” DRG. Thus, at least one objective of the severity-based classification could be served by establishing a separate DRG for live/kidney transplants.

In fact, we believe that a separate DRG is needed to address the significantly higher costs associated with combined liver/kidney transplants. We raised this issue in both FY 2007 and FY 2006 in our comments on the proposed IPPS rule. CMS has previously acknowledged that the costs for a liver-kidney transplant were significantly higher and lengths of stay were considerably longer than those associated with liver transplants alone. Specifically, FY 2004 MedPAR data showed average charges for liver/kidney transplants of \$237,759 and average LOS of 21.3 days compared with \$165,314 for liver transplantation alone. (See August 12, 2005 Federal Register at 47286.) However, CMS determined that there were too few cases (79 out of 959) to justify creation of a new DRG.

With respect to the relatively small number of cases, we note that with the February 2002 implementation of the model end state liver disease (MELD) system to prioritize patients, there has been a substantial increase in the number of patients receiving liver/kidney transplants.⁵ This is due, in large part, to the fact that high creatinine levels affect the MELD score more than other variables. Thus, many of the patients who are priority candidates for liver transplants also have impaired kidney function. In a

⁴ Axelrod D., et al., *The Economic Impact of MELD on Liver Transplant Centers*, Am. J. Trans. 2005; 5: 2297-2301 (Attachment 2). Although this study involves both Medicare and non-Medicare patients, there is no reason to expect that Medicare-only data would differ.

⁵ OPTN data shows 246 cases (Medicare and non-Medicare) in 2003, 279 in 2004, 337 in 2005, and 399 in 2006.

study at one large transplant center, liver/kidney transplants were 6% (n=5) of the total number of liver transplants prior to implementation of the MELD system but 17% (n=22) post-MELD.⁶ That same study found that hospital costs for inpatient stays involving combined liver/kidney transplants were 124% higher than liver transplants alone and the average LOS was 144% longer.

Further, outlier payments are generally inadequate. In the study referred to above, 19% of liver/kidney cases fell in the outlier gap and 44% achieved outlier status. However, the transplant center calculated that its average per case loss for outlier cases was over \$17,000 per liver/kidney transplant. Those that did not qualify for outlier payments resulted in a loss of over \$19,000.

We believe hospital inpatient costs and LOS associated with a liver/kidney transplant are sufficiently higher than those of a liver transplant alone as to justify the creation of a separate DRG. We ask that CMS re-evaluate its earlier decision not to establish a separate DRG for liver/kidney transplants, in light of the most recently available data. We believe the recent increases in volume justify creation of a separate DRG for combined liver/kidney transplants.

C. CMS should reconsider the proposed reduction in the DRG weight for kidney/pancreas transplants.

ASTS is very concerned about the proposed reduction in DRG weight for combined kidney/pancreas procedures. Under the proposed rule, the DRG weight for this procedure would decline from 6.26 to 5.20 – a reduction of 17%. This is much more severe than the reductions proposed for any of the other transplant DRGs. There are no clinical or technological changes that would explain such a sizeable reduction. Nor has CMS offered any explanation in the proposed rule. Reductions in payment of this magnitude are extremely destabilizing for centers that perform these procedures and certainly should not be implemented in a single year. We question whether the proposed weight for this DRG (MS-DRG 8) might be the result of an error in the methodology and ask that CMS review the data for this DRG. If the result is not in error, we ask that CMS consider phasing-in the reduction over more than one year. We also ask that the agency explain, in the final rule, the basis for such a significant reduction.

D. CMS should correct the misclassification of certain transplant cases performed in prior years.

In conducting his analysis of the FY 2008 proposed DRG weights for transplant procedures, ASTS' consultant discovered what appears to be a significant number of transplant discharges from prior years that were not paid as transplant cases or treated as transplant cases in developing the FY 2007 DRG weights. In fact, the consultant, Chris Hogan of Direct Research, identified 422 liver transplant discharges and 50 lung transplant discharges that were apparently misclassified and thus improperly paid in prior years. We ask that CMS review these cases and determine, whether, in fact, these cases were improperly assigned by the fiscal intermediary to non-transplant DRGs.⁷ If the hospital properly coded the case but was improperly paid, we ask that CMS direct the relevant intermediaries to reimburse the hospitals the corrected amount.

⁶ Axelrod DA, et al., *supra*, note 3.

⁷ ASTS is not including in its comments the consultant's analysis and the identification of the specific transplant centers at which the apparent misclassifications took place because of privacy concerns. However, ASTS will provide to CMS the analysis in a separate communication outside of the public rulemaking process.

Further, incorrect DRG assignments of such a large scale may indicate serious technical or methodological problems that must be investigated and corrected for the future. ASTS asks that CMS review this issue and take appropriate action to ensure such misclassifications do not arise in the future.

E. CMS should exempt procedure-based DRGs from the behavioral offset.

The proposed rule includes a 2.4 percent cut in both FYs 2008 and 2009 to address the assumed effect of hospital coding changes based on the introduction of the new MS-DRGs. While ASTS questions the appropriateness of such a cut, we believe it is particularly unwarranted for transplant procedures in which the DRG assignment is based entirely on the procedure. In such cases, the premise for the behavioral offset would not apply. We therefore request that for those small number of DRGs which are assigned based solely on the procedure, that the 2.4 percent reduction not apply.

F. Conclusion

The agency has proposed fundamental changes to the existing DRG system. While we agree with CMS' objective of increasing the accuracy and fairness of the DRG payments, we believe the proposed MS-DRGs for liver and heart transplants may have a significant and destabilizing impact on the transplant centers that perform these procedures and that the proposed classifications do not take into consideration the real factors that distinguish relatively low cost from relatively high cost transplant cases. We further believe that the establishment of a separate kidney-liver DRG could serve the stated objective of adjusting the system to account for severity more reliably and more accurately. ASTS remains interested in working with CMS and others to institute new ICD-9 codes to track donor status and MELD score, both of which could potentially serve as the basis for instituting a more accurate severity adjustment in the future. However, in the interim, ASTS strongly urges that CMS not implement the proposed MS-DRGs for heart and liver transplants. ASTS is committed to working with CMS to develop appropriate hospital reimbursement for all transplant procedures which will more accurately reflect hospital costs.

Sincerely,



Goran Klintmalm, MD, Ph.D., FACS
President

The Economic Impact of MELD on Liver Transplant Centers

David A. Axelrod^a, Alan J. Koffron^a, Talia Baker^a,
Patrice Al-Saden^a, Irma Dixler^b, Gwen McNatt^b,
Scott Sumner^b, Mike Vaci^b and Michael
Abecassis^{a,*}

^aDivision of Transplant Surgery, Department of Surgery,
Feinberg School of Medicine, Northwestern University

^bKovler Transplant Center, Northwestern Memorial
Hospital, Chicago, Illinois, USA

*Corresponding author: Michael Abecassis
mabecass@nmh.org

Adoption of the model for end stage liver disease (MELD) system prioritized patients awaiting liver transplant (LT) by severity of illness including progressive renal dysfunction. Unfortunately, current reimbursement for LT is not adjusted by severity of illness or need for simultaneous liver-kidney transplantation (LKT). This study examines hospital cost and reimbursement for LT and LKT to determine the effect of MELD on transplant center (TC) financial outcomes given current reimbursement practices as well as DRG outlier threshold limits. LT was performed for 86 adults prior to and 127 following the implementation of MELD. Between the eras, there was a substantial increase in the average laboratory MELD score (17.1 to 20.7 $p = 0.004$) and percentage of LKTs performed (5.8% to 17.3% $p = 0.01$). Increasing MELD score was associated with higher costs (\$4309 per MELD point $p < 0.001$) and decreasing TC net income (\$1512 per MELD point $p < 0.001$). In patients not achieving the Medicare outlier status, predicted net loss was \$17 700 for high-MELD patients and \$19 133 for those needing LKT. In conclusion, contractual reimbursement agreements that are not indexed by severity of disease may not reflect the increased costs resulting from the MELD system. Even with outlier thresholds, Medicare reimbursement is inadequate resulting in a net loss for the TC.

Key words: Disease severity, financial outcomes in transplantation, health economics, liver transplantation, MELD

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Introduction

The adoption of a 'sickest patient first' strategy for organ allocation for deceased donor liver transplantation (LT) has resulted in a profound shift in the liver transplant population. While adoption of the model for end stage liver disease (MELD) score to prioritize patients in February 2002 has led to a reduction in mortality, particularly among patients with the highest MELD score, its impact on post-transplant survival is less clear.(1) Furthermore, the increasing complexity and acuity of patients undergoing transplantation is likely to have a significant impact on hospital resource utilization and financial outcomes of the nation's transplant centers (TC).

Two groups of patients have been particularly favored by the current organ allocation system. Under the MELD system, patients with progressive renal impairment receive a very high priority and appear to constitute an increasing proportion of the patients undergoing transplantation. Previous investigations have demonstrated a significant relationship between the degree of renal impairment and the cost of transplant (2). Thus, these patients are likely to have a profound effect on TC economics. Furthermore, an increasing number of these patients require a simultaneous liver-kidney transplant (LKT) that is currently reimbursed by Medicare under the same DRG as liver transplant alone (3).

The second group of patients who have benefited from the MELD score are patients to whom MELD scores are assigned based on exceptions to the MELD system, such as patients with hepatocellular carcinoma (HCC). It is important to differentiate between patients whose calculated MELD scores reflect hepatic decompensation and those who received MELD exceptions. The latter receive MELD point and upgrade to facilitate early transplant, whereas the former are desperately ill, often with multi-organ failure. In order to assess the financial impact of the increased acuity of illness associated with a high MELD score while controlling for secular trends in the cost of care, the cost of LT/LKT in patients with high calculated MELD scores can be compared to those with high-assigned MELD scores, but low calculated scores.

In this investigation, the clinical and financial records for 213 consecutive liver transplant recipients at a single TC spanning the implementation of MELD were assessed to

examine the impact of the new organ allocation system on the cost of transplantation in the context of current contractual reimbursement agreements and determine the impact of MELD on the profitability of the TC.

Materials and Methods

Patient population

Clinical and demographic data for all adult patients ($n = 229$) undergoing liver transplantation ($n = 233$) from January 2000 to December 2003 at a single institution were examined. This analysis included whole organ transplants from a deceased donor (DDLT), split liver transplants (SLT) including both segmental and lobe splits and adult-to-adult live donor liver transplants (ALDLT). A combined liver-kidney transplant (LKT) was performed if the renal failure was thought to be irreversible. Alternatively, patients with renal insufficiency were maintained on dialysis through the perioperative period until adequate return of renal function. Patients undergoing transplant for fulminant hepatic failure ($n = 11$) or undergoing a combined LT and coronary artery bypass grafting procedure ($n = 5$) were excluded from this analysis resulting in 213 transplant patients (216 LTs) for analysis.

MELD

MELD score was calculated using the last laboratory data available prior to transplant for all patients, including patients who were transplanted in the pre-MELD era. For patients on dialysis, a creatinine level of 4.0 was assigned and used to calculate the MELD score. The calculated MELD score was used in all patients. For patients who had been assigned a MELD score upgrade on the basis of a MELD exception granted by the Regional Review Board, the calculated MELD score was used to determine the severity of liver disease.

Cost data

Financial records were extracted from the hospital cost accounting system for the hospital stay in which the transplant occurred. For the small number of patients who were retransplanted during the same hospital stay ($n = 3$) due to primary nonfunction or hepatic artery thrombosis, all costs were assigned to the first transplant. The cost of care was determined using the full allocated cost of care (fixed and variable components) net of organ acquisition cost. Net income reflects the actual difference between allocated cost and hospital revenue. Given the short time period of this analysis, cost data were not adjusted for inflation.

Medicare gap analysis

Using existing Medicare fee schedules for DRG 480 (liver transplant), all cases, regardless of payer, were examined to determine the expected reimbursement under Medicare. For cases in which costs exceeded the outlier threshold, expected reimbursement was calculated using data from the current (2004) Medicare cost report. The outlier payment gap was defined as the amount between reimbursement for DRG 480 and the payment threshold that triggers outlier reimbursement.

Data analysis

Continuous and categorical variables were compared using Student's *t*-test and chi squared analysis as appropriate. Multivariate linear regression was used to assess the independent affect of demographic and clinical variables. A *p*-value < 0.05 was considered significant. Patient outcome at 1 year was assessed using a chi-squared test. All analyses were conducted using Stata 8.0 (Stata Corporation College Station, TX).

Human subjects review

This project was approved by the Northwestern University Institutional Review Board.

Table 1: Patient demographics and transplant results

	Pre-MELD	Post-MELD	p-Value
N	86	127	
Age (years)	50.8 ± 9	53.0 ± 10	0.13
Male (%)	72	68	0.49
DX of HCC	15%	31%	0.009
DX of Hep C	39%	42%	0.07
Average MELD	17.1	20.7	0.004
With MELD > 15 (%)	59	67	0.35
Total LOS (days)	16.1 ± 18	12.1 ± 15	0.08
Pre-TXP LOS, MELD < 15	1.6 ± 5	0.3 ± 1	0.09
Pre-TXP LOS, MELD > 15	7.3 ± 14	4.1 ± 9	0.11
1-year patient survival	85%	91%	0.20

Table 2: Procedures performed prior to and following the implementation of MELD

	Pre-MELD	Post-MELD	p-Value
Liver transplant alone, N (%)	81 (94)	105 (83)	0.01
Deceased donor	62 (76%)	71 (67%)	0.18
Live donor	13 (16%)	23 (22%)	0.32
Split liver	6 (7%)	11 (10%)	0.47
Liver-kidney transplant, N (%)	5 (6)	22 (17)	0.01

Results

Liver transplantation was performed for 86 patients prior to and 127 patients following the implementation of the MELD system of organ allocation in February 2002. Patient characteristics including age, gender and the incidence of hepatitis C were similar across the period of analysis (Table 1). There was a significant increase in the number of patients transplanted for HCC (31% vs. 15% $p = 0.009$) as a result of the MELD upgrade accorded to these patients. Overall, there was a 21% increase in mean calculated MELD score between patients transplanted before and after the MELD system (17.1 vs. 20.7 $p = 0.004$). Among patients receiving a whole organ DDLT (excluding live donor and split liver transplants), the average calculated MELD score increased by 28% (17.8 to 22.8 $p < 0.001$). Overall patient survival was comparable between eras ($p = 0.20$).

As a result of the emphasis placed on renal dysfunction in the MELD score, there was a significant increase in the number of LKTs after the implementation of MELD (Table 2). In the pre-MELD era, LKT represented 6% of transplants, which increased to 17% in the post-MELD era ($p = 0.01$). There was also a trend toward a reduction in the number of whole organ DDLT accompanied by an increased use of live donor and split liver transplant in the post-MELD era.

The increasing severity of illness, as reflected in the higher MELD scores, was associated with dramatically higher costs of care and reduced margins for the TC. When compared to patients with low calculated MELD scores, patients with MELD scores greater than 15 had total

Table 3: Impact of MELD score on resource utilization for liver transplantation

	Relative cost of high (>15) versus low (≤15) MELD LT	p-Value
Total cost	49% increase	<0.001
Room and board	135% increase	<0.001
Operating room	11% increase	0.09
Pharmacy	87% increase	0.02
Laboratory	100% increase	<0.001
Radiology	92% increase	0.007
Supplies	40% increase	0.06
Overall LOS*	108% increase	<0.001
Pre-TXP LOS*	489% increase	<0.001
Net income	114% decrease	0.02

MELD = model for end Stage liver disease; LT = liver transplant. *Increase in days in the hospital.

inpatient costs that were 49% higher ($p < 0.001$; Table 3). The major cost drivers for the increased cost of high MELD patients include higher room and board costs, as well as increased use of laboratory, radiology and pharmacy services (Table 3). High MELD patients were associated with a significant increase in overall length of stay (16.9 vs. 8.1 days $p < 0.001$) as well as longer pre-transplant hospitalization (5.3 vs. 0.9 days $p < 0.001$). Despite the significant increase in resources needed to care for high MELD patients, hospital revenues increased by only 24%. Consequently, average net income was 114% less in high MELD patients ($p = 0.02$), resulting in a net loss for the TC.

Univariate analysis revealed that MELD score, diagnosis of HCC, diagnosis of hepatitis C and living donor liver transplant ($p = 0.02$) were significantly correlated with the cost of liver transplant (Table 4). However, in the multivariate analysis only the MELD score was found to correlate with cost, demonstrating an increase of \$4309 per MELD point. Neither donor type nor diagnosis remained significant after adjustment for MELD score. Univariate analysis revealed that a diagnosis of HCC, MELD score and LRD transplant were all significantly associated with TC income. However, in the multivariate analysis, only MELD score was associated with decreasing TC net income (\$1512 reduction per MELD point $p = 0.002$).

The disparity between cost and revenue was particularly profound for patients who required LKT (Table 5). When

Table 5: Differential in resource utilization for liver-kidney transplant versus liver transplant

	Ratio of LKT to LT alone (%)	p-Value
Total cost	124 increase	<0.001
Net income	388 decrease	0.004
LOS (days)	144 increase	<0.001
Pre-TXP LOS	550 increase	<0.001

LKT = liver-kidney transplant; LT = liver transplant; LOS = length of stay.

compared with patients undergoing liver transplant alone, LKT patients did not differ based on age or gender. The overall LOS following LKT was markedly longer than for LT alone (28.4 days vs. 11.6 days $p < 0.001$). This difference was largely the result of a more complex pre-transplant course, characterized by pre-transplant LOS which was significantly longer (14.3 vs. 2.2. $p < 0.001$). As a result, the mean cost of LKT was 124% higher than for LT and revenues were often inadequate resulting in a net loss for the TC. Compared to LT alone, LKT was associated with a 388% reduction in net income.

An additional analysis was conducted to assess the impact of current Medicare reimbursement policy on TCs. Overall, Medicare was the primary payer for 16% of patients undergoing LT/LKT. Among high MELD patients, 25% met outlier thresholds under current Medicare guidelines, while an additional 19% fell in the gap in which costs exceed reimbursement but fail to qualify for outlier payment. For high MELD patients undergoing liver transplant alone, patients achieving outlier status resulted in a predicted net loss for the TC of \$17 000 while those in the gap had a predicted net loss of \$17 700. Under current Medicare reimbursement schedules, LKT are reimbursed as liver transplant alone. In LK cases achieving outlier status, the predicted loss per patient under current Medicare guidelines was \$17 037. However, among LKT cases falling in the gap the loss was \$19 133 per case.

Discussion

The implementation of the MELD system of organ allocation has resulted in a shift in liver transplant recipients to patients with higher MELD scores and increased

Table 4: Univariate and multivariate analysis of cost drivers

Variable	Cost		Multivariate	p-Value	Net income		Multivariate	p-Value
	Univariate	p-Value			Univariate	p-Value		
Age (per year)	-271	0.64			-532	0.21		
HCC	-43 895	0.001			24 313	0.02		
Hep C	-22 291	0.05			8768	0.33		
MELD (per patient)	4309	<0.001	4309	<0.001	- 1512	0.002	-1512	0.002
Split	-2689	0.89			- 11 170	0.49		
LRD	-35 432	0.02			25 640	0.03		
Pre-MELD	-8102	0.47			-2839	0.75		

Variables are reported in dollar change in cost and net income associated with the variable of interest.

severity of illness. Patients with high MELD scores have longer hospital stays and, thus, incur higher hospital costs. Hospital revenues, however, are frequently either tied to Medicare DRG 480 or are reimbursed on a case rate-based reimbursement that is not indexed to severity of illness. In either situation, outlier payments are meant to provide a safety net for high cost cases, but often result in payments that are either at the margin or below cost. This results in significant reductions in net income, and may lead to a net loss for TC. This disparity is particularly significant in patients undergoing LKT.

The objective of the MELD system is to transplant the patients with the highest likelihood of dying without receiving a transplant. Recent analysis of the MELD system has demonstrated a significant reduction in wait-list mortality among adult and pediatric recipients (>2 year old) (1). Among adults listed for transplant, there was a reduction in the deaths/1000 patient-years from 910 to 743. Despite the increased severity of illness in patients undergoing transplantation, overall patient and graft survival have improved in the post-MELD era (4). Even for patients with high MELD scores, the outcome of transplant is often favorable. Although MELD scores are a relatively poor predictor of long-term outcome, in patients with scores greater than 24, there is a only 7% reduction in 5-year survival when compared to scores less than 10 (5). Conversely, those patients with low calculated MELDs who are awarded upgrade points for HCC are likely to benefit significantly from early transplant.

While transplantation of patients with high MELD scores has been shown to be of substantial clinical benefit (6), this shift in the transplant population will, predictably, increase the cost of transplantation. Prior to the implementation of MELD, improvements in clinical care and reduction in hospital stay had led a reduction in the cost of care. From 1993 to 1998, the average cost of liver transplantation performed in the Medicare population decreased from \$201 677 to \$143 363 (7). In the pre-MELD era, analyses of the cost of liver transplantation have identified several recipient factors that were associated with high costs. In a multi-center analysis, Showstack and colleagues demonstrated increased costs associated with older donor age, older recipient age, alcoholic liver disease, Child-Pugh class C cirrhosis and hospitalized patients. (8) Markman and colleagues identified several additional variables in their large single center study including donor sodium level, recipient creatinine and recipient ventilator requirement pre-transplant. (2) Thus, it is the patients most likely to be prioritized under the MELD system who can be expected to have the highest costs associated with liver transplantation. The cost of care is likely to be further increased by the increased reliance on older and marginal donors (e.g. nonheart beating DDLT), both of which have been associated with higher costs, and longer lengths of stay.

While reimbursement varies considerably depending upon contractual negotiations between TC and third-party payers, many follow the current Medicare practice of case rate-based reimbursement that is not adjusted for severity of illness. Current practice does allow for some reimbursement for true outliers. Outlier protection typically consists of a stepwise or incremental payment methodology whereby cases at the margin will receive no additional reimbursement or payment until a certain outlier threshold is met. Thus for patients who exceed this threshold, payment in addition to the case rate will be made to the TC based on a percentage of charges, whereas for those patients who fail to meet the threshold, the TC receives no additional payment. Unfortunately, a significant percentage of high MELD patients (19%) fell in the Medicare outlier gap between hospital cost and the outlier provision threshold. Even among those patients (25%) who exceed this threshold, revenues frequently failed to cover hospital costs. For LKTs, this problem is particularly severe with 19% falling in the outlier gap and 44% achieving outlier status. Outlier payments were often inadequate resulting in a calculated average per case loss of over \$17 000 per LKT, while those in the gap resulted in a loss of more than \$19 000.

This study is limited in its general applicability because of the use of a single center's cost accounting information. Changes in clinical practice may reflect local practice and as well as the known variations in MELD score at transplantation, which occur between regions. (9) However, multiple studies have documented the relationship between increasing severity of illness and the cost of liver transplant. Thus, the conclusion that the MELD allocation system is likely to increase liver transplant costs is likely to be robust. With regard to reimbursement, by utilizing current Medicare guidelines in addition to actual TC experience to assess the impact of current reimbursement policies, including outlier threshold costs, on TC profitability our findings should be generalizable at least to this population nationwide.

In conclusion, the shift in the allocation policy for liver transplantation has resulted in the transplantation of patients with higher acuity of illness who incur significantly higher costs. The change to the MELD system has led to higher costs for LT and will negatively impact TC profitability unless current reimbursement policies are changed. A modified reimbursement policy to a system indexed by severity of illness is needed to protect TCs from financial losses due to the MELD policy. Specifically, a new DRG is needed for LKT, which reflects the significant increase in costs associated with this procedure. Finally, TCs should consider case rate reimbursement contracts with third-party payers that account for the higher costs incurred by the TC as a result of allocation policies that favor transplantation for the sickest patients first.

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The Economic Impact of the Utilization of Liver Allografts with High Donor Risk Index

D. A. Axelrod^{a,*}, M. Schnitzler^b,
P. R. Salvalaggio^c, J. Swindle^b and
M. M. Abecassis^d

^aDivision of Solid Organ Transplantation,
Dartmouth-Hitchcock Medical Center, Lebanon, New
Hampshire

^bSt. Louis University Center for Outcomes Research,
Department of Internal Medicine, St. Louis University,
St. Louis, Missouri

^cDivision of Transplant Surgery, Department of Surgery,
St. Louis University, St. Louis, Missouri

^dDivision of Transplant Surgery, Feinberg School of
Medicine, Northwestern University, Chicago, Illinois

*Corresponding author: David A. Axelrod,
david.axelrod@hitchcock.org

The disparity between the organ supply and the demand for liver transplantation (LT) has resulted in the growing utilization of 'marginal donor' organs. While economic outcomes for subsets of 'marginal' organs have been described for renal transplantation, similar analyses have not been performed for LT. Using UNOS data for 17 710 LTs performed between 2002 and 2005, we assessed the relationship between recipient model for end-stage liver disease (MELD) score, organ quality as defined by donor risk index (DRI, Feng et al. 2005) and hospital length of stay (LOS). Single-center cost-accounting data for 338 liver transplants were then analyzed with a multivariate linear regression model to determine the estimated cost associated with a day of LOS. Overall, 8.4% of donor organs were classified as high risk (DRI > 2–2.5) and 1.9% as very high risk (DRI > 2.5). In the lowest MELD group (0–10), the LOS difference between 'ideal' donors (DRI < 1.0) and very high risk (DRI > 2.5) was 10.6 days which was associated with an estimated incremental cost of \$47 986. For patients with MELD > 35, the average LOS increased from 23.2 to 41.8 days when very high DRI donors were used, resulting in an estimated increase in cost of nearly \$84 000. We conclude that the use of marginal liver grafts results in increased hospital costs independent of recipient risk factors.

Key words: Donor risk index, economics, liver transplant, marginal donors

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Introduction

The cost of liver transplantation (LT) continues to rise as a result of current allocation systems for deceased donor organs that require that the 'sickest' be transplanted first, while reimbursement is static or declining leading to significant financial risk for the nation's transplant centers (1–5). Furthermore, despite a reduction in wait-list mortality following the implementation of model for end-stage liver disease (MELD), patients continue to die awaiting an organ leading to national efforts to expand access to transplantation through the utilization of 'marginal donors' (6). Over the past decade, the number of LTs performed using allografts from donors older than 65 has doubled (5% to 9.8%) and the use of organs from donors after cardiac death (DCD) is 10-fold higher (0.3% to 4.0%) (7).

While no exact definition of expanded criteria donors (ECD) exists for liver allografts as has been defined for renal allografts, it is widely appreciated that a variety of donor factors have been associated with worse outcomes. The donor risk index (DRI) described by Feng and colleagues is one measure of organ quality (8). The DRI incorporates multiple aspects of donor quality including age, cause of death, race, height and DCD; as well as organ specific factors: partial or split allograft, location (local, regional or national sharing) and cold ischemic time. Increasing DRI has been strongly correlated with decreasing graft and patient survival. While these 'marginal' organs can be successfully used in the proper patient, they are at higher risk of graft dysfunction, graft failure and potentially decreased patient survival (9–12).

Analysis of the impact of donor factors on cost of LT has been largely limited to assessment of donor age. Allografts from donors >60 years old have been associated with a significant increase in resource utilization (2). However, little data are available on the financial impact or other significant donor risk factors on the cost of transplant which are included in the DRI. Furthermore, while it is intuitively clear that the use of marginal organs in profoundly ill recipients is likely to increase transplant costs, this relationship has not been closely examined.

The purpose of this study is to estimate the financial impact of increased donor risk factors on resource utilization following LT. Because no large, universal data source includes both cost and clinical data, this analysis combines

cost-accounting data from a single academic medical center with national clinical and length of stay (LOS) data in order to estimate the impact of marginal donors on overall transplant cost.

Materials and Methods

Clinical outcome data

Clinical data for 17 710 liver transplants performed from 2002 to 2005 were analyzed using data from the United Network for Organ Sharing (UNOS). The following patients were excluded from this analysis: status 1 patients and live donor recipients. Donor data were abstracted and used to calculate the DRI as described by Feng et al. (8). Recipient data were used to determine the LOS posttransplant and to adjust for recipient characteristics in the multivariate model. The actual laboratory (calculated) MELD/PELD score was used in all analyses to assess the degree of physiological illness among transplant recipients.

Multivariate analyses were performed following the elimination of certain subgroups which might bias the analyses. Patients transplanted by MELD exemption were considered as one group at risk of higher than average costs given comorbid conditions (e.g. pulmonary hypertension). Because there is no specific variable for this group, patients were identified if their MELD score at transplant differed from their calculated MELD score by more than 1 standard deviation. This method identified 1016 potential recipients in this category, representing 5.7% of the total population. We also performed the multivariate analysis both with and without recipients of combined liver-kidney analyses and with and without adjustment for patient death within 30 days of transplant. Finally, we presented univariate data on DCD, split liver and donor following brain death (DBD) separately for both primary and retransplant recipients, respectively.

Statistical analyses, including one-way analysis of variance and chi-square analysis, were used to determine the impact of DRI and recipient characteristics on hospital LOS following transplant. LOS was defined as the duration of hospitalization from the day of transplant to the day of transplant discharge, excluding days prior to transplant. All MELD and DRI categories were determined *a priori* to reduce the risk of bias. The data were subsequently reanalyzed using a linear regression analysis to determine the independent impact of increasing DRI. To account for the natural right skew in LOS data, a logarithmic transformation was performed. All beta coefficients were then reconverted to allow easier interpretation. A variable was included for UNOS region to control for potential regional differences in the impact of organ quality. Unfortunately, center identified data were not available for use in this analysis.

Financial data

Hospital cost-accounting data were retrospectively reviewed for 338 consecutive adult liver transplant procedures performed at Northwestern Memorial Hospital from 2000 to 2005. Patients undergoing living donor transplants and those with fulminant hepatic failure were excluded from this analysis.

Patient and donor characteristics were determined from chart review and UNOS records for all patients. Cost-accounting data included all inpatient costs associated with the initial hospitalization. For the small number of patients retransplanted during their initial hospitalization, all costs were combined into a single analysis. Calculated MELD score was used in all analyses.

Multivariate linear regression was used to estimate the incremental cost of each additional day of LOS on overall hospital costs. Regressions were performed using both cost and logarithm of cost without significant differences in the resulting beta coefficient for LOS. Thus, the untransformed results are reported for ease of interpretation.

Combined analysis

The beta coefficient determined from the cost-accounting data was used as an estimate of the incremental resources associated with each additional day of hospitalization. This coefficient was then multiplied by the incremental LOS associated with very high DRI organs to estimate the incremental cost of utilizing these organs in recipients within given MELD strata.

IRB approval

This study was approved by the Institutional Review Boards of the Feinberg School of Medicine at Northwestern University and the Saint Louis University School of Medicine.

Results

National MELD and DRI results

Recipient characteristics for patients undergoing deceased donor LT are summarized in Table 1. High-risk recipients with MELD scores greater than 30 constituted nearly 20% of transplants performed. There were statistically significant differences in demographic characteristics (age, gender and race) of liver transplant recipients across MELD categories, although it is unlikely that these small differences were clinically significant.

Although the majority of donor organs fell into a low donor risk category, 8.4% of organs fell into a high-risk group with

Table 1: Characteristics of recipients by MELD category

	MELD category				
	0-10 (n = 836)	11-20 (n = 5291)	21-30 (n = 7528)	31-35 (n = 1430)	36+ (n = 1609)
Age (mean)	41.2 (21.8)	50.0 (13.7)	51.3 (12.4)	50.1 (12.9)	49.8 (11.2)
Male (%)	54.3	65.9	71.2	67.8	68.7
White (%)	75.8	79.6	72.8	67.2	64.1
Diagnosis					
Chronic liver disease	78.2	85.7	74.7	81.1	83.9
Malignancy	7.7	3.2	14.2	5.8	2.6

MELD = model for end-stage liver disease.

Table 2: Characteristics of donor organs by donor risk index category

	Donor risk index				
	0.0-1.0 (n = 1686, 11.5%)	1.0-1.5 (n = 7337, 50.0%)	1.5-2.0 (n = 4156, 28.3%)	2.0-2.5 (n = 1233, 8.4%)	2.5+ (n = 274, 1.9%)
DCD (%)	0.0	0.9	4.3	9.7	20.4
White (%)	99.5	71.9	65.9	52.3	38.7
Split (%)	0.0	1.1	4.7	3.2	2.2
Regional/National (%)	4.0	20.8	32.8	62.9	85.0
CIT (h)	7.3 (3.1)	7.6 (3.6)	7.9 (3.8)	8.5 (3.9)	8.9 (3.4)
Height (cm)	181.6 (6.1)	172.1 (10.8)	166.1 (16.2)	155.6 (28.6)	122.9 (46.8)

DCD = donation after cardiac death; CIT = cold ischemia time.

DRI between (2.0-2.5) and 1.9% into the very high-risk group with DRI greater than 2.5 (Table 2). These organs were more likely to come from non-white, DCD donors and split donors ($p < 0.001$). Other high-risk factors included a substantially greater number of regional or nationally shared organs ($p < 0.001$) with significantly longer cold ischemic time ($p < 0.001$). As shown in Figure 1, the high DRI organs were more likely to come from the extremes of age, either very young or very old. Over the period of this study, the percent of donor organs in the high-risk group (DRI > 2.0) was found to have increased over the period of analysis from 8.3% in 2002 to 12.8% in 2005 ($p < 0.001$), although LOS overall fell across MELD categories for patients receiving these DRI organs (Table 3).

As expected overall LOS increased as both recipient MELD score and donor DRI increased. This effect, however, was not confined to high MELD or high DRI organs. Nationally, increasing DRI organs were found to be associated with a significant increase in hospital LOS within each MELD group studied ($p < 0.001$) (Figure 2). The incremental LOS

associated between the best organs (DRI < 1.0) and the worst organs (DRI > 2.5) ranged from 10.6 days for patients with MELD score <10 to 18.6 days for the patients with MELD scores greater than 35.

The impact of DRI on hospital LOS remained largely consistent for various high-risk groups (Table 4-6). For DBD donors, in low MELD patients (<30), increasing DRI resulted in an extension of LOS from 12.7 days in low-risk donors to 28.1 days among the highest risk donors. The impact of DRI was even more profound in the high MELD patients (>30) in which very high DRI organs were associated with a doubling in the average LOS. For DCD donors, the DRI gradient was apparent only in the low MELD patients, perhaps reflecting the small number of DCD organs being used in high MELD patients. Finally, in patients undergoing retransplant, there was a dramatic increase in the LOS associated with very high DRI organs.

Multivariate regression analysis was then performed to assess the independent impact of increasing DRI on the

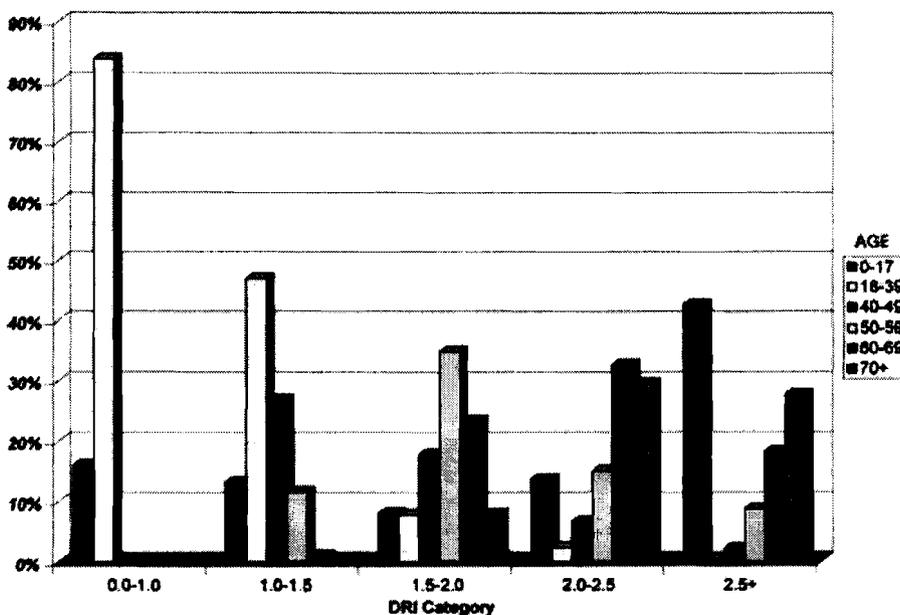


Figure 1: Donor age characteristics of liver donors as categorized by donor risk index score.

Table 3: Average length of stay (with DRI ≥ 2.0)

MELD category	Transplant year			
	2002 (n = 266, 8.3%)	2003 (n = 434, 10.2%)	2004 (n = 466, 10.2%)	2005 (n = 341, 12.8%)
0-10	26.3 (43.9)	20.5 (33.8)	14.5 (12.9)	13.0 (6.5)
11-20	21.2 (23.4)	16.4 (17.7)	18.6 (24.0)	16.4 (13.0)
21-30	23.3 (28.2)	21.8 (29.0)	20.6 (23.9)	16.4 (16.1)
31-35	34.4 (39.0)	19.9 (15.5)	28.2 (27.1)	26.0 (17.6)
36+	32.7 (27.3)	39.3 (50.7)	37.8 (47.0)	25.1 (23.0)

MELD = model for end-stage liver disease; DRI = donor risk index.

hospital LOS controlling for recipient characteristics and clustering by UNOS region (Table 7). As noted, patients transplanted by MELD exemption points other than HCC were excluded. In this analysis, when compared with donors with DRI 1.0–1.5, donors in the lowest risk group (DRI < 1.0) were associated with a 6.5% reduction in LOS ($p < 0.001$). In comparison, donors organs with a high DRI (2.0–2.5) were associated with a 9% increase in LOS and very high DRI donors (>2.5), which comprise the greatest risk, were associated with a 30% increase ($p < 0.001$ for both). The impact of this result was similar to that of female recipients and older recipients. These results did not differ when patients receiving a liver-kidney transplant were excluded nor when recipient death was included as an independent variable (data not shown).

Institutional cost analysis

The demographic characteristics of the 338 patients transplanted at single academic medical center were similar to national data. The average age was 53 years and 66% were

male. The mean calculated MELD score at transplant was 22, and 15% of the patients had MELD scores greater than 35. Forty-four percent were transplanted for HCC and 22% required combined liver/kidney transplants.

Donor characteristics also reflected national trends. The average age at donation was 37 years. A cerebral vascular accident was the cause of donor death in 26%, 9% died from anoxic injuries, while the remainder died as a result of trauma, CNS tumors or other causes. DCD donor livers represented 3% of the transplanted organs.

Average LOS in this population was 14 days. Multivariate analysis of perioperative hospital costs revealed three major cost drivers: hospital LOS, MELD score and a diagnosis of HCC. Overall, hospital costs were found to increase by \$4527 per day of LOS. MELD score was associated with an increase in cost of \$1138 per MELD point, while a diagnosis of HCC decreased hospital costs by \$9674. The reduction in the cost of care for HCC patients reflects their relatively improved physiologic status made possible by MELD upgrades for patients with this malignancy. Reestimation of the cost per day of transplant after the exclusion of patients receiving a combined liver/kidney transplant was minimally changed to \$4387 per day of LOS. In this data set MELD score was no longer predictive of overall cost once LOS was controlled for.

Combined analysis

To estimate the incremental cost of care associated with the use of high-risk organs, the incremental LOS associated with very high-risk organs (DRI > 2.5) and the increased cost of care associated with longer hospitalization were combined. As shown in Table 8, the estimated incremental costs associated with a longer LOS varied by MELD group studied. For low MELD patients, the organs with a DRI >2.5 compared to a DRI <1.0 can be expected to add nearly \$50 000 to the cost of the transplant. For high-risk recipients (MELD > 35), this incremental cost may be as much as \$84 000, which represents an increase of nearly 60% over the mean cost of transplant.

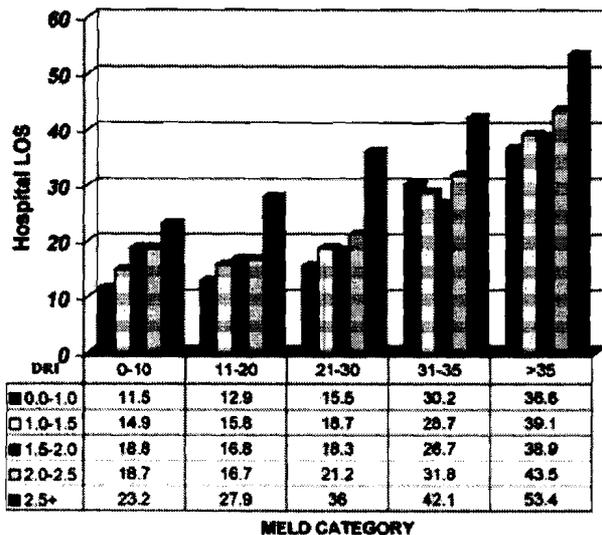


Figure 2: Relationship between the recipient model for end-stage liver disease score, liver allograft donor risk index and hospital length of stay among liver recipients transplanted from 2002 to 2005.

Discussion

LT remains the sole therapeutic option for patients with end-stage liver disease. Many patients continue to die from

Table 4: Impact of DRI on length of stay by transplant type (with and without previous transplant)

Transplant type	Donor risk index				
	0.0–1.0	1.0–1.5	1.5–2.0	2.0–2.5	2.5+
MELD 0–30					
DBD whole LT	12.7	14.4	15.9	16.9	28.1
DCD whole LT	–	13.7	17.4	19.0	–
Split LT	–	19.7	19.6	17.5	22.0
LKT (except DCD LKT)	18.3	16.9	16.7	38.6	–
MELD 31+					
DBD whole LT	21.6	24.0	22.7	29.9	42.1
DCD whole LT	–	37.4	24.3	26.6	7.0
Split LT	–	22.1	23.2	16.0	25.0
LKT (except DCD LKT)	20.4	22.0	33.5	26.0	–

MELD = model for end-stage liver disease; DBD = donation after brain death; DCD = donation after cardiac death; LT = liver transplant; LKT = liver and kidney transplant.

their illness while waiting for transplant, leading to important efforts to expand the number and use of available organs. Use of these organs can be expected to improve survival when used in appropriate patients (11,13,14). However, the cost of using marginal organs as defined by the DRI, appears likely to increase resource utilization, hospital LOS, and therefore, hospital costs. This trend is consistent across MELD categories and appears to increase with higher DRI.

Nationally, the severity of illness among patients reaching transplantation has been rising. Following the implementation of the MELD system of organ allocation, the number of recipients with a MELD score greater than 30 has increased from 10% to 14% (15). By transplanting patients most likely to die without a transplant, the MELD system has been very successful in achieving the goal of lowering wait-list mortality. Unfortunately, this rising severity of illness is also likely to increase the overall cost of LT, particularly in regions in which increased competition and demand for organs results in a higher MELD score at transplantation (1,5,16).

Although no exact definition exists for 'marginal liver grafts', clinical results utilizing donors with less than opti-

mal donors have been gratifying. While older donors were initially rejected, recent large series have reported excellent outcomes in the nonhepatitis C population (12,14,17). In the non-HCV group, there was no demonstrable difference in survival between older donor livers and standard livers. Likewise, in carefully selected patients, livers from DCD donors can also be used successfully (11). Mateo and colleagues recently reported that in 'low-risk patients', use of 'low-risk DCD livers' in which the cold ischemic time was less than 10 h and warm ischemic time is less than 30 min, resulted in equivalent graft and patient survival rates to standard livers (10). The authors argue for targeted use of this new source of donor livers. However, transplant centers may need to adjust their clinic practice to permit safe use of these organs (e.g. decreasing cold ischemic time). Other markers of high donor risk including positive viral serologies, a history of high-risk behavior or the presence of neurologic malignancy may also need to be considered as they are not captured using the DRI to define a 'extended' or 'marginal' liver.

Our analysis suggests that although excellent outcomes can be achieved with marginal liver allografts, the overall cost of this care is likely to be significantly higher. As has been shown in the kidney literature with ECD allografts, the use of marginal donors may increase the upfront

Table 5: Impact of DRI on length of stay by transplant type (primary transplants only)

Transplant type	Donor risk index				
	0.0–1.0	1.0–1.5	1.5–2.0	2.0–2.5	2.5+
MELD 0–30					
DBD whole LT	12.6	14.1	15.5	16.2	27.7
DCD whole LT	–	11.9	17.4	19.1	–
Split LT	–	19.7	18.6	17.0	22.0
LKT (except DCD LKT)	17.4	17.3	16.9	41.1	–
MELD 31+					
DBD whole LT	20.6	23.8	21.9	30.9	42.1
DCD whole LT	–	41.1	25.4	20.0	7.0
Split LT	–	22.1	23.3	16.0	25.0
LKT (except DCD LKT)	20.8	22.1	31.1	27.1	–

Table 6: Impact of DRI on length of stay by transplant type re-transplant recipients

Transplant type	Donor risk index				
	0.0–1.0	1.0–1.5	1.5–2.0	2.0–2.5	2.5+
MELD 0–30					
DBD whole LT	15.0	19.4	24.0	38.0	62.5
DCD whole LT	–	43.3	17.3	16.5	–
Split LT	–	20.0	54.5	22.7	–
LKT (except DCD LKT)	24.7	13.8	15.8	11.0	–
MELD 31+					
DBD whole LT	31.6	25.3	30.2	16.5	–
DCD whole LT	–	11.0	19.5	35.3	–
Split LT	–	–	22.3	–	–
LKT (except DCD LKT)	19.1	21.5	47.9	16.0	–

costs, as well as potentially increase the long-term cost of transplantation (18,19). In renal transplantation, increased costs reflect the prevalence of delayed graft function in the ECD organs (20). The cause of the longer LOS following LT demonstrated in this analysis is likely multifactorial.

Table 7: Multivariate regression analysis

Variable	% Increase in LOS	p-Value
DRI		
0.0–1.0	–6.5 (–10.3, –2.7)	<0.001
1.0–1.5	Reference	–
1.5–2.0	3.7 (0.9, 6.4)	0.009
2.0–2.5	9.0 (4.5, 13.4)	<0.001
2.5+	29.7 (20.7, 38.7)	<0.001
Recipient age (years)		
0–24	19.3 (13.5, 25.1)	<0.001
25–34	–2.9 (–10.0, 4.1)	0.417
35–44	3.2 (–0.8, 7.1)	0.116
45–54	Reference	–
55–64	7.7 (4.8, 10.5)	<0.001
65+	7.0 (2.7, 11.3)	0.002
Recipient gender		
Male	–8.4 (–11.0, –5.9)	<0.001
Female	Reference	–
Recipient race		
Black	–1.3 (–5.5, 2.8)	0.532
Other	Reference	–
MELD		
0–10	–12.4 (–18.0, –6.7)	<0.001
11–20	–13.4 (–16.1, –10.6)	<0.001
21–30	Reference	–
31–35	41.1 (36.9, 45.4)	<0.001
36+	77.6 (73.3, 81.8)	<.001
Cause of liver disease		
Cholestatic	Reference	–
Noncholestatic	5.0 (1.6, 8.5)	0.005
Metabolic	14.4 (7.9, 20.8)	<0.001
Malignancy	–18.9 (–23.9, –13.9)	<0.001
Other	20.6 (15.0, 26.2)	<0.001
Previous transplant		
Yes	19.8 (14.6, 24.9)	<0.001
No	Reference	–

DRI = donor risk index; MELD = model for end-stage liver disease; LOS = length of stay.

Marginal donors may have a higher incidence of primary nonfunction. This is particularly true of organs with longer ischemic times and those from anatomic variants. These grafts may also have primary dysfunction resulting in longer ICU stays, a greater requirement for blood products and resuscitation and increased risk of infection.

It is likely that this analytical approach underestimates the true incremental cost of the use of these high DRI organs. In their analysis, Feng and colleagues demonstrated that the use of organs with a DRI greater than 2.0, resulted in a reduction in 3-year graft survival of 20% (80% for DRI < 1.0 to 60% for DRI > 2.0) (8). This early graft failure will result in increased need for retransplantation which has dramatically increased cost compared to primary transplant procedures (21,22). Other high cost complications which occur with greater frequency with high-risk donors include biliary leaks in both DCD (23) and anatomic variant grafts (24), early aggressive recurrence of hepatitis C in older liver grafts (12) and higher incidence of kidney allograft failure among recipients of liver/kidney transplants from marginal donors (25).

Our analysis has several potential limitations. The use of hospital LOS, although highly correlated, is not a direct measure of true hospital costs. However, LOS has been found in previous reports to be an accurate reflection of resource utilization in LT (2). The use of institutional cost

Table 8: Estimated impact of highest DRI organs on overall hospital costs

MELD category	LOS (mean days)			Estimated increased cost
	Low DRI (0.0–1.0)	Highest DRI (2.5+)		
0–10	11.7 (7.2)	22.3 (38.1)		\$47986
11–20	12.2 (11.2)	26.0 (28.5)		\$62473
21–30	13.5 (14.0)	29.0 (35.0)		\$70169
31–35	19.5 (17.3)	33.3 (22.2)		\$62473
36+	23.2 (24.8)	41.8 (53.4)		\$84202

DRI = donor risk index; MELD = model for end-stage liver disease; LOS = length of stay.

data provides an estimate of the order of magnitude of the cost implications of the use of marginal donors. Furthermore, complicated cases that require longer operating times, more blood transfusions and a higher utilization of resources in general are likely to result in a longer LOS. Thus, we believe that LOS constitutes an excellent marker of clinical acuity and a reliable proxy for resource utilization. To more accurately estimate costs, a larger study including cost data from multiple institutions in a variety of regions including posthospitalization care would be needed to perform a more complete analysis. However, such studies are complex, expensive and rarely performed.

The second limitation is that the national data include results from a variety of centers, undoubtedly at varying positions along the learning curve in the use of marginal, and in particular DCD, organs. Clearly, there appears to be a national learning curve reflected in reductions in LOS observed across MELD and DRI categories over the course of the 5 years of this analysis. Recent data suggest that more experience and proper selection of DCD organs in particular may help to avoid many of the complications leading to high upfront cost (10,13,14). Whether or not the cost differential inherent in the use of these organs will diminish over time is an empirical question which can only be answered by further analysis as the use of these organs continues to grow.

Given that transplant center profitability is determined by the difference between reimbursement and cost, it is imperative that the economic impact of high-risk donors be considered in any financial evaluation of LT (26). Since the case rates which dictate transplant reimbursement often include organ acquisition costs, we propose that a consideration should be given to a discounted price from OPOs for marginal organs in general, and liver allografts with very high DRIs in particular, to avoid a serious financial disincentive for their use. Alternatively, reimbursement policies will need to be better correlated with donor and recipient risk so that they can be more aligned with cost.

In conclusion, expansion of the donor pool remains a vital activity for the entire transplant community. However, the success of the organ cooperative and other efforts to expand donation is likely to be limited if transplant centers are economically disadvantaged by the aggressive use of marginal organs. Currently, reimbursement is not indexed by the quality of the donor or, in general, the severity of illness of the recipient. We have demonstrated that both DRI and recipient MELD score are closely correlated with hospital costs. Therefore, public policy reform may be needed to ensure that transplant centers can continue to accept and utilize this new organ supply in increasingly sick recipients without incurring an undue economic burden.

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**CMS-1533-P-211 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Ellen Kugler

Date & Time: 06/08/2007

Organization : National Association of Urban Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-211-Attach-1.DOC

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

June 8, 2007

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

Attention: File Code CMS-1533-P

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) to express our views on the proposed rule governing the Medicare inpatient prospective payment system published in the *Federal Register* (Volume 72, Number 85, p. 24680) on May 3, 2007 ("Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates").

Specifically, we would like to comment on the aspects of the proposed rule governing the following areas:

- the Medicare DRG system
- DRG relative weights
- the standardized amount
- the outlier threshold
- post-acute transfers
- capital payments
- indirect medical education
- the rural floor for budget neutrality
- hospital-acquired conditions

We address each of these individual issues below.

The Medicare DRG System

(Issue Identifier: DRG Reform and Proposed MS-DRGs)

Ever since our founding, NAUH has called for the adoption of a severity-based DRG system for Medicare. Now, we are pleased that the Centers for Medicare & Medicaid Services (CMS) is moving in this direction and we are cautiously optimistic about the MS-DRG system that the agency now proposes. We would, however, like to raise two concerns.

First, we are concerned about the possibility that this new system could be an interim measure. As you know, last year CMS previewed a different severity-based system that it intended to introduce in FY 2008. When that proposal incurred significant opposition from the hospital industry, CMS subsequently hired a consultant, the RAND Corporation, to evaluate that proposal, study alternative severity-based DRG systems, and develop recommendations for future action. As of this writing, RAND still has not completed its work, creating the

possibility that the proposed MS-DRG system could be displaced after only one year. While NAUH continues to support the implementation of a severity-based DRG system, we believe it might be more appropriate to wait until RAND makes its final report before acting. Both for CMS and for hospitals, a great deal of work and change are associated with introducing a new DRG system, and we do not believe so much work should be undertaken for a system that may last only one year and leave us all in a position of needing to undertake a similar process next year. Thus, we believe a one-year delay, until RAND issues its report and CMS can evaluate that report and plan its next move with the benefit of its insights, would be more appropriate.

Second, we believe CMS should consider adopting a more robust severity-based DRG system than the proposed MS-DRGs. Last year's proposed system was a modified version of the APR-DRG system, and it elicited protest from the hospital industry in which NAUH participated. Despite this, NAUH has a very high regard for the APR-DRG system and does not necessarily believe it needed to be abandoned because it is more complicated to implement and because of the controversy surrounding its implementation. Because it is a more robust, accurate, and precise system – as RAND has noted its preliminary report – we are reluctant to see CMS abandon this superior system entirely before receiving RAND's final report and recommendations. While MS-DRGs would unquestionably represent a major improvement over the current Medicare classification system, we believe CMS can and should introduce a better, more robust system that better captures severity of illness and should continue exploring its options in the year ahead while awaiting RAND's final report.

DRG Relative Weights (Issue Identifier: DRGs: Relative Weight Calculations)

Prior to the current 2007 fiscal year, Medicare DRG relative weights were calculated using hospital charges. In its FY 2007 Medicare inpatient prospective payment system regulation, however, CMS unveiled a three-year transition from charge-based DRG relative weights to cost-based DRG relative weights. Accordingly, FY 2007 DRG relative weights are calculated based two-thirds on hospital charges and one-third based on hospital costs. FY 2008 DRG relative weights are to be based one-third on hospital charges and two-thirds on hospital costs. Finally, in FY 2009, DRG relative weights will be based 100 percent on hospital costs.

Last year, when CMS proposed moving away from charge-based relative weights in FY 2007 and at the same time indicated its desire to introduce a new severity-based DRG system in FY 2008, NAUH objected, maintaining that a new DRG system should be introduced simultaneously with a phased transition to calculating DRG relative weights based on hospital costs rather than hospital charges. We continue to believe this is the best approach.

For this reason, we have two perspectives on this issue.

First, if CMS implements the proposed MS-DRG system substantially as proposed, NAUH requests that the agency delay moving to the second year of the three-year transition from charge-based DRG relative weights to cost-based DRG relative weights and continue its approach to year one – DRG relative weights calculated based two-thirds on hospital charges and one-third on hospital costs – for another year. This request is based on our belief that the new DRG system should be introduced simultaneously with the beginning of a phased transition in the manner in which DRG relative weights are calculated. After FY 2008, the three-year phased transition then could proceed. Doing otherwise would have an especially damaging effect on urban hospitals because of their higher charge structures.

Second, if CMS does not implement the proposed MS-DRG system, NAUH also requests that the agency delay moving to the second year of the three-year transition. This request is based on our position that these new relative weights, when paired with the current DRG system, do not allocate Medicare resources to the

services that they would when those relative weights are paired with the proposed MS-DRGs. In fact, our analysis suggests that in many situations, they will allocate resources in opposite directions. Because urban hospitals have higher charge structures than rural hospitals, we believe urban hospitals have been harmed by the beginning of the three-year transition in FY 2007 and would be harmed even more in year two of that transition in FY 2008 and FY 2009 if the proposed MS-DRG system is not implemented.

**The Standardized Amount
(Issue Identifier: DRG Reform and Proposed MS-DRGs)**

In proposing a shift from the current Medicare DRG system to MS-DRGs, CMS also proposes reducing the annual Medicare inpatient update from the expected 3.8 percent to just 1.4 percent. The difference – 2.4 percent for each of the next two years – is characterized as a “behavioral offset” that reflects CMS’s expectation that through enhanced coding of Medicare claims under the new system, CMS will pay out approximately 4.8 percent more in Medicare inpatient claims in FY 2008 than it believes it should through the proposed MS-DRG system because this enhanced coding will increase hospitals’ case-mix indexes.

NAUH believes the size of this behavioral offset is arbitrary and overstated and that this is the case because it is based on recent experience in Maryland in which a one-rate payment system with few meaningful coding options was replaced by a DRG system with many more coding options. In the rest of the country, hospitals submit claims to many payers with different coding incentives, so they are more likely to have a history of submitting robust coding to Medicare. As a result, Maryland’s transition to a new classification system is not nearly as analogous to Medicare’s proposed transition from its current system to MS-DRGs as CMS suggests by proposing such a large “behavioral offset.”

In fact, NAUH questions the desirability of employing such an offset at all. When Medicare first introduced its prospective payment system, it did not propose a behavioral offset – nor did it do so when it introduced its inpatient rehabilitation prospective payment system. Instead, it made any necessary adjustments retroactively.

NAUH prefers retroactive adjustment because a behavioral offset the size that CMS proposes in this regulation brings with it a great deal of risk, and on the whole, we believe the federal government is far better equipped to shoulder such risk than individual hospitals. We especially believe this to be the case because in the proposed regulation, CMS notes that it does not intend to review this situation until data is available from FY 2008 and FY 2009, at which point it would consider possible adjustments for FY 2010 and 2011. If, as NAUH suspects, the proposed behavioral offset is too large, hospitals would be forced to suffer from that problem – and the losses it produces – for two or more years. This would be a considerable financial burden for them to bear, and for this reason, NAUH believes that the federal government, not hospitals, should assume the risks inherent in the implementation of MS-DRGs and make any necessary adjustments only *after* examining the impact of the new classification system.

If CMS insists on this behavioral offset, NAUH urges the agency to employ a much more modest offset. In addition, we ask CMS to supplement any such adjustment, large or small, with more timely analysis and specific regulatory provisions for retroactive adjustments and reimbursement to hospitals if that analysis reveals that hospitals have in any way been shortchanged as a result of that adjustment.

The Outlier Threshold
(Issue Identifier: DRG Reform and Proposed MS-DRGs)

NAUH is pleased that CMS proposes reducing the Medicare outlier threshold from the current \$24,475 to \$23,015 in FY 2008. Reducing the threshold is, in our view, entirely appropriate – but we also think it could be reduced even more. Medicare outlier payments are supposed to amount to between five and six percent of inpatient payments a year, but they have not done so for a number of years. Even this year, outlier payments are only on target to account for about 4.9 percent of inpatient claims. This failure to meet the congressionally mandated target penalizes some hospitals – especially hospitals that provide the kinds of services that are most likely to result in outlier cases. To a significant degree, we believe it has penalized large, non-profit urban safety-net hospitals over the years because typically, these are the very hospitals that provide such services – they provide them despite knowing they will lose large amounts of money and they provide them because they know their communities needs these services and that if they do not provide them, no one else will. In all the years in which outlier payments have failed to meet their congressionally mandated threshold, moreover, no effort has been made to reconcile the shortfall of outlier payments to hospitals and reimburse hospitals for the losses they suffered because that threshold had not been reached. NAUH continues to believe that all hospitals should help pay for outlier care, not just those that provide the services usually associated with outliers, and that the best way to ensure this is to reach the congressional goal for outlier payments each and every year.

NAUH recognizes that the introduction of the proposed MS-DRG system poses a new challenge for CMS. Because this system will more precisely account for severity of illness, it is more likely to capture some claims that previously became outliers. This most likely contributed to CMS's decision to lower the outlier threshold. To ensure that Medicare pays out at least five percent of its inpatient claims as outliers, however, NAUH urges CMS to lower the outlier threshold even further so that, for the first time in many years, Medicare will reach Congress's target for outlier payments and the financial damage suffered by hospitals that provide the kind of services that typically become outlier cases can be reduced to a more reasonable level.

Post-Acute Transfers
(Issue Identifier: DRG Reform and Proposed MS-DRGs)

Several years ago, CMS introduced new criteria for determining which DRGs would be subject to its post-acute transfer policy. It then evaluated all DRGs according to those criteria and published a list of those to which the policy would apply. With the implementation of MS-DRGs, CMS proposes starting this process over, evaluating all of the new MS-DRGs according to those criteria.

NAUH has misgivings about the timing of this planned reassessment. In the absence of solid data and experience under the new MS-DRGs, we fear that the policy could have a damaging effect on the financial health of hospitals by inappropriately limiting their Medicare payments in too many cases. In fact, we believe the proposed approach could have as significant an impact on hospital finances as the proposed MS-DRGs and the reduced increase in the standardized amount.

Consequently, instead of the proposed approach, NAUH urges CMS to suspend application of the post-acute transfer policy for one year, until sufficient data is available, and then apply the criteria anew to the MS-DRGs. Alternatively, we encourage CMS to limit the application of the rule as much as possible, until better data is available, and at least not increase the average length of stay for less-complicated DRGs over their current levels.

Capital Payments
(Issue Identifier: Capital IPPS)

In the proposed regulation, CMS proposes two capital payment policies that would hurt urban safety-net hospitals and lays the groundwork for two future policy changes that would similarly affect urban hospitals.

Proposal for No Capital Update for Urban Hospitals in FY 2008

CMS proposes providing no annual update for capital payments for urban hospitals in FY 2008; on the other hand, it proposes a modest update for capital payments for rural hospitals. This is based on the agency's conclusion that the Medicare capital margins of urban hospitals are "relatively high" and that this could be because "the updates to the capital IPPS rates have been higher than the actual increases in Medicare inpatient capital costs that hospitals have experienced in recent years" or because "the payment adjustments under the system are too high." The proposed regulation also does not explain why rural hospitals should receive an update even though their apparently lower capital margins often can be explained by the conversion of many rural hospitals to critical access hospital status in recent years.

NAUH disagrees strongly with this proposal. The capital demands that urban hospitals face are greater than ever. Many of these hospitals are located in older buildings that no longer can overcome the ravages of time or meet the demands of modern technology, so they must be substantially renovated or replaced; they must constantly purchase and update technology to keep up with the state of the art in health care; and they now face a growing demand – much of it from Medicare itself – to invest millions of dollars in new information technology systems to meet the continuing call for patient record interoperability and the regular reporting of data regarding how they deliver care and other patient safety- and quality-related information. With so many of these information technology demands coming from the public sector, NAUH believes it is inappropriate for the public sector to demand more of hospitals and then turn around and give them fewer resources with which to attempt to meet those demands. Medicare is a major payer – and for many urban safety-net hospitals, their biggest and most important payer – and Medicare should not reduce its financial commitment to doing its part to meet the capital needs of hospitals at the same time that it is making growing capital demands of those hospitals.

Proposal to Eliminate the Large Urban Hospital Capital Add-On

In the same regulation, CMS proposes eliminating, effective FY 2008, the three percent supplemental Medicare capital payment it has long provided to large urban hospitals – the so-called large urban capital add-on. Large urban hospitals currently receive these funds because the federal government recognizes that such institutions have greater capital and infrastructure needs than the average American hospital. That has not changed: their capital and infrastructure needs remain greater, large urban hospitals still need these funds, and for the same reasons noted above, NAUH opposes this proposal and urges CMS not to discontinue the large urban add-on.

NAUH believes it is inappropriate to attempt to look at the Medicare capital margins of hospitals in isolation because such a narrow perspective yields an extremely narrow view. As MedPAC noted in its March report to Congress, "Hospitals with consistently lower Medicare margins over the last three years tend to have higher private payer payments and thus are under less pressure to control costs." This observation strongly suggests that the hospitals that are most dependent on Medicare revenue, and on Medicare supplemental payments, do the best job of controlling their costs – in other words, behaving precisely as Medicare would like them to behave.

By any reasonable measure, the financial performance of large urban hospitals in recent years has been worse than that of any other group of private hospitals in the country – and far worse, clearly worse, and definitively worse than that of rural hospitals. Private, non-profit urban hospitals, and especially large urban hospitals, are a vital part of the health care safety net in the U.S. today. They care for more Medicare patients than the other private hospitals around them, they care for more Medicaid patients than the other private hospitals around them, and they care for more uninsured patients than the other private hospitals around them. They offer the services their communities need even when some of those services cannot possibly make money, and in fact lose substantial amounts of money, doing so because the residents of their communities desperately need those services – and this is reason enough for these mission-driven institutions. They are the institutions to which other hospitals turn with their most complex cases, they are the destinations for most medical helicopters transporting sick and injured people, and they are the providers of last resort for many urban Americans with few, if any, health care alternatives. Depriving them of a modest annual update, and then adding to that the elimination of the large capital add-on, would unquestionably cause financial harm to these hospitals, many of which already are in considerable financial jeopardy. This, in turn, would jeopardize their ability to treat the many elderly and low-income patients who turn to them for care. NAUH urges CMS to reconsider these proposals and to reverse them.

Invitation to Comment on Possible Elimination of IME and DSH Capital Adjustments

The proposed regulation states that CMS intends to reevaluate the merits of continuing to make indirect medical education (IME) and disproportionate share hospital (DSH) adjustments to capital payments, again citing the Medicare capital margins of the affected hospitals and suggesting that such adjustments could be reduced or eliminated. NAUH disagrees with this notion as well – for the same reasons we oppose eliminating the FY 2008 update and the large urban add-on. Hospitals with medical education programs, and that qualify for DSH payments, typically treat more Medicare patients, more Medicaid patients, and more uninsured patients than other hospitals. They also tend to be the hospitals that provide the most advanced types of care – the hospitals to which other hospitals send their most difficult cases. Medicare needs these hospitals – needs them to provide the care that other hospitals cannot, needs them to care for the Americans for which the federal government has assumed a measure of responsibility for their health care, and needs them to serve as a vital part of the health care safety net in low-income urban communities throughout the country. Taking away the resources these hospitals need, and upon which they have come to rely, to fulfill these important roles is not a way to ensure their continued existence, ensure their continued availability to serve the sickest of the sick, ensure that they continue caring for Medicare recipients, or ensure that the safety net is preserved. NAUH hopes CMS will recognize this by maintaining the current level IME and DSH adjustments to Medicare capital payments in the future.

Indirect Medical Education (Issue Identifier: IME Adjustment)

The proposed regulation seeks to clarify accounting for medical residents' time by declaring that hospitals cannot include residents' vacation and sick time in their FTE calculations. NAUH opposes this proposal: we believe the amount of work needed to implement this change, which accounts for a very minor portion of residents' time, does not justify the effort or the potential savings. The cost of tracking this information, we believe, will exceed the potential savings, so NAUH urges CMS to withdraw this provision from the proposed regulation.

**Rural Floor for Budget Neutrality
(Issue Identifier: Wage Index)**

In the proposed regulation, CMS states that it will offset future increases in the rural floor by reducing hospitals' wage index. This represents a major change in policy: for years, Medicare has offset increases in the rural floor by reducing the standardized amount.

NAUH opposes this change. The proposed regulation does not explain why this change is being proposed, what CMS seeks to accomplish with this change, or what impact this change would have on hospitals. In the absence of such explanations and analysis, NAUH urges the agency to maintain the current, long-time approach to offsetting increases in the rural floor.

**Hospital-Acquired Conditions
(Issue Identifier: DRGs: Hospital-Acquired Conditions)**

NAUH supports CMS's efforts to use Medicare reimbursement as a tool for improving accountability for hospital performance and generally endorses the proposals set forth in the proposed regulation. We do, however, have one concern: on occasion, the hospital that treats a hospital-acquired condition is not necessarily the hospital that caused that condition. In such cases, we believe the hospital treating a condition that a patient acquired at another hospital should be paid appropriately for its efforts.

While we are not sure such circumstances could arise, NAUH wants to make certain that CMS has considered this possibility. For example, if an object left in a patient during surgery is later removed in the same hospital in which the original surgery took place, the proposed regulation should definitely apply. If, however, the patient becomes ill after being discharged from the hospital and subsequently goes to another hospital, where the item left in the patient is discovered and removed, this second hospital should be paid appropriately because it is helping restore the patient's health and is correcting a problem created at another hospital. NAUH urges CMS to recognize this in the proposed regulation and ensure that hospitals that identify and correct the failures of others are not financially penalized for their good work.

* * *

We appreciate your attention to our comments and welcome any questions you may have about them. We also are prepared to meet with CMS officials, if you so desire, to explain our views further and to offer our suggestions for how this process might proceed in a productive manner.

Sincerely,

Ellen J. Kugler, Esq.
Executive Director

**CMS-1533-P-212 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. James T. Kirkpatrick

Date & Time: 06/08/2007

Organization : Massachusetts Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-212-Attach-1.DOC



Massachusetts Hospital Association

June 8, 2007

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

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

Dear Ms. Norwalk:

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed rule for the FY 2008 Inpatient Prospective Payment System (IPPS). We must express our serious concern with the proposals in the rule, particularly the provisions pertaining to the behavioral offset, the Diagnosis Related Groups (DRG) expansion; the wage index changes, and the capital large urban add-on.

Proposed Changes to the DRG Classification System and Behavioral Offset

The proposed changes to the DRGs classification system through the addition of "major complication and comorbidity" DRGs (called Medicare-Severity DRGs or MS-DRGs) are of deep concern. A rationale for the adoption of this new system is CMS's belief that it will allow Medicare to better recognize the complexity of cases and adjust payments accordingly. However, preliminary analysis of the estimated impact on Massachusetts hospitals - which deliver a high volume of care in very complex cases - indicates that the MS-DRG system will reduce Medicare reimbursement to the majority of hospitals in the state. Such an outcome would appear to run counter to expectations under a system designed to better align payments with level of care and would seem to indicate that there is still work which needs to be done to fine tune payments under the new system.

The table below summarizes the analysis:

Table with 3 columns: Hospital Type, Percent negatively impacted by move to MS-DRGs, Average Change in Case Mix due to MS-DRGs. Rows include Major Teaching Hospitals, Community Hospitals, and All Hospitals.

Our analysis indicates that the MS-DRG system will result in a decrease in reimbursement to Massachusetts hospitals of over \$36 million in operating payments alone in 2008. It is incomprehensible that CMS is proposing a change in the DRG

classification system that will have such a huge negative impact without any transition or hold harmless provisions AND *at the same time*, proposing a behavioral offset that will further decrease payments to Massachusetts hospitals by **\$67 million** in 2008. In fact, the combined impact of the DRG, behavioral offset, wage index and capital proposals in the rule will result in ***an absolute decline in payments*** to hospitals in the state of over \$23 million, even after the inflationary update is applied. With these draconian impacts, it is clear that the proposals must be revised.

We believe that the MS-DRG system should only be implemented after CMS has sufficiently tested it and studied the results and unintended consequences. At a minimum, a four-year transition period should be provided and until CMS can document and demonstrate that any increase in case mix results from changes in coding practices rather than real changes in patient severity, ***there should be no behavioral offset.*** We believe that CMS's stated rationale for the behavioral offset is flawed. It is CMS' belief that, with implementation of the MS-DRG system, hospitals will change their coding behavior. However, hospitals which have more than two decades of experience with the DRG system are already highly efficient in their coding practices. Most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding CCs at high rates for many years. Hospitals' assumed ability to use even more CCs under MS-DRGs is very low.

We believe it is unrealistic to forecast the types of changes in coding behavior anticipated by CMS and ***certainly unjustified to prospectively impose cuts of this magnitude, without the benefit of directly relevant empirical justification.***

Revisions to the CC List:

It is our understanding that a condition was included on the revised CC list if it could be demonstrated that the presence of the condition would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). However, the AHA has shared with us the results of their efforts to perform a meaningful review of the revised CC list, and like the AHA, we disagree with the removal of many common secondary diagnoses. Specifically, it is unclear what threshold levels were used and at what point in the analysis the CCs were removed. For example, what was considered "intensive monitoring"? Does intensive monitoring refer to additional nursing care on a daily basis, additional testing, intensive care unit care, extended length of stay, all of these factors, or some other factor? In some instances, similar or comparable codes within the same group have remained a CC/MCC, while other clinically similar codes or codes requiring similar resources may have been omitted. Without greater transparency, and a code-by-code explanation, we are unable to determine why significant secondary diagnoses requiring additional resources have been removed from the CC list. We urge CMS to consider the hospital industry's recommendations with regard to the CC list:

- **CMS should make the final revised CC list publicly available as quickly as possible** so that hospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.
- **CMS should consider additional refinements to the revised CC list** and, in particular, address issues where the ICD-9-CM codes may need to be modified to provide the distinction between different levels of severity.
- **In situations where a new code is required, CMS should default to leaving the codes as CCs until new codes can be created.**

Proposed Changes to the Hospital Wage Index:

The rule proposes several wage index changes that are of significant importance to Massachusetts: the discontinuation of the imputed rural floor, the allocation of a multi-campus hospital's wage data between campuses, the conversion prohibition of critical access hospitals to PPS under certain circumstance, and finally the proposed change in the calculation of the outmigration adjustment, which impacts Middlesex, Essex, and Worcester counties. We have joined our hospitals in numerous calls with CMS officials that past year to discuss these issues and are disappointed to see the proposed rule. Particularly in the case of the critical access conversion, the rule appears to be written solely to prevent Massachusetts institutions from doing what is allowed elsewhere nationwide.

Conversion of CAH to PPS:

MHA has major concerns about CMS' one-sided presentation and with CMS' unprecedented and, we believe, erroneous, assertion of its statutory authority on this issue. We are submitting comments on this matter in a separate letter.

Wage Index for Multi-Campus Hospitals:

MHA appreciates CMS' presentation of this critical issue and proposals for handling it. We are submitting comments and contingent alternative proposals in a separate letter.

Contiguous Rural Floor

In the final rule for 2007, CMS put in place a provision whereby the data from a "new rural hospital" that opens up in a previously all-urban state, either as an entirely new facility or a Critical Access Hospital (CAH) converting to PPS would not be included in the wage index *until four years later*. In the meantime, the hospital would be paid at a wage index level which might well have no relationship whatsoever to its actual cost experience. The hospital may very well as a result suffer Medicare under-reimbursement losses for four years, and might even close, before CMS will consider paying the hospital with an appropriate wage adjustment. We unsuccessfully urged CMS to reconsider this proposal last year and to include the new hospital's data in the wage index as soon as a full year's cost report with the hospital operating as a PPS hospital is available. *We*

continue to believe that the 4 year lag in wage data inclusion is unfair, inconsistent and unnecessary and urge CMS to reverse this policy.

Failing that, ***MHA strongly supports the use of a contiguous rural floor in cases where a new rural hospital that opens in an area where there was previously no PPS hospital and hence no wage data available to base the rural wage index on. We believe that the contiguous rural wage index is at least an acceptable alternative. This is because it takes into account the wage levels of hospitals that are in contiguous areas and with which the “new” hospital will have to compete for labor.***

Proposed FY 2008 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees.

The MMA required that CMS develop an adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index. Qualifying hospitals were to receive an adjustment to their wage index based on the percentage of county residents who commute to the other area. Hospitals in Middlesex, Essex and Worcester Counties in Massachusetts were eligible for the outmigration adjustment in 2005, 2006 and 2007. But the proposed rule deems Worcester County hospitals ineligible for the adjustment in 2008 onwards. The reason for this is a change in the way the adjustment is determined:

In the proposed rule, CMS states that the “out-migration adjustment should be determined using the *post-reclassified wage index that reflects the budget neutrality adjustment for application of the rural floor*” (emphasis added). We are confused by the use of the term “post reclassified”: if CMS, by this term, means a wage index that all final adjustments including the rural floor budget neutrality adjustment (as implied in the proposed regulation) we have no argument with this. However, if CMS intends by this to justify determining the adjustment using diluted reclassified wage index values for comparison purposes, we feel that CMS has missed a fundamental element of the outmigration adjustment:

As a concrete example, hospital workers from Worcester County, Massachusetts (average hourly wage 35.1528) commute to the Boston-Quincy CBSA in order to take advantage of the higher wages prevalent in the *core* Boston-Quincy CBSA (average hourly wage 36.2971). For 2008, hospitals in Essex, Middlesex, Worcester and Bristol counties are eligible for reclassification to the Boston-Quincy CBSA and to receive the “diluted” reclassified Boston-Quincy wage index (1.1256) which is much lower than the core Boston-Quincy wage index (1.1710). Naturally, the underlying commuting patterns from Worcester County to the Boston-Quincy *core* area remain. But the proposed rule deems Worcester County hospitals ineligible for the outmigration adjustment in 2008 onwards because it compares the “core” Worcester CBSA wage index to the diluted reclassified Boston CBSA wage index (which is an average of the wage levels of Boston PLUS all the reclassified counties), instead of the “core” adjusted Boston CBSA wage index,

On page 28267 of the proposed inpatient PPS rule for 2005, CMS described the implementation of the wage index out- commute (outmigration) adjustment requirement

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We believe, and CMS appears to agree, based on its statement in the 2005 proposed rule (above) that the commuting adjustment is to be based on comparison of “core” wage indices of the resident county to “core” wage indices of the work county. By switching to using the diluted reclassified Boston Quincy wage index for determining eligibility, CMS is comparing the Worcester wage index of 1.1341 to the diluted Boston-Quincy wage index of 1.1256 and has deemed Worcester County hospitals ineligible for the adjustment. ***This is clearly a complete mismatch which ignores underlying labor market realities and certainly violates the spirit of the Section 505 provisions of the MMA. We recommend that CMS continue to use the core wage index of the CBSA rather than the diluted wage index in computing these adjustments.***

In other words, we believe that the wage indices in Table 4A of the proposed rule: Wage Index and Capital Geographic Adjustment (GAF) for Urban Areas by CBSA are adjusted for rural floor budget neutrality (per CMS’ requirement) and CMS should use the “core” Boston-Quincy CBSA wage index and the “core” Worcester CBSA wage index as a basis for determining the amount of, and eligibility for, the out-commute adjustment. Further, if CMS uses the pre-reclassification wage index, a special provision to allow an extension of time for additional possible terminations of wage indexes reclassification as a result of the re-computation for FFY 2008 out-migration adjustments is needed.

Application of Rural Floor Budget Neutrality. For the first time CMS is proposing to reverse the prior years Budget Neutrality Adjustment for the impact of the Rural Floor provisions on the Wage Index pursuant to Section 4410 of the Balanced Budget Act of 1997. This is an adjustment that has needed to be made for several years and we agree with the concept of making this adjustment for Federal Fiscal Year 2008.

CMS proposes to make this adjustment as a part of the Wage Index Calculation, rather than the traditional methodology of adjusting the standardized amount. However, as proposed in the Rule CMS has bifurcated this adjustment and is proposing to add back the effect of the prior years Rural Floor Adjustment in a standardized amount adjustment in the amount of 1.002214 (see Page 24839 of the May 3, 2007 Federal Register). It is not clear if this 1.002214 is a single year’s budget neutrality adjustment (for FFY 2007) or if this adjustment is to correct the cumulative adjustment of the prior years’ adjustments from FFY 1999 through FFY 2007. We ask that CMS quantify the computation of this adjustment by year for each year from FFY 1999 through FFY 2007 to allow for the testing of the reasonableness of the CMS calculations.

Additionally, on Page 25123 of the above-referenced Federal Register the effect of the FFY 2008 Rural Adjustment of .997084 which CMS proposes to adjust through the wage index is included in the footnotes to Table I. In the calculations of the wage indexes, CMS has inflated the national average hourly wage in order to re-compute wage indexes and apply the FFY 2008 portion of the Budget Neutrality Adjustment (the negative portion of the adjustment) even though the prior year's positive adjustment is made to the standardized amount. As CMS noted in the Proposed Rule, this affects hospitals with a wage index of lower than 1.0000 differently than it affects hospitals that have a wage index of 1.0000 or more because the labor related share is only .62 for the lower wage indexes compared to .697 for the wage indexes of 1.0000 and higher.

Further, CMS provides no justification as to why CMS proposes to make half of the budget neutrality adjustment in the wage index. *This treatment creates a further complication of the already difficult computation of the wage index* – and further reduces transparency. We ask CMS to report the amounts of the Rural Floor Standardized Amount Adjustments from 1999 through 2007, as well as provide the amount of the adjustment applicable to FFY 2008. In the interest of promoting further transparency, these adjustments should be fully explained and the prior year adjustments should be enumerated for each year in making the cumulative adjustment that is needed to correct prior inequities.

Work Sheet S-3 Wage Data for the Proposed FY 2008 Wage Index.

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

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

Imputed Rural Floor

CMS is proposing to discontinue the Imputed Rural Floor provision since they “do not believe that it is necessary to have an imputed rural floor in States that have no rural areas

or no rural hospitals”. This clearly contradicts the rationale in the Proposed Inpatient PPS rule for 2005 which noted that hospitals in these states (i.e. states without rural areas or rural hospitals) are disadvantaged by the absence of a rural floor. Given that the original rationale for imputing the rural floor still holds true, it is not too surprising that hospitals that benefit from it were counting on the provision being continued for another 3 years. Such flip-flopping on the part of CMS has serious consequences for hospitals operating in these difficult times, struggling to balance budgets and provide the best possible care to beneficiaries.

The loss of the imputed rural floor in Massachusetts will result in a drop in Medicare reimbursement to eight western Massachusetts hospitals of over \$8 million, or an average of 3.9% of their Medicare inpatient and outpatient revenue. Swings in reimbursement of this magnitude should be minimized in a *prospective* payment system. ***At the very least, the imputed rural floor should be phased out over 2 years to cushion the negative impact.***

We also disagree with CMS’ stance that one of our hospitals has converted to rural using the provisions of 42 CFR 412.103 and hence Massachusetts is no longer eligible for the imputed rural floor. This is inconsistent with the fact that hospitals subject to the rural floor in Connecticut are *held harmless* from the conversion of one of their hospitals to rural status using the same provision (42 CFR 412.103). If the imputed rural floor is equivalent to the rural floor, then the former should be subject to the same hold harmless provisions as the latter.

Proposed Changes to Capital Payments:

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

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. According to MedPAC, overall Medicare margins will reach a 10-year low in 2007 at ***negative*** 5.4 percent. With overall Medicare margins decreasing, hospitals have been forced to subsidize operating losses with money that should otherwise be devoted to capital – leading to a shortage of investment into IT and other capital needs. As average age of plant increases and hospitals continue to put off capital investments in order to maintain everyday operations, the need for adequate capital funding will increase – not decrease.

Reducing capital payments would create significant financial difficulties and amounts to Medicare renegeing on the full cost of caring for America’s seniors and disabled. These changes in capital payments would make it much more difficult for hospitals to enhance clinical innovation and cutting edge research, to purchase advanced technology, to further advance health information technology, and to adjust for rising energy costs by

converting to more fuel efficient systems. Hospitals make long-term commitments to capital acquisitions and this proposal clearly falls into the category of penny-wise and pound foolish. Pulling the rug out from under the financial obligations to maintain and improve their physician facilities will only cost more in the long run and undermine patient needs.

We strongly oppose the proposal to freeze capital payments made to large urban hospitals and the elimination of the 3 percent large urban add-on for capital. MHA also opposes possible future cuts to the IME and DSH adjustments under the capital system. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications.

Hospital Acquired Conditions

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

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

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

Conditions to include for FY 2009. MHA believes that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. Massachusetts' hospitals are committed to patient safety and strive to ensure that these events do not happen.

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

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

Quality and Safety Provisions

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

New quality measures.

We applaud CMS' actions to propose only adding new measures in FY 2009 that are adopted by the Hospital Quality Alliance and endorsed by the National Quality Forum and urge that future measure additions meet the same conditions. We also endorse the advance notice of plans for FY 2009 with the lead time provided in this proposed rule and urge that this timely advance notice be provided for future additions to measurement and reporting requirements.

The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality – hospitals, purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment. The measures proposed for FY 2009 are well-designed, represent aspects of care that are important to patients, and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors.

Because we believe that all measures for public reporting should be adopted by the HQA, endorsed by the NQF and tested in the field before implementation, we have concerns with some measures listed by CMS for possible implementation for FY 2009 or subsequent years because they do not fulfill these criteria. We urge CMS to carefully evaluate the value of the measures considered for reporting. Measures should be evidence-based, contribute to the comprehensiveness of performance measurement, be under a hospital's control and account for potential unintended consequences. We urge CMS only to propose and select measures that meet all of these conditions. **If the measures are NQF-endorsed and HQA-adopted, CMS can be assured that they meet these conditions. Therefore, CMS should only choose measures that have been selected by these two groups.**

The NQF currently is developing national quality goals. **We believe that CMS should look to the NQF goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should indicate its intent to follow the national goals as well.

We commend CMS for including in the proposed rule the measures that hospitals will be required to report to receive their full FY 2009 inpatient payments, as this early notice allows hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking to notify hospitals of the reporting requirements for the next fiscal year.**

IME Adjustment

In the FY 2007 final rule, CMS finalized a policy to exclude residents' time spent in non-patient care activities from the resident count for purposes of IME (in all settings) and direct graduate medical education (in non-hospital settings) payments. Under the

proposed rule, vacation and sick time would be removed from the total time considered to constitute an FTE resident. Thus, it would be removed from both the numerator and denominator of the FTE calculation.

MHA appreciates CMS' efforts to clarify its policies, and its attempt to not penalize hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through. **We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count.** We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor affects, nationally speaking, while having major implications at the individual hospital level.

We hope you will give serious consideration to the concerns we have outlined. Thank you for your attention to these important issues.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Kirkpatrick". The signature is fluid and cursive, with a large initial "J" and "K".

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care

**CMS-1533-P-213 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. James T. Kirkpatrick

Date & Time: 06/08/2007

Organization : Massachusetts Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1533-P-213-Attach-1.DOC



Massachusetts Hospital Association

June 8, 2007

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

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

Dear Ms. Norwalk:

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed rule for the FY 2008 Inpatient Prospective Payment System (IPPS). We must express our serious concern with the proposals in the rule, particularly the provisions pertaining to the behavioral offset, the Diagnosis Related Groups (DRG) expansion; the wage index changes, and the capital large urban add-on.

Proposed Changes to the DRG Classification System and Behavioral Offset

The proposed changes to the DRGs classification system through the addition of "major complication and comorbidity" DRGs (called Medicare-Severity DRGs or MS-DRGs) are of deep concern. A rationale for the adoption of this new system is CMS's belief that it will allow Medicare to better recognize the complexity of cases and adjust payments accordingly. However, preliminary analysis of the estimated impact on Massachusetts hospitals - which deliver a high volume of care in very complex cases - indicates that the MS-DRG system will reduce Medicare reimbursement to the majority of hospitals in the state. Such an outcome would appear to run counter to expectations under a system designed to better align payments with level of care and would seem to indicate that there is still work which needs to be done to fine tune payments under the new system.

The table below summarizes the analysis:

Table with 3 columns: Hospital Type, Percent negatively impacted by move to MS-DRGs, Average Change in Case Mix due to MS-DRGs. Rows include Major Teaching Hospitals, Community Hospitals, and All Hospitals.

Our analysis indicates that the MS-DRG system will result in a decrease in reimbursement to Massachusetts hospitals of over \$36 million in operating payments alone in 2008. It is incomprehensible that CMS is proposing a change in the DRG

classification system that will have such a huge negative impact without any transition or hold harmless provisions AND *at the same time*, proposing a behavioral offset that will further decrease payments to Massachusetts hospitals by **\$67 million** in 2008. In fact, the combined impact of the DRG, behavioral offset, wage index and capital proposals in the rule will result in ***an absolute decline in payments*** to hospitals in the state of over \$23 million, even after the inflationary update is applied. With these draconian impacts, it is clear that the proposals must be revised.

We believe that the MS-DRG system should only be implemented after CMS has sufficiently tested it and studied the results and unintended consequences. At a minimum, a four-year transition period should be provided and until CMS can document and demonstrate that any increase in case mix results from changes in coding practices rather than real changes in patient severity, ***there should be no behavioral offset.*** We believe that CMS's stated rationale for the behavioral offset is flawed. It is CMS' belief that, with implementation of the MS-DRG system, hospitals will change their coding behavior. However, hospitals which have more than two decades of experience with the DRG system are already highly efficient in their coding practices. Most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding CCs at high rates for many years. Hospitals' assumed ability to use even more CCs under MS-DRGs is very low.

We believe it is unrealistic to forecast the types of changes in coding behavior anticipated by CMS and ***certainly unjustified to prospectively impose cuts of this magnitude, without the benefit of directly relevant empirical justification.***

Revisions to the CC List:

It is our understanding that a condition was included on the revised CC list if it could be demonstrated that the presence of the condition would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). However, the AHA has shared with us the results of their efforts to perform a meaningful review of the revised CC list, and like the AHA, we disagree with the removal of many common secondary diagnoses. Specifically, it is unclear what threshold levels were used and at what point in the analysis the CCs were removed. For example, what was considered "intensive monitoring"? Does intensive monitoring refer to additional nursing care on a daily basis, additional testing, intensive care unit care, extended length of stay, all of these factors, or some other factor? In some instances, similar or comparable codes within the same group have remained a CC/MCC, while other clinically similar codes or codes requiring similar resources may have been omitted. Without greater transparency, and a code-by-code explanation, we are unable to determine why significant secondary diagnoses requiring additional resources have been removed from the CC list. We urge CMS to consider the hospital industry's recommendations with regard to the CC list:

- **CMS should make the final revised CC list publicly available as quickly as possible** so that hospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.
- **CMS should consider additional refinements to the revised CC list** and, in particular, address issues where the ICD-9-CM codes may need to be modified to provide the distinction between different levels of severity.
- **In situations where a new code is required, CMS should default to leaving the codes as CCs until new codes can be created.**

Proposed Changes to the Hospital Wage Index:

The rule proposes several wage index changes that are of significant importance to Massachusetts: the discontinuation of the imputed rural floor, the allocation of a multi-campus hospital's wage data between campuses, the conversion prohibition of critical access hospitals to PPS under certain circumstance, and finally the proposed change in the calculation of the outmigration adjustment, which impacts Middlesex, Essex, and Worcester counties. We have joined our hospitals in numerous calls with CMS officials that past year to discuss these issues and are disappointed to see the proposed rule. Particularly in the case of the critical access conversion, the rule appears to be written solely to prevent Massachusetts institutions from doing what is allowed elsewhere nationwide.

Conversion of CAH to PPS:

MHA has major concerns about CMS' one-sided presentation and with CMS' unprecedented and, we believe, erroneous, assertion of its statutory authority on this issue. We are submitting comments on this matter in a separate letter.

Wage Index for Multi-Campus Hospitals:

MHA appreciates CMS' presentation of this critical issue and proposals for handling it. We are submitting comments and contingent alternative proposals in a separate letter.

Contiguous Rural Floor

In the final rule for 2007, CMS put in place a provision whereby the data from a "new rural hospital" that opens up in a previously all-urban state, either as an entirely new facility or a Critical Access Hospital (CAH) converting to PPS would not be included in the wage index *until four years later*. In the meantime, the hospital would be paid at a wage index level which might well have no relationship whatsoever to its actual cost experience. The hospital may very well as a result suffer Medicare under-reimbursement losses for four years, and might even close, before CMS will consider paying the hospital with an appropriate wage adjustment. We unsuccessfully urged CMS to reconsider this proposal last year and to include the new hospital's data in the wage index as soon as a full year's cost report with the hospital operating as a PPS hospital is available. *We*

continue to believe that the 4 year lag in wage data inclusion is unfair, inconsistent and unnecessary and urge CMS to reverse this policy.

Failing that, ***MHA strongly supports the use of a contiguous rural floor in cases where a new rural hospital that opens in an area where there was previously no PPS hospital*** and hence no wage data available to base the rural wage index on. We believe that the contiguous rural wage index is at least an acceptable alternative. This is because it takes into account the wage levels of hospitals that are in contiguous areas and with which the “new” hospital will have to compete for labor.

Proposed FY 2008 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees.

The MMA required that CMS develop an adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index. Qualifying hospitals were to receive an adjustment to their wage index based on the percentage of county residents who commute to the other area. Hospitals in Middlesex, Essex and Worcester Counties in Massachusetts were eligible for the outmigration adjustment in 2005, 2006 and 2007. But the proposed rule deems Worcester County hospitals ineligible for the adjustment in 2008 onwards. The reason for this is a change in the way the adjustment is determined:

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Further, CMS provides no justification as to why CMS proposes to make half of the budget neutrality adjustment in the wage index. *This treatment creates a further complication of the already difficult computation of the wage index* – and further reduces transparency. We ask CMS to report the amounts of the Rural Floor Standardized Amount Adjustments from 1999 through 2007, as well as provide the amount of the adjustment applicable to FFY 2008. In the interest of promoting further transparency, these adjustments should be fully explained and the prior year adjustments should be enumerated for each year in making the cumulative adjustment that is needed to correct prior inequities.

Work Sheet S-3 Wage Data for the Proposed FY 2008 Wage Index.

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

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

Imputed Rural Floor

CMS is proposing to discontinue the Imputed Rural Floor provision since they “do not believe that it is necessary to have an imputed rural floor in States that have no rural areas

or no rural hospitals”. This clearly contradicts the rationale in the Proposed Inpatient PPS rule for 2005 which noted that hospitals in these states (i.e. states without rural areas or rural hospitals) are disadvantaged by the absence of a rural floor. Given that the original rationale for imputing the rural floor still holds true, it is not too surprising that hospitals that benefit from it were counting on the provision being continued for another 3 years. Such flip-flopping on the part of CMS has serious consequences for hospitals operating in these difficult times, struggling to balance budgets and provide the best possible care to beneficiaries.

The loss of the imputed rural floor in Massachusetts will result in a drop in Medicare reimbursement to eight western Massachusetts hospitals of over \$8 million, or an average of 3.9% of their Medicare inpatient and outpatient revenue. Swings in reimbursement of this magnitude should be minimized in a *prospective* payment system. ***At the very least, the imputed rural floor should be phased out over 2 years to cushion the negative impact.***

We also disagree with CMS’ stance that one of our hospitals has converted to rural using the provisions of 42 CFR 412.103 and hence Massachusetts is no longer eligible for the imputed rural floor. This is inconsistent with the fact that hospitals subject to the rural floor in Connecticut are *held harmless* from the conversion of one of their hospitals to rural status using the same provision (42 CFR 412.103). If the imputed rural floor is equivalent to the rural floor, then the former should be subject to the same hold harmless provisions as the latter.

Proposed Changes to Capital Payments:

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

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. According to MedPAC, overall Medicare margins will reach a 10-year low in 2007 at ***negative*** 5.4 percent. With overall Medicare margins decreasing, hospitals have been forced to subsidize operating losses with money that should otherwise be devoted to capital – leading to a shortage of investment into IT and other capital needs. As average age of plant increases and hospitals continue to put off capital investments in order to maintain everyday operations, the need for adequate capital funding will increase – not decrease.

Reducing capital payments would create significant financial difficulties and amounts to Medicare renegeing on the full cost of caring for America’s seniors and disabled. These changes in capital payments would make it much more difficult for hospitals to enhance clinical innovation and cutting edge research, to purchase advanced technology, to further advance health information technology, and to adjust for rising energy costs by

converting to more fuel efficient systems. Hospitals make long-term commitments to capital acquisitions and this proposal clearly falls into the category of penny-wise and pound foolish. Pulling the rug out from under the financial obligations to maintain and improve their physician facilities will only cost more in the long run and undermine patient needs.

We strongly oppose the proposal to freeze capital payments made to large urban hospitals and the elimination of the 3 percent large urban add-on for capital. MHA also opposes possible future cuts to the IME and DSH adjustments under the capital system. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications.

Hospital Acquired Conditions

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

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

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

Conditions to include for FY 2009. MHA believes that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. Massachusetts' hospitals are committed to patient safety and strive to ensure that these events do not happen.

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

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

Quality and Safety Provisions

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

New quality measures.

We applaud CMS' actions to propose only adding new measures in FY 2009 that are adopted by the Hospital Quality Alliance and endorsed by the National Quality Forum and urge that future measure additions meet the same conditions. We also endorse the advance notice of plans for FY 2009 with the lead time provided in this proposed rule and urge that this timely advance notice be provided for future additions to measurement and reporting requirements.

The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality – hospitals, purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment. The measures proposed for FY 2009 are well-designed, represent aspects of care that are important to patients, and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors.

Because we believe that all measures for public reporting should be adopted by the HQA, endorsed by the NQF and tested in the field before implementation, we have concerns with some measures listed by CMS for possible implementation for FY 2009 or subsequent years because they do not fulfill these criteria. We urge CMS to carefully evaluate the value of the measures considered for reporting. Measures should be evidence-based, contribute to the comprehensiveness of performance measurement, be under a hospital's control and account for potential unintended consequences. We urge CMS only to propose and select measures that meet all of these conditions. **If the measures are NQF-endorsed and HQA-adopted, CMS can be assured that they meet these conditions. Therefore, CMS should only choose measures that have been selected by these two groups.**

The NQF currently is developing national quality goals. **We believe that CMS should look to the NQF goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should indicate its intent to follow the national goals as well.

We commend CMS for including in the proposed rule the measures that hospitals will be required to report to receive their full FY 2009 inpatient payments, as this early notice allows hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking to notify hospitals of the reporting requirements for the next fiscal year.**

IME Adjustment

In the FY 2007 final rule, CMS finalized a policy to exclude residents' time spent in non-patient care activities from the resident count for purposes of IME (in all settings) and direct graduate medical education (in non-hospital settings) payments. Under the

proposed rule, vacation and sick time would be removed from the total time considered to constitute an FTE resident. Thus, it would be removed from both the numerator and denominator of the FTE calculation.

MHA appreciates CMS' efforts to clarify its policies, and its attempt to not penalize hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through. **We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count.** We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor affects, nationally speaking, while having major implications at the individual hospital level.

We hope you will give serious consideration to the concerns we have outlined. Thank you for your attention to these important issues.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Kirkpatrick". The signature is fluid and cursive, with a long, sweeping underline that extends to the left.

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care

CMS-1533-P-214 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Thomas Ahrens

Date & Time: 06/08/2007

Organization : Barnes-Jewish Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Re: DRG Reforms and Proposed MS-DRGs.
CMS-1533-P

I appreciate your efforts to better align costs with reimbursement. I know how difficult a job this is and I applaud your efforts. The area of my particular interest is in sepsis and especially severe sepsis reimbursement. As a clinician who has worked with this exceeding complex area for the past 25 years, I know how difficult and costly it is to manage patients with severe sepsis. I am very appreciative of the current effort to better align reimbursement with the real costs of patients with severe sepsis. The proposed change regarding CMS-1533-P is particularly relevant and far sighted. This is the most logical approach to reimbursing severe sepsis that has ever been advanced. I strongly encourage adoption of this proposal.

Best regards,

Tom Ahrens DNS RN FAAN
Research Scientist
Nursing Services
Barnes-Jewish Hospital
St. Louis, MO 63110
314-362-5637
Tsa2109@bjc.org (office)
Tsa51@aol.com (home)

CMS-1533-P-215 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Robert Wetz

Date & Time: 06/08/2007

Organization : Dr. Robert Wetz

Category : Physician

Issue Areas/Comments

Impact--Overall Conclusion

Impact--Overall Conclusion

Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

File Code: CMS-1533-P

Re: Payment for Direct Graduate Medical Education

Dear Ms. Norwalk:

I write regarding the proposal for removing vacation and sick leave in the FTE resident count for purposes of payment for direct graduate medical education. I would like to bring to your attention the increased administrative burden that compliance with your proposal would cause for residency and fellowship programs.

There are 94 residents in the internal medicine residency program at my institution. To track their time on an hour by hour basis will cost the program a lot of money per month. This is not a negligible effect. Also the chance for a reporting error, by tracking everything on a daily or hourly basis must be considered. The American Board for Internal Medicine also requires that all residents make up such sick time, but CMS does not allow this made up time to be reflected in the cost report. Calling in sick once or twice a year does not make you less of an FTE, therefore, tracking this is a burden with no benefit for anyone. Is not our time best served teaching residents rather than being bogged down with nuisance administrative demands?

CMS must consider the local effect before it proposes these rules. I encourage CMS to finalize a rule that eliminates the local costs of complying with yet another regulation.

Robert V. Wetz, M.D., F.A.C.P.

CMS-1533-P-216 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Arnold Eiser

Date & Time: 06/08/2007

Organization : Dr. Arnold Eiser

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

File Code: CMS-1533-P
Re: Payment for Direct Graduate Medical Education

Dear Ms. Norwalk:

I write regarding the proposal for removing vacation and sick leave in the FTE resident count for purposes payment for direct graduate medical education. I would like to bring to your attention the increased administrative burden that compliance with your proposal would cause for residency and fellowship programs.

There are 113 number of residents in the GME program at my institution, Mercy Catholic Medical Center. To track their time on an hour by hour basis will cost the program several hundred dollars per month for the program. This is not a negligible effect. CMS must consider the local effect before it proposes these rules. I encourage CMS to finalize a rule that eliminates the local costs of complying with yet another regulation.

We are required by regulations to provide vacation and sick time off and should not be penalized for providing these essential components of training.

Moreover we provide safety net hospitals in an area with low reimbursements already.

Physician training is vital to our country.

Please act responsibly.

Thank you,

Arnold R. Eiser, MD FACP
Vice President, Medical Education
Mercy Catholic Medical Center
Associate Dean and Professor of Medicine
Drexel University College of Medicine

CMS-1533-P-217 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Gina Dibella

Date & Time: 06/08/2007

Organization : MCHC

Category : Health Care Provider/Association

Issue Areas/Comments

MedPAC Update

Recommendation

MedPAC Update Recommendation

attachment

Wage Data

Wage Data

attachment

Wage Index

Wage Index

attachment

CMS-1533-P-217-Attach-1.DOC

CMS-1533-P-217-Attach-1.DOC

CMS-1533-P-217-Attach-1.DOC



#217

MCHC
Metropolitan Chicago
Healthcare Council

222 South Riverside Plaza
Chicago, Illinois 60606-6010
Telephone 312-906-6000
Facsimile 312-993-0779
<http://www.mchc.org>

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(Blue Island)

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Peter J. Murphy

President/Chief Executive Officer
St. James Hospital & Health Centers

Jesus M. Ong

President/Chief Executive Officer
South Shore Hospital

Paul Pawlak

President/Chief Executive Officer
Silver Cross Hospital

James H. Skogsbergh

President/Chief Executive Officer
Advocate Health Care

Sister Donna Marie Wolowicki, CR

Group Vice President & Executive
Vice President/Chief Executive Officer
Resurrection Medical Center

June 8, 2007

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

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

Dear Ms. Norwalk:

On behalf of our nearly 140 hospitals and health systems in metropolitan Chicago and surrounding counties, the Metropolitan Chicago Healthcare Council (MCHC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (IPPS).

After a review of the proposed rule's provisions we offer the following comments:

WAGE DATA

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

However, we believe that the impact is greater than suggested by CMS due to an error in the calculation. We agree that lines 22.01 (Contract A&G Services), 26.01 (Contract Housekeeping Services) and 27.01 (Contract Dietary Services) are and should be included in Step 4. The purpose of Step 4 is to allocate a portion of overhead wages and wage-related costs to the excluded areas, and then to subtract a commensurate amount from wages and wage-related costs included in the wage index. However, while line 9.03 (Contract Management and Administrative) was included in the total wages in Step 2, lines 22.01, 26.01 and 27.01 were not.

This results in a double negative effect. First, the contract labor for those three lines was never included. And second, a portion of those same costs are being subtracted from the wages and wage-related costs included in the wage index.

CMS should fix the calculation and then reassess the impact on hospitals. While the MCHC supports the inclusion of contract labor, as it discourages outsourcing in order to raise average wage levels and thus wage indices, a transition should be considered if the impact on any individual hospital is great.

WAGE INDEX

In FY 2009, CMS is required by law to consider changes to the area wage index. MCHC agrees that the wage index is not functioning and alternatives should be considered. Thus, we would like to take this opportunity to describe some of the fundamental concerns our members have with the wage index, as well as with MedPAC's recommendation for CMS' deliberation over the next year.

1. Volatility of wage index year to year.
2. Self-perpetuating – hospitals with low wage indices are unable to increase wages to become competitive in the labor market.
3. Geographic boundaries create “cliffs” where adjacent areas have very different indices.
4. Inaccurate measure of actual labor costs.
5. Fiscal intermediaries are inconsistent in their interpretations.
6. Hospitals can be penalized for erroneous data submitted by other hospitals in the same geographic area.
7. Exclusion of some personnel from the wage index calculation – outsourcing of low-wage workers raises an area's wage index.

Regarding MedPAC's recommendation, which will be released in its June report, we raise the following concerns.

Data source. MedPAC considered the use of Bureau of Labor Statistics (BLS) data rather than the hospital-reported data collected on CMS' Medicare cost reports. While this approach may be significantly less burdensome for hospitals, there are critical differences between the two data sets that must be carefully evaluated. The new data source is the cornerstone of the MedPAC approach and represents a fundamental change. Many of the other aspects of the draft proposal possibly could be applied using hospital wage data as it is currently collected. Key differences between the CMS and BLS methodologies include:

vary wage indices by county – may be more realistic and less arbitrary. On the other hand, the “smoothing” approach, whereby wage index values or wages of neighboring areas are artificially constrained to allow only a 10 percent difference in wage indices, may mask actual variation in wages between areas. For example, there may be real, greater differences between outlying counties and an urban core.

In addition, MedPAC plans to use the decennial Census to determine variation between the counties. So, for 2008, MedPAC would use the 2000 Census data to establish the relationship between counties within a metropolitan statistical area until the 2010 Census is available. Using data this old may create differences in wage indices that are inconsistent with the actual difference experienced in wages.

- **Year-to-year volatility** – Volatility in wage indices from one year to the next makes it difficult for hospitals to estimate Medicare payments for budgeting purposes. While the three-year rolling average employed by BLS may reduce volatility, alternative approaches should be examined, including those that do not rely on BLS data.

We appreciate CMS’ consideration of the issues raised and remain available to answer any questions you may have.

Sincerely,



Dan Yunker
Vice President/CFO
MCHC



Gina Dibella
Director, Finance & Reimbursement
MCHC

cc: Kevin Scanlan, President, MCHC

**CMS-1533-P-218 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mrs. Karen Heller

Date & Time: 06/08/2007

Organization : Greater New York Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-218-Attach-1.PDF



Greater New York Hospital Association

555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / (212) 262-6350

Kenneth E. Raske, President

June
Eight
2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule, *Federal Register* 72, no. 85 (May 3, 2007): 24679-25135. [CMS-1533-P]

Dear Ms. Norwalk:

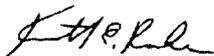
On behalf of the more than 150 hospitals that make up the membership of the Greater New York Hospital Association (GNYHA), I appreciate this opportunity to comment upon the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2008 inpatient prospective payment system (IPPS). This year's rule includes many significant proposed changes to the IPPS. We have chosen to focus on the following six topics:

- **Recalibration of DRG weights.** We support implementation of the short-term recommendations made in the RTI report on charge compression, and we encourage CMS to implement the intermediate- and long-term recommendations as well.
- **DRG reclassifications.** We endorse implementation of the revised Complication/Comorbidity (CC) list and the new Medicare Severity diagnosis-related groups (MS-DRGs). However, we urge an attenuated transition in order to minimize the amount of case-mix creep-related overpayments and, therefore, the size of the recoupment. We also recommend that the overpayment amount be computed retrospectively. We think it is absolutely essential to minimize the recoupment *if it must be made across-the-board* because the overpayments will not be made across-the-board.

- **Capital IPPS.** We vehemently oppose (1) the proposed elimination of the urban hospital update and the 3% large urban add-on in FY 2008; and (2) reduction or elimination of the indirect medical education (IME) and disproportionate share hospital (DSH) adjustments. We do not believe it is appropriate to base capital IPPS policy on a review of margins because the promise of the capital IPPS was that hospitals could accrue surpluses during the low-spending phase of their capital cycle to supplement the receipt of merely average payments when they re-entered the high-spending phase of their capital cycle. Moreover, these proposals were not empirically based and our research shows they are unfounded.
- **DRGs: hospital-acquired conditions.** We support CMS's adoption of the three serious preventable events in its CC suppression policy, but oppose inclusion of the three infection conditions. Based on our research and the expertise of our Infection Control Workgroup, we do not believe that the infections are reasonably avoidable for high-risk patients, and CMS did not propose excluding these patients. Therefore, instead of adopting these conditions in the CC suppression policy, we recommend that CMS add risk-adjusted infection rates to *Hospital Compare* and possibly to its value-based purchasing (VBP) plan.
- **Wage index.** During the next year, CMS must develop at least one proposed modification of the hospital wage index and must take into consideration recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its forthcoming *Report to Congress*. We urge CMS to focus on the aspect of MedPAC's report that centers on blending wage indices between and within core-based statistical areas (CBSAs), and to eschew MedPAC's recommendation to switch the wage index data source from the cost reports to Bureau of Labor Statistics (BLS) data. We believe the BLS data are corruptible and insufficient, and would unnecessarily limit CMS's flexibility in defining or refining labor markets.
- **Value-based purchasing plan.** We appreciate CMS's decision to model the VBP on the Reporting of Hospital Quality Data for the Annual Payment Update (RHQDAPU) program, and we provide several technical suggestions. Our most important recommendation is that CMS should set the thresholds for both regular and topped-out measures at the lower of 60% or the national median, and that CMS should set the benchmarks for both types of measures at the lower of 90% or the average score of hospitals performing at or above the 90th percentile. We also strongly favor the implementation option that would phase in the share of the withhold amount that would be based on performance.

Attached is a more detailed discussion of our analysis and recommendations. If you or your staff have any questions or would like to discuss our comments further, please contact Karen S. Heller, Senior Vice President and Executive Director of The Health Economics and Outcomes Research Institute (THEORI), who can be reached at (212) 506-5408 or at heller@gnyha.org.

Sincerely,



Kenneth E. Raske, President

Greater New York Hospital Association Analysis of the Medicare Inpatient Prospective Payment System Fiscal Year 2008 Proposed Policies and Rates and Recommendations for the Final Rule

(Recommendations are presented in bold and italics.)

RECALIBRATION OF DRG WEIGHTS

Last year, we spent considerable time analyzing the challenges associated with changing the basis for the diagnosis-related group (DRG) weights from charges to cost. The most significant problem we identified was that there are large and widespread discrepancies between how hospitals report charges by cost center in the Medicare cost reports and how their charges are sorted into revenue centers on the *Medicare Provider Analysis and Review* (MedPAR) file. We also noted mismatched costs and charges within the cost report for a significant number of hospitals.

We urged the appointment of a workgroup to develop recommendations for resolving these problems so that correct cost-to-charge ratios (CCRs) in the cost reports could appropriately be applied to charges in the MedPAR file to estimate cost. We are very grateful that the American Hospital Association, the Association of American Medical Colleges, and the Federal of American Hospitals collaborated to sponsor such a workgroup of which we were a member. The principal recommendations for short-term remediation of the problems were: that hospitals ensure that costs and charges for particular items and services are reported in the same cost centers on the cost reports; that hospitals change the cost centers in which they report items and services to match the automatic assignment of charges to revenue centers in MedPAR; and that hospitals utilize standard cost centers whenever feasible. ***We now urge the Centers for Medicare and Medicaid Services (CMS) to instruct the fiscal intermediaries to allow changes made for this purpose in the service of payment accuracy.***

While in the near term, we agree that hospitals should change their reporting to conform to MedPAR, as a longer-term project, we believe that the assignment of revenue codes and charges to revenue centers in MedPAR should be reviewed and changed, as necessary, to better reflect hospital accounting practices. That way, the cost report could be a resource for hospitals and researchers as well as a document for reimbursement. ***We, thus, hope that the national associations will continue their cost report workgroup and that CMS will allow joint meetings and collaboration with its internal cost report workgroup.***

Another problem that was brought to light last year—and has been noted repeatedly in the past—was that the combination of certain items and services in the same cost and revenue centers inappropriately dilute the estimated cost of the higher-cost items. This has the effect of compressing the range of the DRGs weights and, thus, of over-correcting for the problem that charge-based weights seemed to overpay high-technology surgical DRGs and underpay medical DRGs. We much appreciated that CMS contracted with RTI, Inc., to investigate options for disaggregating high- and low-cost items and services, and were also grateful for the opportunity to participate on the Technical Expert Panel.

We have carefully reviewed the RTI report and think it provided an excellent presentation of the issues, that it reflected sound and comprehensive research, and that its recommendations were appropriate. *We thus urge CMS to implement the report's short-term, medium-term, and long-term recommendations.* The report's short-term recommendations were as follows:

- Expand the cost report edits to identify and reject those with extreme CCR values.
- Encourage providers to review and correct the assignment of costs and charges before filing their cost reports.
- Revise the cost report instructions to reduce cost and charge mismatching and program charge misalignment.
- Separate Emergency Room from "Other Services" and compute a 14th national CCR for the DRG cost computations.
- Consider separating Blood and Blood Products from "Other Services" and computing a 15th national CCR for the DRG cost computations.
- Use regression-based estimates to disaggregate national average CCRs for Medical Supplies, Drugs, and Radiology.
- Routinely collect a limited number of Inpatient Standard Analytical File (SAF) variables for use in computing statistically-adjusted CCRs.

DRG RECLASSIFICATIONS

CMS is proposing to refine the CMS-DRGs by implementing Medicare Severity DRGs (MS-DRGs). Both systems start with 335 base DRGs and then subdivide them based on patient severity of illness. The base DRG splits in the CMS-DRG system result in 538 final DRGs, while the base DRG splits in the MS-DRG system result in 745 final DRGs. Thus, the MS-DRG system is much more refined. It is also a logical, transparent, and non-proprietary system, which well suits the needs of the health care community. We greatly appreciate CMS's responsiveness to issues that were raised in last year's discussion of refined DRGs and approve of CMS's proposal to implement the MS-DRGs.

In developing the MS-DRGs, CMS found that it had to overhaul the Complication/Comorbidity (CC) list, mostly by adding *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes utilized by other refined groupers, including New York State's All-Patient DRGs (AP-DRGs) and 3M's All Patient Refined DRGs (APR-DRGs). In addition, for the first time since the CC list was developed, CMS evaluated the existing codes and removed some based on several criteria. We compared the old and revised CC lists and found that the revision added 2,002 codes and dropped 425 codes, for a net increase of 1,577 codes. Even though the number of added codes far exceeds the number of dropped codes, in the last three MedPAR files, the dropped codes were used an average of 40,864 times, while the added codes were used an average of only 887 times.

Many of the dropped codes pertain to unspecified conditions for which more specific codes are available and included on the revised CC list. The most dramatic example is ICD-9-CM code 428.0, Congestive heart failure, unspecified, which was applied to an average of 2.3 million Medicare fee-for-service cases a year during the past three years. This was the most widely used

secondary diagnosis code, despite the fact that 12 more specific codes were added in FY 2003. As shown in Table 1, the new codes were used far less frequently.

Table 1. Incidence of Secondary Diagnosis Coding for Heart Failure, FY 2004–FY 2006

ICD-9- CM Code	Description	New in FY 2003	Average Annual Number of Cases With the Code, from FY 2004–FY 2006
428.0	Congestive heart failure, unspecified		2,342,901
428.1	Left heart failure		4,298
428.20	Systolic heart failure; unspecified	✓	19,276
428.21	Systolic heart failure; acute	✓	3,490
428.22	Systolic heart failure; chronic	✓	7,152
428.23	Systolic heart failure; acute on chronic	✓	4,377
428.30	Diastolic heart failure; unspecified	✓	85,703
428.31	Diastolic heart failure; acute	✓	6,511
428.32	Diastolic heart failure; chronic	✓	13,573
428.33	Diastolic heart failure; acute on chronic	✓	6,579
428.40	Combined systolic and diastolic heart failure; unspecified	✓	4,949
428.41	Combined systolic and diastolic heart failure; acute	✓	874
428.42	Combined systolic and diastolic heart failure; chronic	✓	1,470
428.43	Combined systolic and diastolic heart failure; acute on chronic	✓	1,529
428.9	Heart failure, unspecified		6,490

If the revised CC list were implemented before hospitals had a chance to improve their coding to accommodate the revisions, then case-mix creep and inpatient prospective payment system (IPPS) overpayments would ensue. This is because, if CMS computed DRG weights based on current coding practices, then it would effectively assume that roughly 1.6 million cases, or 12% of all cases, would be down-weighted.

In reviewing the data, we found that most of the cases that would be regrouped into a lower-weighted DRG have charges that are lower than the charges of the remaining cases in the higher-weighted DRG but higher than the charges of the cases in the lower-weighted DRG. Regrouping the mid-range cases would, therefore, have the effect of increasing the weights of all the DRGs. The national case mix index would remain the same, however, because there would be a higher proportion of cases in the lower-weighted DRGs. However, if hospitals substituted included CCs for dropped CCs in the payment year, then the mix of lower-weighted and higher-weighted cases would not change as much as expected and the national CMI would increase, leading to unwarranted, higher IPPS payments.

Since hospitals vary greatly in the specificity of their coding practices and in their proportionate of cases with split DRGs, the overpayments would not be distributed across-the-board, but rather to the hospitals that had the most opportunity for coding correction and coding refinement. The hospitals that already use the more specific codes and those with a low proportion of cases in

split DRGs would receive fewer, if any, overpayments because their case mix indices would not increase as much, or at all.

New York hospitals, in particular, would have less opportunity for coding improvement than other hospitals because the union of the Medicare CC list and the New York State CC list has 279 more codes than the Medicare CC list alone. Thus, moving from the union CC list to the revised CC list would add only 1,298 codes, 279 fewer codes than in the rest of the country. Furthermore, New York hospitals are well-practiced in using specific codes because the New York State AP-DRG grouper differentiates between CCs and major CCs, as the MS-DRG grouper would do.

Since overpayments would not be distributed proportionately to each hospital, it would be unfair to recoup the overpayments through an across-the-board cut. Unfortunately, however, CMS may not have the option to recoup overpayments on a hospital-specific basis, as is done in New York. The statute authorizing CMS to avoid or recoup creep-related overpayments, Section 301(e) of the Benefits Improvement and Protection Act of 2000 (BIPA), seems to require that CMS do so by reducing the operating and capital standardized amounts:

Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes. §1886(d)(3)(A)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(A)(vi))

Therefore, CMS proposed to avoid creep-related overpayments by reducing the standardized amounts by 2.4% in FY 2008 and by 4.8% in FY 2009. The CMS actuary estimated these “behavioral offsets” based on a study conducted by 3M of the experience of Maryland hospitals when that state’s all-payer reimbursement system adopted APR-DRGs.

We have two problems with the proposed behavioral offsets. First, we suspect they are too high because hospitals in other states—particularly New York—have more experience with secondary diagnosis coding than the Maryland hospitals had before their change to APR-DRGs. Therefore, hospitals in other states probably have less room for improvement and would likely generate less creep. Second, even though the BIPA requires creep avoidance or recoupment by cutting the standardized amounts, doing so as CMS proposed would greatly harm hospitals that have put the time and effort into accurate coding, as well as hospitals with a low proportion of cases in split DRGs. For those hospitals, the rate reductions would not offset higher case mix indices, yielding no effect on payments; rather, they would result in significant payment losses.

To resolve these problems, we recommend the following:

1. ***CMS should retrospectively determine the national rate reduction to offset case-mix creep, even though the reduction would be made to future rates.*** Retrospective determination is specifically authorized in Section 301(e) of the BIPI and that is the only way to ensure that the level of the reduction is accurate.
2. ***CMS should phase in the revised CC list and MS-DRGs to reduce the amount of creep-related overpayments that would be made in the first place. We recommend a five-year phase in during which the blend of the old CC list/CMS-DRG weights and the new CC list/MS-DRG weights would be 80%/20% in FY 2008, 60%/40% in FY 2009, 40%/60% in FY 2010, 20%/80% in FY 2011, and 0%/100% in FY 2012.***
3. ***CMS should release the MS-DRG grouper software as soon as possible and should also encourage vendors to release products as soon as possible that ensure that both old and new CCs are listed among the first eight secondary diagnoses, as these are the only ones that can be used for payment purposes.***
4. ***CMS should revise its systems so that all secondary diagnoses can be used for payment purposes in the future.***

With respect to the phase in, we believe it is prudent to begin to use the new CC list/MS-DRGs in FY 2008 so that hospitals are compelled as soon as possible (1) to improve their coding, and (2) to educate their physicians about complete documentation. *However, we would not want the new DRG weights to represent a majority of the blend until they can be based on the first year of corrected data.* The FY 2010 weights would be based on the FY 2008 cases, so they would reflect the first year's coding corrections and would presumably be more accurate. Since it can take several years for hospitals and physicians to adjust to new documentation and coding requirements, continuing blended payments in FY 2011 would be important to minimize creep-related overpayments.

Again, the goal is to minimize the aggregate level of creep-related overpayments so that hospitals not generating creep are not unfairly penalized by an across-the-board reduction. If overpayments could be recouped on a hospital-specific basis, an attenuated phase-in would not be necessary, but this may not be an option. We realize that our recommended phase in would be cumbersome because each case would have to be grouped twice to determine the DRG assignment under the CMS- and MS-DRG groupers. However, we believe this is the lesser of two evils, since the alternative for good-coding hospitals and those with relatively few patients in split DRGs would be to effectively eliminate the IPPS update for two years.

CAPITAL IPPS

What is most interesting about the capital PPS is that it is not actually a capital PPS. It would more correctly be described as an empirically-derived PPS for total inpatient acute care costs, with the standardized amount truncated to 7.8% of the total standardized amount. In 1991, after exhaustive research, CMS concluded that the appropriate way to reimburse capital costs under

the PPS was to add them to the operating PPS and then revise the regression model to develop empirical adjustments based on total cost rather than operating costs alone.¹ This is how capital costs have been incorporated into all the other prospective payment systems.

The reason why CMS did not combine the operating and capital PPS systems after the 10-year capital transition period was that it did not have authority to change the operating IME and DSH adjustments, since they are set in statute. The Agency did not want to apply the statutory IME and DSH adjustments to capital costs because they include “policy” adjustments, which are payments above the empirical level.

Nevertheless, the large urban, labor share, IME, and DSH adjustments in the capital PPS reflect empirical adjustments from a total cost model, as well as CMS’s updated thinking regarding variable specification.

Proposed Cuts are Excessive and Not Empirically Based

While CMS still does not have the authority to change the operating PPS adjustments, it retains its authority to update the total cost model used for the capital PPS. For FY 2008, CMS has proposed to make two major changes to the capital PPS: it would eliminate the inflation update for urban hospitals for two years and eliminate the 3% large urban add-on altogether. CMS also requested comments on reducing or eliminating the IME and DSH adjustments. The savings generated from these proposals would not be reinvested in the federal rate, but taken as Medicare program savings.

Unfortunately, these changes are not empirically-based. Based on our own empirical analysis conducted during this brief comment period,² *we believe that the cuts that CMS is proposing to urban and large urban hospitals, and the cuts that CMS may be contemplating for teaching and DSH hospitals are grossly excessive and we strongly oppose them.*

We believe that if CMS wishes to update the capital PPS, then it should do so by revising its total cost regression model. If the Agency did that, we predict it would find that the large urban, teaching, and DSH variable coefficients are all still substantial and statistically significant. While the IME coefficient is lower than it was in 1991, the DSH coefficient is higher and the labor share is much higher, in the area of 85%.

¹ Prospective Payment System for Inpatient Hospital Capital-Related Costs; Final Rule, *Federal Register* 56, no. 169 (August 30, 1991). [BPD-681-F]

² We are not describing our models and presenting results with these comments because our research was necessarily limited and was conducted solely to determine whether the large urban, teaching, and DSH adjustments were still warranted. Our data sources were the 2004 cost reports, the FY 2004 MedPAR file for which we derived cost per case for last year’s comment letter, and the FY 2007 final rule Impact file. We used the same dependent and independent variables as the 1991 capital PPS regression model, and the same functional form of both the model and the variables.

Margin Analysis was Too Limited

The impetus for CMS's proposals to eliminate the urban update and the large urban add-on, and to request comments on the IME and DSH adjustments, was that the Agency observed that large urban, teaching, and DSH hospitals had higher-than-average capital PPS margins from 1996–2004, which led to a concern that perhaps the payment adjustments were too generous. We also replicated CMS's margin analysis and determined that it was too limited to form the basis for the Agency's conclusions and proposals.

While we observed the same 8-year margin trend in the capital PPS, we also examined the trend in the combined operating and capital PPS margin—both with and without the operating PPS policy adjustments³—the trend in the total (all payer) margin, and the trends in unit price and cost growth. We present these results in Tables 3 and 4.

Table 3. Comparative Medicare and Total Margins, 2004

	Medicare Inpatient Acute Care Margins			Total Margins (All Payers)	
	Capital	Operating and Capital, <u>with</u> Policy Adjustments	Operating and Capital, <u>without</u> Policy Adjustments	<u>With</u> Medicare Policy Adjustments	<u>Without</u> Medicare Policy Adjustments
All Hospitals	5%	0%	-10%	5%	3%
Large Urban	8%	2%	-10%	4%	2%
Not Large Urban	3%	-2%	-11%	6%	4%
High DSH	7%	4%	-10%	4%	2%
Other DSH	1%	-8%	-11%	6%	5%
Teaching	11%	4%	-8%	4%	2%
Non-Teaching	-3%	-6%	-14%	5%	4%
Large Urban, High DSH, and Teaching	12%	9%	-8%	3%	0%
Not Large Urban, High DSH, or Teaching	-9%	-11%	-13%	6%	5%

³ Our data source was the HCRIS file, so our IME payments include payments made on behalf of Medicare Advantage enrollees. The proper way to identify the empirical IME and DSH amounts would have been to apply the capital PPS IME and DSH adjustments to the operating and capital PPS base payment amounts. Then the policy-related IME and DSH amounts would be the difference between the total payments and the empirical amounts. We did not have time to assemble the database we would have needed to properly derive empirical IME and DSH amounts, since the capital IME and DSH adjustments were not available on the cost reports for all hospitals during the capital PPS transition period and we do not have Impact files dating from FY 1998 (corresponding with 1996 cost report data). Therefore, we defined policy-related DSH payments as all operating DSH payments and policy-related IME payments as the amount of operating IME payments represented by the declining constant on the IME formula. Our shortcut both understates and overstates the policy amounts.

Table 4. Compound Annual Growth in Unit Price and Unit Cost, 1996–2004

	Medicare Capital		Medicare Operating and Capital <u>With</u> Policy Adjustments		Medicare Operating and Capital <u>Without</u> Policy Adjustments	
	Price	Cost	Price	Cost	Price	Cost
All Hospitals	0.1%	2.1%	2.1%	4.4%	2.1%	4.4%
Large Urban	-0.4%	1.4%	1.4%	3.9%	1.5%	3.9%
Not Large Urban	0.5%	2.7%	2.7%	4.7%	2.5%	4.7%
High DSH	0.0%	1.8%	1.9%	4.3%	2.0%	4.3%
Other DSH	0.0%	2.4%	1.9%	4.4%	2.0%	4.4%
Teaching	-0.4%	1.0%	1.3%	3.6%	1.5%	3.6%
Non-Teaching	-0.1%	2.8%	2.3%	4.7%	2.0%	4.7%
Large Urban, High DSH, and Teaching	-0.5%	0.8%	0.8%	3.5%	1.4%	3.5%
Not Large Urban, High DSH, or Teaching	0.8%	4.4%	2.8%	5.2%	2.7%	5.2%

We believe that it is not appropriate to examine capital PPS margins alone to ascertain whether the capital PPS adjustments are excessive because the adjustments were derived from a total cost regression model. That is why we looked at the combined operating and capital PPS margins.

What we observed was the following:

- *The combined operating and capital PPS margin was zero in 2004. Therefore, if CMS revises its capital PPS adjustments, they should be budget neutral.*
- When removing the IME and DSH policy payments, the combined operating and capital PPS margin was significantly negative for all classes of hospitals, including large urban, teaching, and high-DSH hospitals, which we defined as hospitals having a disproportionate patient percentage of at least 17.5%. Therefore, the cuts enacted in the Balanced Budget Act of 1997 (BBA) were excessive. Furthermore, hospitals receiving IME and DSH policy payments are now having to divert some of those payments to cover their Medicare inpatient losses rather than using all of them to help finance their social missions.
- Even with the Medicare IME and DSH policy payments, the total margins of large urban, teaching, and high-DSH hospitals were lower than the margins of other hospitals. Without the policy payments, hospitals with all three characteristics would have had a zero total margin compared with a 5% total margin for hospitals with none of these characteristics. Therefore, targeting large urban, teaching, and DSH hospitals for cuts, as CMS proposed and is otherwise considering, is not only wrong because the cuts are not empirically justified, but also wrong because they could lead to access problems for Medicare beneficiaries.
- Large urban, teaching, and high-DSH hospitals have all experienced slower capital unit cost growth than other hospitals over the 8-year study period. This may be because these hospitals have been in a lower-spending phase of their capital cycle than other hospitals. This is

possible, since the capital cycle is roughly 20 years, far longer than the 8-year study period. To the extent that this is the case, cutting the payment adjustments would violate the promise of the capital PPS, which was that hospitals could accumulate surpluses during their low-spending phases to supplement merely average payments when they re-entered the high-spending phase.

We know for a fact that our member hospitals, which are virtually all large urban, teaching, and DSH hospitals, are in the low-spending phase of their capital cycle because they underwent major modernizations at the same time in the early 1990s. They were put on the same capital cycle by the New York State Department of Health (DOH), when DOH imposed a moratorium on major modernizations in the 1980s. When the moratorium was lifted, the backlogged projects were all initiated at the same time.

Another possible explanation for the lower capital unit cost growth of large urban, teaching, and high-DSH hospitals could be that since Medicare capital payments are no longer tied to Medicare capital costs, these hospitals have the flexibility to spend their scarce resources on their most pressing needs, which might overwhelm the need for continued growth in capital investment.

We know that our member hospitals are not investing in information technology and funding their depreciation at the rate of other hospitals, since those needs must compete with unfunded priorities, including: complying with new state laws on charity care and services to patients with limited English proficiency; reducing outcome disparities between majority and minority communities; complying with quality improvement and quality-related data reporting requirements; maintaining primary care, standby capacity for emergency and trauma care, and other money-losing services; subsidizing losses from private payers who inappropriately deny payment for medically necessary services; and paying the enormous and ever-growing cost of medical liability insurance.

Given these burdens, it is absolutely essential that CMS not target arbitrary cuts at large urban, teaching, and DSH hospitals. *Furthermore, when or if CMS does update its total cost regression model, then we believe that the Agency should publish its results for public comment before proposing changes in the payment system.*

DRGs: HOSPITAL-ACQUIRED CONDITIONS

Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) required the following:

1. By October 1, 2007:
 - a. Hospitals must identify whether secondary diagnoses were present on admission (POA), and
 - b. The Secretary must select at least two conditions that: (1) if developed in the hospital, could reasonably have been prevented through the application of evidence-based guidelines; (2) cause patients to be grouped into a DRG with a CC; and (3) have a high cost, a high volume, or both.

2. In FY 2009, CMS must ignore the identified conditions for DRG grouping purposes if they were not POA. This would be accomplished by suppressing the pertinent ICD-9-CM secondary diagnosis codes in the DRG grouping process. Therefore, we refer to this provision as the *CC suppression policy*.

In the proposed rule, CMS provided its condition selection criteria and recommended that six be subject to the new policy. All six are represented by a unique ICD-9-CM code, except that decubitus ulcers can be identified by one of nine codes, some of which identify the location of the ulcer on the patient's body. The affected ICD-9-CM codes are shown in Table 4.

Table 4. Proposed ICD-9-CM Codes to be Suppressed if Hospital-Acquired Conditions

Proposed Condition	ICD-9-CM Code	Description	Average Annual Cases with Code, FY 2004–FY 2006
1.	996.64	Infection and inflammatory reaction; due to indwelling urinary catheter	12,844
2a.	707.00	Decubitus ulcer; unspecified site	14,159
2b.	707.01	Decubitus ulcer; elbow	2,261
2c.	707.02	Decubitus ulcer; upper back	4,033
2d.	707.03	Decubitus ulcer; lower back	111,738
2e.	707.04	Decubitus ulcer; hip	19,395
2f.	707.05	Decubitus ulcer; buttock	38,898
2g.	707.06	Decubitus ulcer; ankle	10,308
2h.	707.07	Decubitus ulcer; heel	66,054
2i.	707.09	Decubitus ulcer; other site	44,866
3.	998.4	Foreign body accidentally left during a procedure	861
4.	999.1	Complication of medical care; air embolism	47
5.	999.6	Complication of medical care; ABO incompatibility reaction	57
6.	038.11	Staphylococcus aureus septicemia	36,601

After reviewing the selection criteria and proposed conditions, and conferring with our Infection Control Workgroup and our Quality Improvement Organization (IPRO), we have determined that we can support the inclusion of the three serious preventable events in the new policy:

1. Foreign body accidentally left during a procedure (998.4);
2. Air embolism (999.1); and
3. ABO incompatibility reaction (999.6).

We believe these conditions are appropriate for the new policy because it is easy to determine whether they developed in the hospital or prior to admission, they are definitely preventable, and,

although they occur infrequently, they are serious and expensive events. Thus, they meet the selection criteria set forth in the DRA.

We do not believe that the other proposed conditions (catheter-associated urinary tract infections, decubitus ulcers, and Staphylococcus aureus septicemia) are appropriate for the new policy because they are not always reasonably preventable and, with only one exception, CMS did not propose criteria for excluding patients in whom those conditions would probably not be preventable. It would be inappropriate to withhold funding without examining the clinical conditions in which complications occur and making allowances for unavoidable complications.

On the other hand, we appreciate the desire by Congress and CMS to associate financial penalties with avoidable complications. Therefore, we recommend that CMS develop risk-adjusted models for infection rates that could be incorporated into *Hospital Compare* and possibly into CMS's value-based purchasing plan. Like the mortality models, infection models would control for the patient characteristics and diagnoses that would otherwise serve as exclusion criteria under the CC suppression policy. Furthermore, if important risk factors were missing from the claims database, they could be added by assigning new ICD-9-CM codes.

Approaching infection control through the quality program rather than through the reimbursement system—although the quality program is about to have financial repercussions—would benefit patients as well as providers. By comparing actual and expected complication rates, CMS could identify hospitals with statistically significant infection control and other problems and work with them individually. In addition, the national average complication rates would improve steadily as hospitals strove to obtain more VBP points.

Below, we comment briefly on the problems associated with including the proposed infections in the CC suppression policy.

Catheter-associated Urinary Tract Infections (UTIs)

According to the Centers for Disease Control (CDC) prevention guidelines, using a closed drainage system is the key to preventing catheter-associated UTIs because none of the other recommended prevention steps have been shown to be as effective. Using a closed method for drainage substantially reduces the risk compared with using an open drainage system. However, even if this guideline were followed faithfully, CDC estimates that 20% of catheterized patients would still be expected to develop a UTI. Moreover, some risk factors—e.g., admission with a catheter, advanced age, debilitation, and being postpartum—predispose patients for catheter-associated UTIs.

Because such a high percentage of patients are expected to develop catheter-associated UTIs, even when the hospital adheres to best practices, and because patients with a high risk of developing these infections would not be excluded from the CC suppression policy, we believe this condition does not meet the selection criterion of being reasonably preventable.

Furthermore, our Infection Control Workgroup was concerned about the ability to identify patients with a UTI present on admission. They advised that the only way to be sure whether a

UTI was POA would be to screen all patients likely to have a urinary catheter during their hospital stay, which would be an unfortunate diversion of scarce resources. Even then, pre-admission UTIs would not be detected for nursing home residents admitted with a catheter in place and who were on or recently completed antibiotic therapy for treatment of a UTI, since their urine cultures would be negative for bacterial growth.

Decubitus Ulcers

The guidelines for avoiding pressure ulcers are clear and there are good diagnostic scales for identifying high-risk patients to whom the protocol should be applied. However, there is insufficient evidence that pressure ulcers can reasonably be prevented in high-risk patients, despite good compliance with the prevention protocol. Therefore, to include this condition in the CC suppression policy, CMS would have to identify criteria for excluding certain patients, which the Agency did not propose.

Again, we believe that the better route to reducing pressure ulcers would be for CMS to develop a risk-adjusted model for evaluating hospital ulcer rates. If CMS followed that course, then we would also recommend the development of ICD-9-CM codes that would capture each patient's level of risk for developing a pressure ulcer. This would be similar to the body mass index and other V-code scales that have been introduced in recent years. Simply adjusting for this risk factor would motivate all hospitals to improve their patient assessment, which, in turn, would help them better identify patients who should receive the prevention protocol.

***Staphylococcus aureus* Septicemia**

S. aureus septicemia is the most problematic of the conditions proposed for the CC suppression policy because there are so many co-occurring conditions that place patients at high risk, all of which would significantly reduce the ability to avoid the condition, even with careful application of the prevention protocols. CMS appropriately proposed to exclude patients admitted to the hospital with *S. aureus* pneumonia. However, many other patients are at high risk of developing *S. aureus* septicemia, including—but not limited to—patients admitted with portals for infection such as cellulitis or abscesses, and patients admitted with suppressed immune systems such as patients with HIV/AIDS or patients receiving chemotherapy or corticosteroids.

WAGE INDEX: MEDPAC STUDY AND CMS PROPOSALS FOR FY 2009

The Tax Relief and Health Care Act of 2006 (TRA) required the Medicare Payment Advisory Commission (MedPAC) to submit a report to Congress that addresses several issues of concern pertaining to the hospital wage index. MedPAC's report will be published by the end of this month, June 2007. In addition, in the FY 2009 proposed rule, CMS must propose at least one revision to the hospital wage index and must consider MedPAC's report in developing its proposal(s).

Rather than merely studying the issues of concern to Congress, MedPAC will propose a major overhaul of the hospital wage index in its June 2007 report. We have had the opportunity to thoroughly review this proposal—although we have not yet modeled its financial impact—and

would like to share our views about its strengths and weaknesses. In particular, there is a feature of the proposal that we like and another that we dislike immensely.

Customizing Labor Markets

The feature that we like is that MedPAC would sculpt the current labor markets, which are plains and mesas, into hills and valleys, both between and within Core-Based Statistical Areas (CBSAs). By limiting the difference between wage indices of contiguous counties in different CBSAs, MedPAC would reduce unfair payment differences that have given rise to the proliferation of formula-driven and political reclassifications. And by adjusting for wage level differences within CBSAs, MedPAC would address the problem that some CBSAs combine dissimilar labor markets, which has harmed the higher-wage areas.

While we like this feature conceptually, we do not favor the technical approach that MedPAC suggests. The Agency proposes an arbitrary—and expensive—10% limit on the difference between the wage indices of contiguous counties, and proposes to use outdated decennial census data to disaggregate wage levels within CBSAs.

We much prefer an empirical approach, an example of which is the out-migration adjustment provided by Section 505 of the Medicare Modernization Act of 2003 (MMA). The “505” adjustment blends the wage indices of contiguous CBSAs for counties in which a high proportion of hospital employees reside in a different CBSA. The commutation data are provided by BLS in the form of a table that provides the number of workers who live and work in every combination of counties.

During the next few months, we will model different approaches to implementing a similar methodology both across and within CBSAs and share our results with CMS. The first option we are interested in exploring would be to compute county-level wage indices from the cost report data for counties with a minimum population and/or number of hospitals. Then, based on the BLS commutation data, we would compute a blended wage index for each county in which a hospital is located based upon the residential distribution of the county’s workforce among different counties or CBSAs. We would not restrict ourselves to contiguous counties.

If the cost reports had a worksheet in which hospitals provided the number of FTEs living in each county, we could customize a wage index for each hospital, which might be ideal. That was the spirit behind CMS’s nearest neighbor proposal in 1994; however, those wage indices had a far weaker empirical basis.

Using BLS Data to Derive the Wage Indices

MedPAC will strongly recommend that CMS change the data source for the wage indices from hospital cost report data to BLS data. We vigorously oppose this recommendation.

Our greatest concern about the use of BLS data is that using them for a purpose other than statistical comparisons might invite a corruption of the data. The BLS survey data are “pure” because they are only used for statistical reporting. If the data were used for Medicare

reimbursement and if any organization could obtain and submit a survey, then providers in any CBSA could collude to bias the results. This would render the data useless for the entire U.S. economy.

Regardless of any safeguards that might exist today, an entire infrastructure of auditors would need to be built around the BLS survey process to protect its integrity. This would be redundant to the cost report auditors and, therefore, wasteful of government resources. On the other hand, if BLS specifically restricted its data collection to a sample of employers, then its choice of employers would be vulnerable to criticism. In the end, the cost report data—while admittedly imperfect—are still the most reliable for Medicare wage index construction.

Other limitations of the BLS data include the following:

- The BLS data contain no fringe benefits, which must be included to fully reflect regional differences in compensation levels. To accommodate this problem, MedPAC imputed a fringe benefit adjustment for each CBSA from the cost report data. This is problematic because the fringe benefit adjustment reflects skill mix while the BLS data do not. Since the benefit share of total compensation declines as salaries increase, the fringe benefit adjustment is too low for tertiary hospitals, which have a more expensive mix of personnel. Therefore, MedPAC's approach underestimates the wage levels of areas with high concentrations of tertiary hospitals. In addition, when hospitals were missing benefits on Worksheet A or when the benefits were outliers, MedPAC used Worksheet S-3, Part II data. This is problematic because those data would not be available if the wage index survey were discontinued—another feature of MedPAC's proposal. If hospitals had to continue to fill out the wage index survey to meet this need, then there would be no reduction in reporting burden, and no benefit whatsoever to using BLS data.
- MedPAC excluded Part A physicians, which causes an understatement of wage levels in inner-city communities. While most Part A physicians are teaching physicians and, therefore, excluded from the wage index, many hospitals employ physicians to staff outpatient clinics. This tends to occur in inner-city communities where hospital clinics serve as the family doctor. Patients generally do not have access to private physician offices because physician reimbursement is inadequate from the State Medicaid programs. MedPAC excluded physicians from the BLS data because they would have been over-represented in the occupational mix compared with their representation in the hospital cost report data. However, this decision underestimates the wage levels of inner-city communities.
- MedPAC was forced to weight the occupational data based on each occupation's share of wages instead of hours or even employees. This also leads to error.
- Using BLS data restricts CMS's flexibility to revise or customize labor markets.

In preparing its proposals for FY 2009, we implore CMS not to switch the wage index data source to BLS data and to continue to use the hospital cost report survey. Despite its problems, we believe it is the best and most reliable data source.

VALUE-BASED PURCHASING PLAN

Section 5001(b) of the DRA required CMS to develop a VBP plan. While further legislation would be needed to implement the plan, the prior Congress aimed for implementation to begin in FY 2009. During the past year, CMS has developed a plan and shared it in the context of an evolving options paper and in listening sessions with the public. We have followed that development and have also analyzed and modeled the plan as outlined in the version of the options paper issued April 12, 2007.

At the outset, we want to commend CMS for the basic structure of the plan. It is modeled on the RHQDAPU program in that it would withhold a certain percentage of funding from each hospital, which the hospital could earn back by meeting certain performance goals. Since the performance goals are always based on a prior year's data, theoretically at least, any hospital could earn back its entire withhold. This contrasts with the Premier demonstration project under which all the rewards were distributed to hospitals performing in the top two deciles. It is appropriate that the structure of the VBP and Premier plans is different because the financing of the incentive payments under the two plans is different: the Premier plan was financed with new money, while the VBP plan is financed by withholds.

Because we believe that the opportunity must be available for all hospitals to earn back their full without amount, we strongly recommend that CMS preserve its policy to base the performance goals on a prior year's data.

Essentially the VBP plan works as follows (italicized words are VBP terms of art):

- CMS would compute an *overall score* for each hospital by dividing the number of points the hospital earned by the maximum number of points it was possible for the hospital to earn. Then the overall score would be converted into an earned share of the withhold amount through an *exchange function*.
- The overall score would be based on points earned for each measure in the VBP portfolio. The conditions currently evaluated by CMS—i.e., heart attack, heart failure, pneumonia, and surgical infection prevention—would not be weighted equally; rather they would be weighted indirectly by the number of measures included for each condition.
- Points for each measure would be the higher of *attainment* or *improvement* points, with each type conferring between zero and 10 points. For each type, one point would be conferred for achieving a *threshold* score and 10 points would be conferred for achieving a *benchmark* score. All thresholds and benchmarks would be computed from the prior year's data.
- For any given measure, the attainment range would be the same for all hospitals. Its threshold would be the median score (1 point) and its benchmark would be the average score for hospitals at or above the 90th percentile (10 points). The exception to this would be that for *topped-out measures*, the threshold for all measures would always be a score of 60% and the benchmark for all measures would always be a score of 90%.

- The improvement range would be hospital-specific. Its threshold would be the hospital's prior year score, while its benchmark would be the attainment benchmark.

After modeling how the plan would work, we developed several recommendations, which center on hospital and data exclusions, point scoring, identifying topped-out measures and setting their attainment range, the exchange function, the use of unearned withholds, and the timing of implementation.

The data source we used to analyze the VBP plan was the *Hospital Compare* database, and the releases we used were the March 2007 file for the "current" year and the March 2006 file for the "prior" year. The March 2007 file included data from the fourth quarter of 2005 through the third quarter of 2006, and the March 2006 file included data from the fourth quarter of 2004 through the third quarter of 2005. Again, data from the prior year are used to compute the national attainment range for each measure and the hospital-specific improvement range for each measure.

Hospital and Data Exclusions

According to the options paper, a hospital would be excluded from VBP if it did not have at least 50 cases among measures with at least 10 cases. In addition, a hospital that is otherwise included would be excluded from any particular measure for which it had fewer than 10 cases. *We recommend that whenever a hospital is excluded from performance evaluation, its data also be excluded from computation of the threshold and benchmark scores.* Since these scores are based on percentiles, including hospital data that are not good predictors of performance would be inappropriate and would bias the results.

Point Scoring

The options paper says that a hospital would receive 10 points on any measure if its performance was greater than or equal to the benchmark. However, to receive lower point values, the hospital's performance would have to be greater than the threshold and interim scores, which would include even a slight fraction above those values but not the values themselves. This inconsistency is aesthetically disrupting and makes virtually no difference in the outcome. *Thus, we would appreciate it if CMS would confer points for hospital performance that is greater than or equal to the threshold and interim scores, as well as the benchmark.*

Identifying Topped-Out Measures and Setting their Attainment Range

The options paper established a fixed attainment range for topped-out measures based on compliance scores of 60% to 90%, meaning that the threshold would be 60%, at which hospitals would receive one point, and the benchmark would be 90%, at which hospitals would receive 10 points. Furthermore, the options paper said that topped-out measures would be identified as those in which the 75th percentile score was statistically indistinguishable from the 90th percentile score, and it indicated which of the candidate VBP measures were topped out.

Because the options paper did not provide the formula it used to measure the statistical significance of the difference between the 75th and 90th percentile scores, we tried to replicate the paper's identification of topped-out measures using several different formulas, but were unable to do so. Part of our problem was surely that we used different databases, but we are nevertheless concerned that the options paper did not designate certain measures as topped out which we believe would meet the criteria.

Below we provide graphs of all the *Hospital Compare* process measures, which show where the regular and topped-out attainment ranges would be for each measure. We derived these ranges from both the March 2006 and March 2007 releases of the *Hospital Compare* database to observe the stability of the results, and show the ranges for both timeframes. Simply based on visual inspection, we would identify only three measures from the March 2006 database and only one measure from the March 2007 database that is not topped out (AMI-7 Thrombolytic within 30 minutes).

Since the thresholds and benchmarks differ greatly for regular and topped-out measures while their actual scores are not very dissimilar, we believe that CMS should eliminate the distinction between regular and topped-out measures and simply set 60% and 90% as threshold and benchmark caps, respectively. That is, the thresholds for all measures would be the lower of 60% or the measure-specific median, and the benchmarks for all measures would be the lower of 90% or the measure-specific average scores of hospitals at or above the 90th percentile.

The Exchange Function

The options paper presented two alternative exchange functions for converting overall scores into earned shares of the withhold amount:

- A linear exchange that would provide a positive share for any score above zero, and would provide 100% of the withhold amount for any score at or above 85%; and
- An exponential exchange that would provide a positive share for any score above 10%, and would provide 100% of the withhold amount for any score at or above 90%. The exponential function would provide higher shares for lower scores than the linear function.

We believe that the exchange function should accommodate the distribution of the overall scores. If the thresholds are set at the lower of 60% or the median, then hospitals will accrue relatively high scores and the linear function could be appropriate. However, if the thresholds are set higher so that hospitals accrue relatively low scores, then the exponential function would be more appropriate.

Regardless, we urge CMS to release a public use file with the hospital-specific data it used to prepare the options paper (with encrypted provider numbers and no names or state identifications), along with the formula it used to identify topped-out measures, and the threshold and benchmark scores it computed. We would like to study how different scoring methodologies and exchange functions affect the earned withhold shares so we can provide more specific recommendations to CMS.

Use of Unearned Withholds

The options paper presented alternative ways to spend the unearned withhold amounts in any given year, including: (1) using them to reward the best performing hospitals—e.g., the 10% of hospitals with the best performance; or (2) distributing them in proportion to each hospital's earned withhold amount. *Of those two options, we would favor the latter because it would distribute funding to more communities.* Since not all patients can go to only 10% of the nation's hospitals, concentrating the unearned withhold amounts in those communities would be inequitable.

For the same reason—i.e., concern about community services—we would like CMS to consider the possibility of spending at least a portion of the unearned withholds on strategies to improve quality in poor performing hospitals, especially if those hospitals are the only provider in their communities.

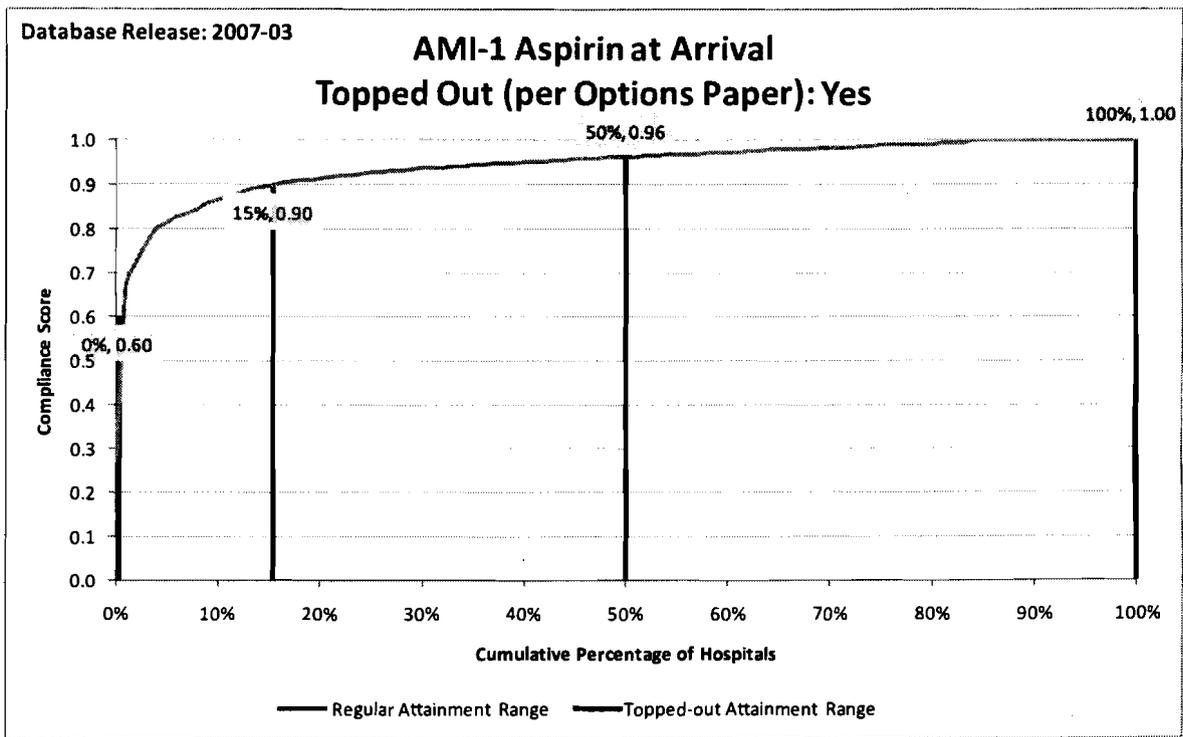
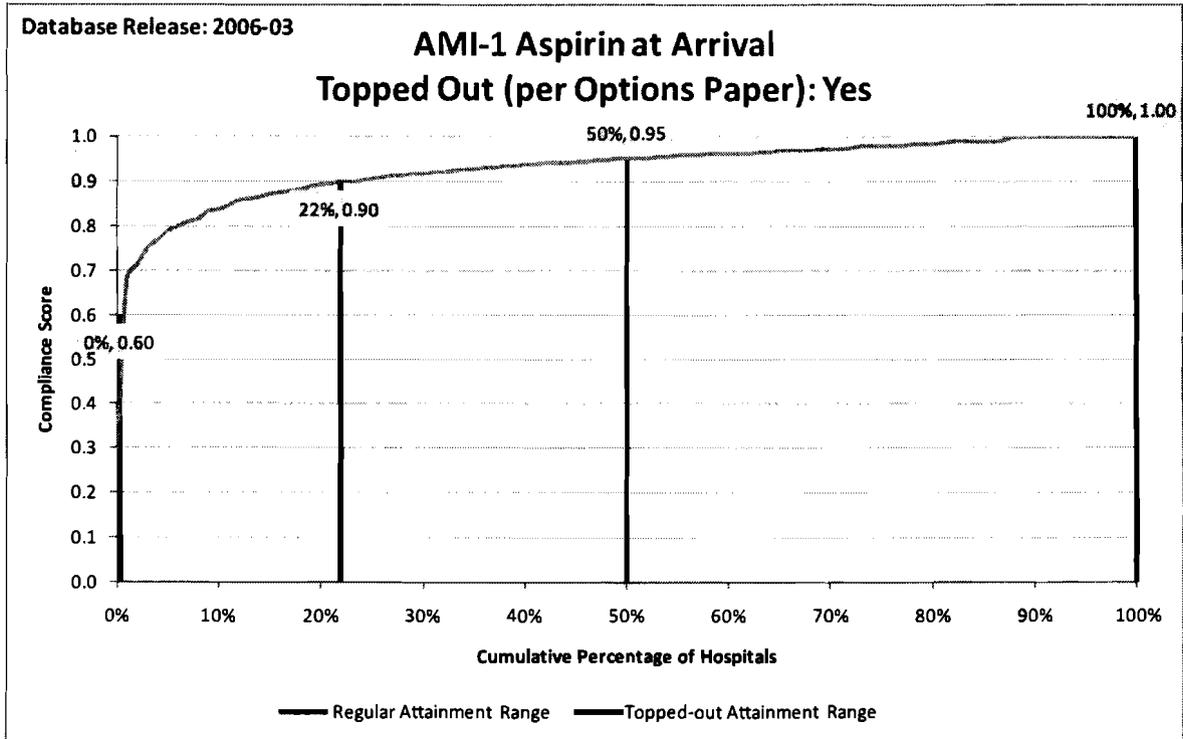
Timing of Implementation

The options paper presented two alternatives for implementation:

1. The first alternative was a phase in. In FY 2009, earning 100% of the withhold amount would continue to be based upon the RHQDAPU criteria. In FY 2010, earning 50% of the withhold amount would be based on the RHQDAPU criteria and 50% would be based on performance. In that year, 2007 data would be used to set the thresholds and benchmarks for the attainment and improvement ranges, and 2008 data would be used to compute the current year's performance. In FY 2011, earning 100% of the withhold amount would be based on performance. In that year, 2008 data would represent the prior year and 2009 data would represent the current year.
2. The second alternative was no phase in. In FY 2009, earning 100% of the withhold amount would be based on performance. In that case, 2006 data would be used to set the thresholds and benchmarks for the attainment and improvement ranges, while 2007 data would represent the current year's performance.

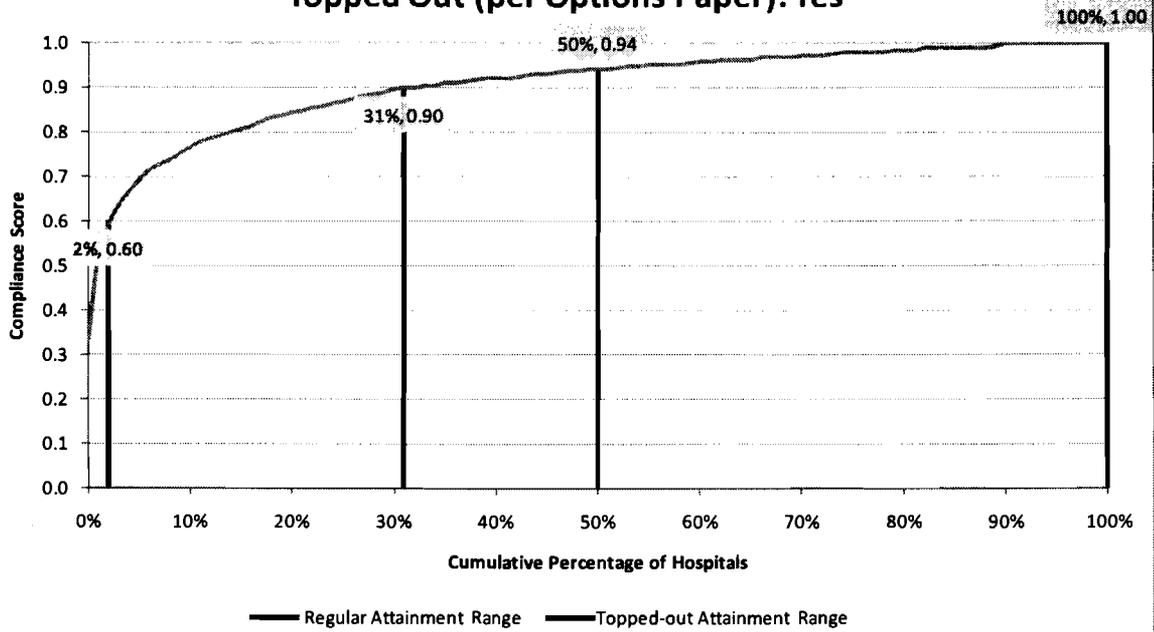
Given that we are almost half-way through 2007, we think it would be unfair to base the FY 2009 withhold on 2007 data. Hospitals should be given notice about VBP implementation before the first "current" year begins. Therefore, we strongly favor option 1.

Value-Based Purchasing Plan Regular and Topped-Out Attainment Ranges



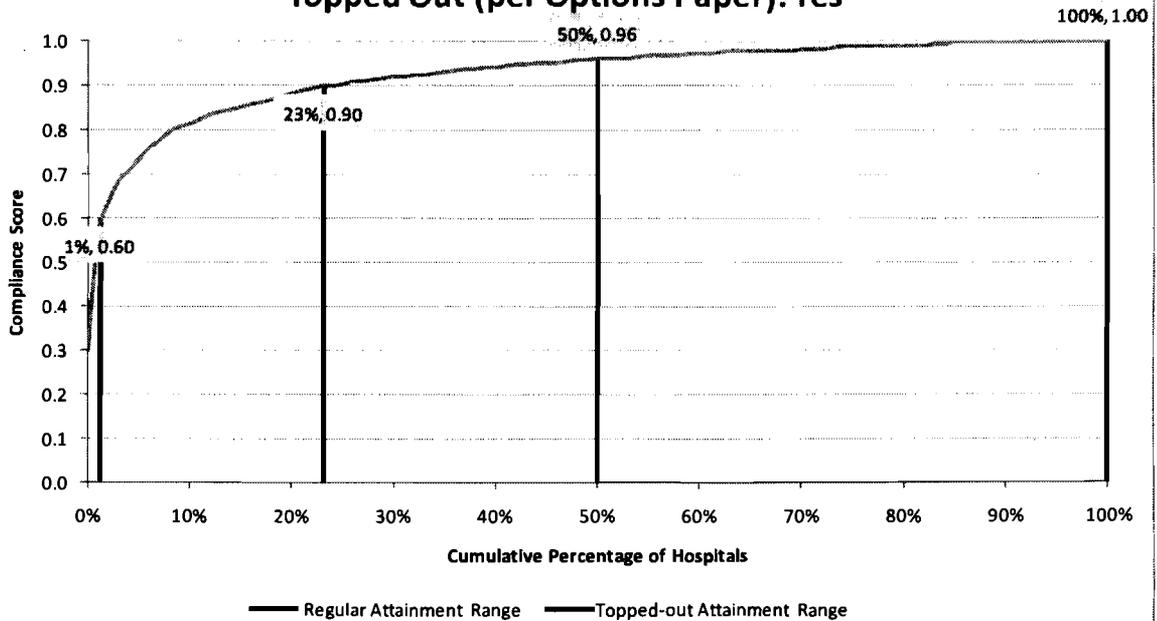
Database Release: 2006-03

AMI-2 Aspirin at Discharge Topped Out (per Options Paper): Yes



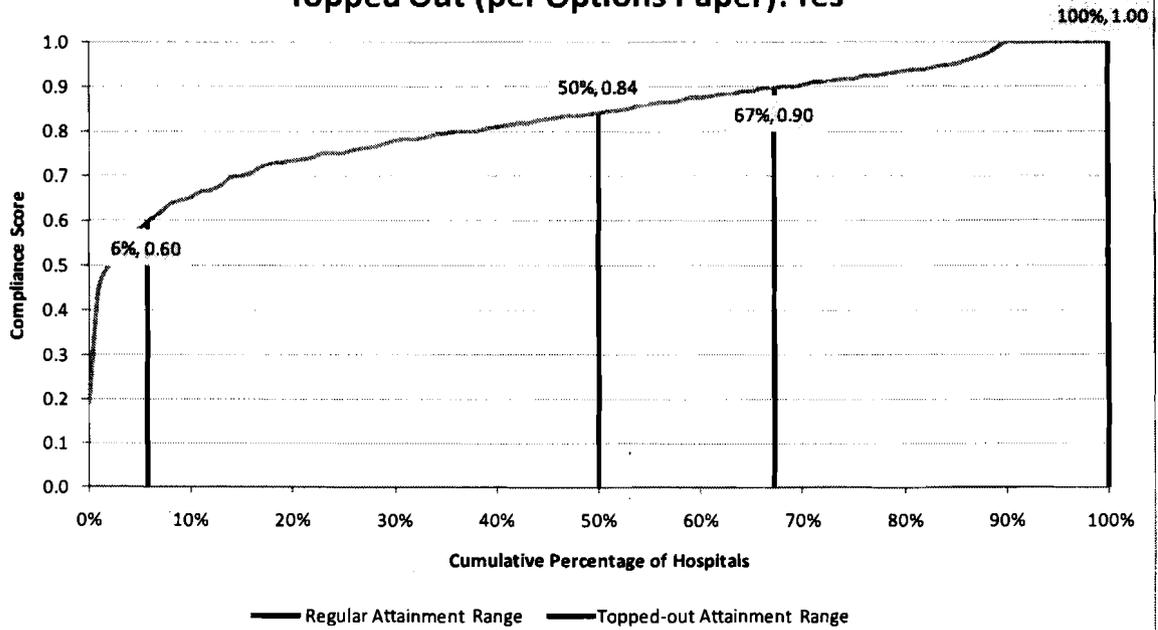
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AMI-2 Aspirin at Discharge Topped Out (per Options Paper): Yes



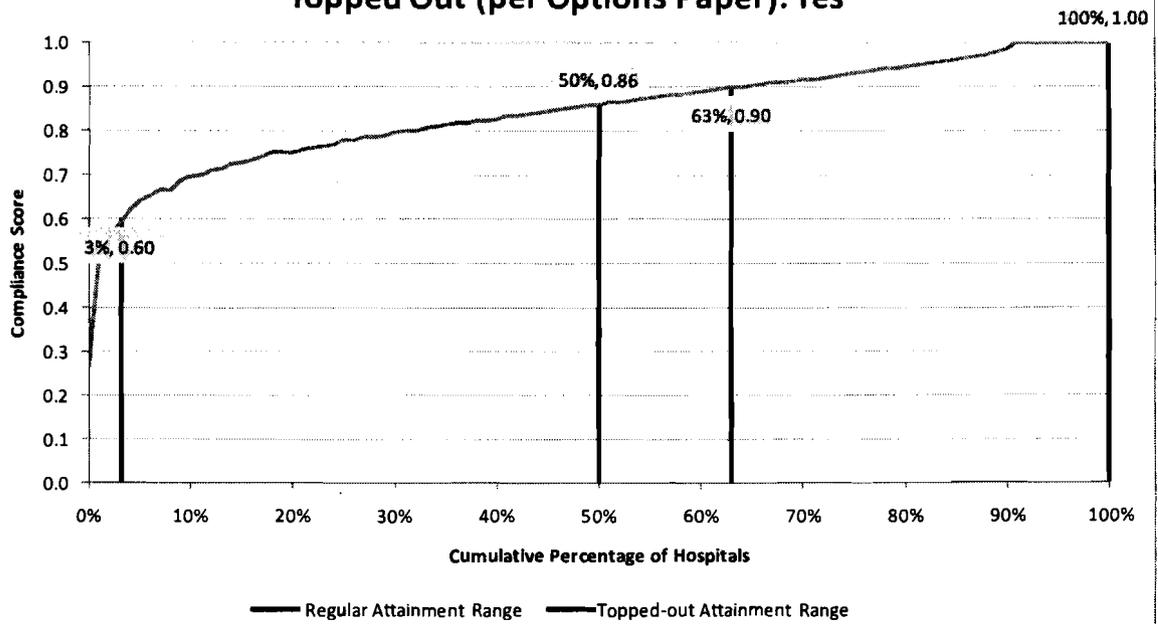
Database Release: 2006-03

AMI-3 ACEI or ARB for LVSD Topped Out (per Options Paper): Yes



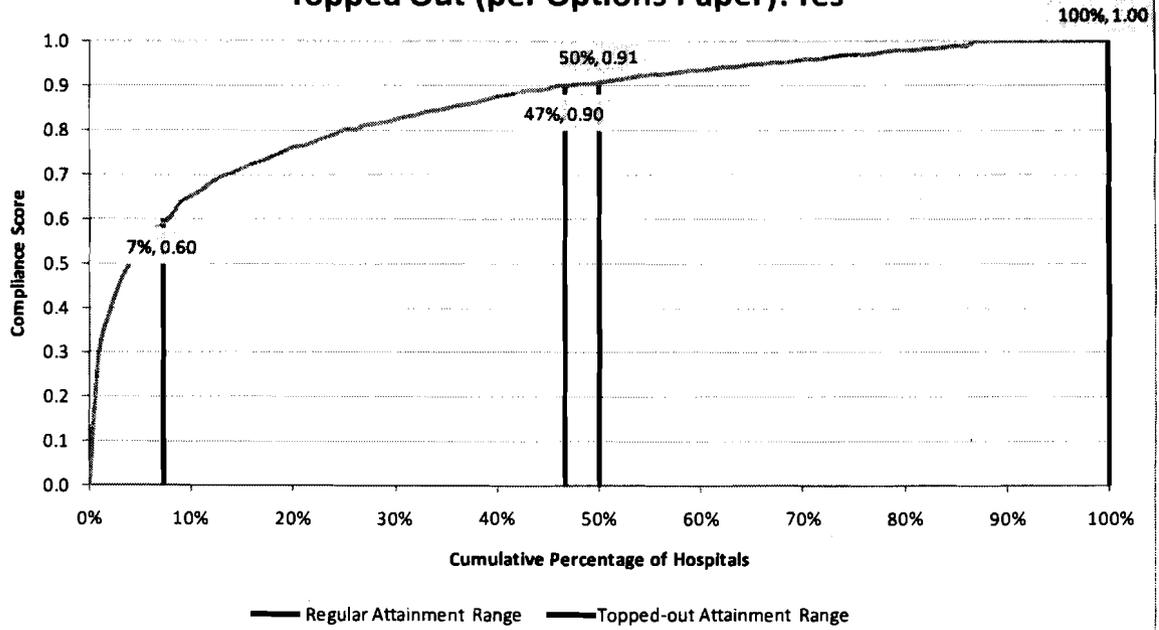
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AMI-3 ACEI or ARB for LVSD Topped Out (per Options Paper): Yes



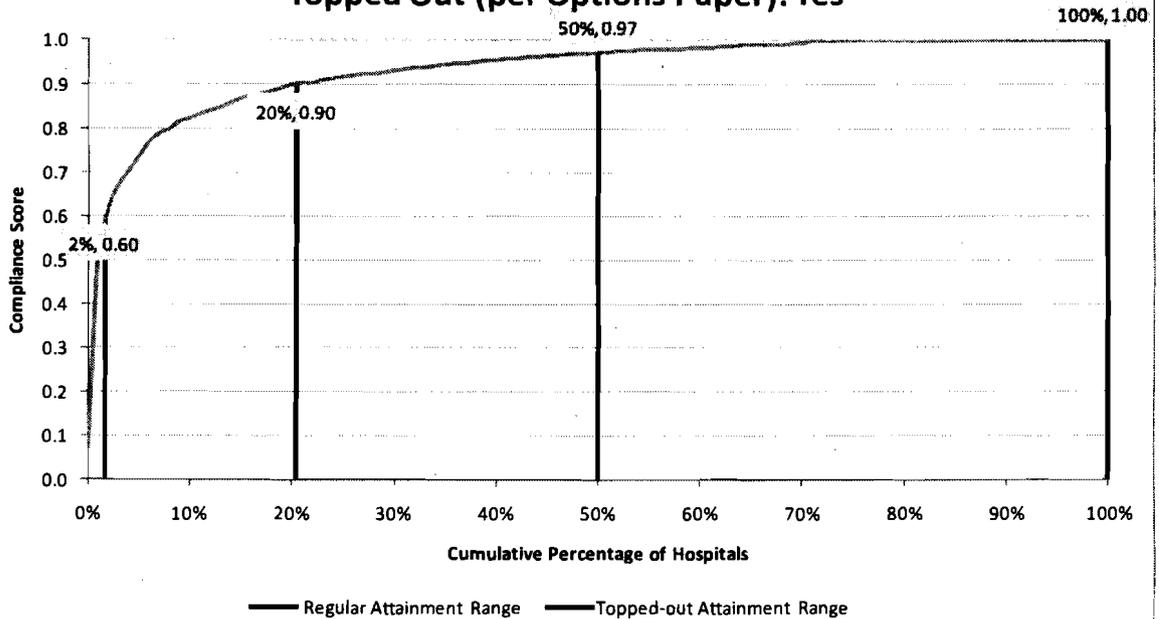
Database Release: 2006-03

AMI-4 Smoking Cessation Topped Out (per Options Paper): Yes



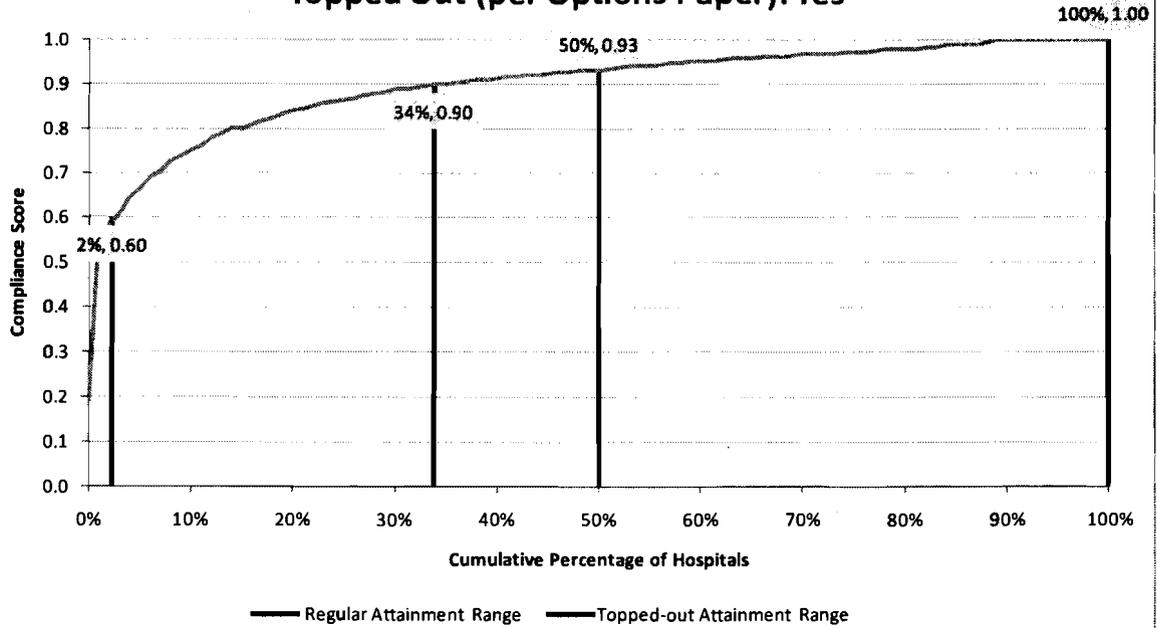
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AMI-4 Smoking Cessation Topped Out (per Options Paper): Yes



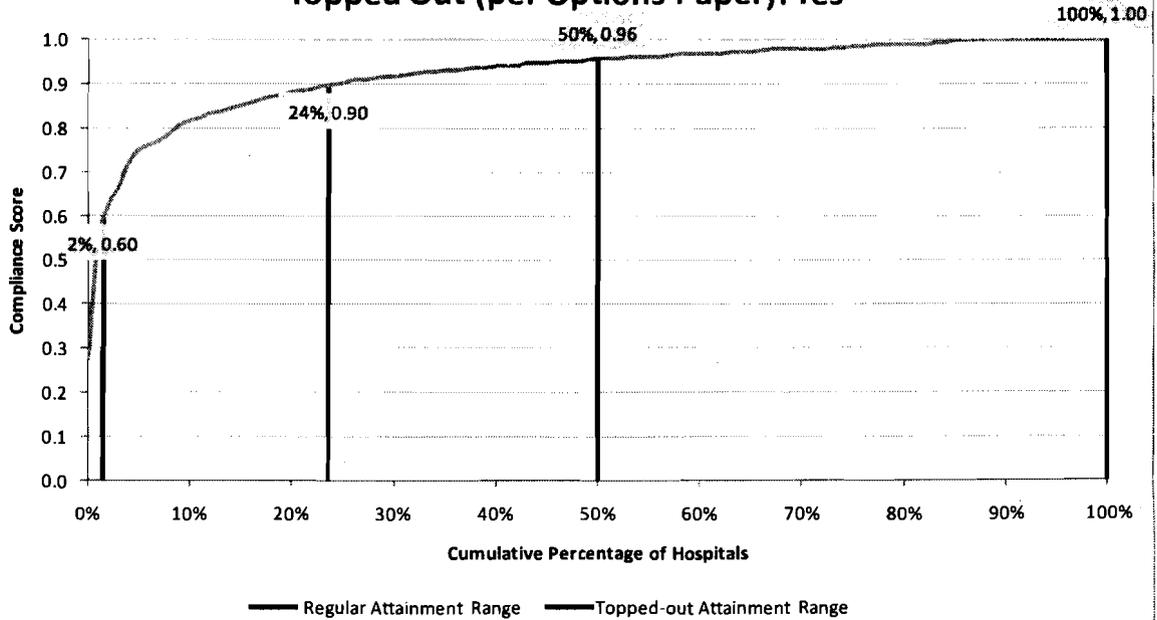
Database Release: 2006-03

AMI-5 Beta Blocker at Discharge Topped Out (per Options Paper): Yes



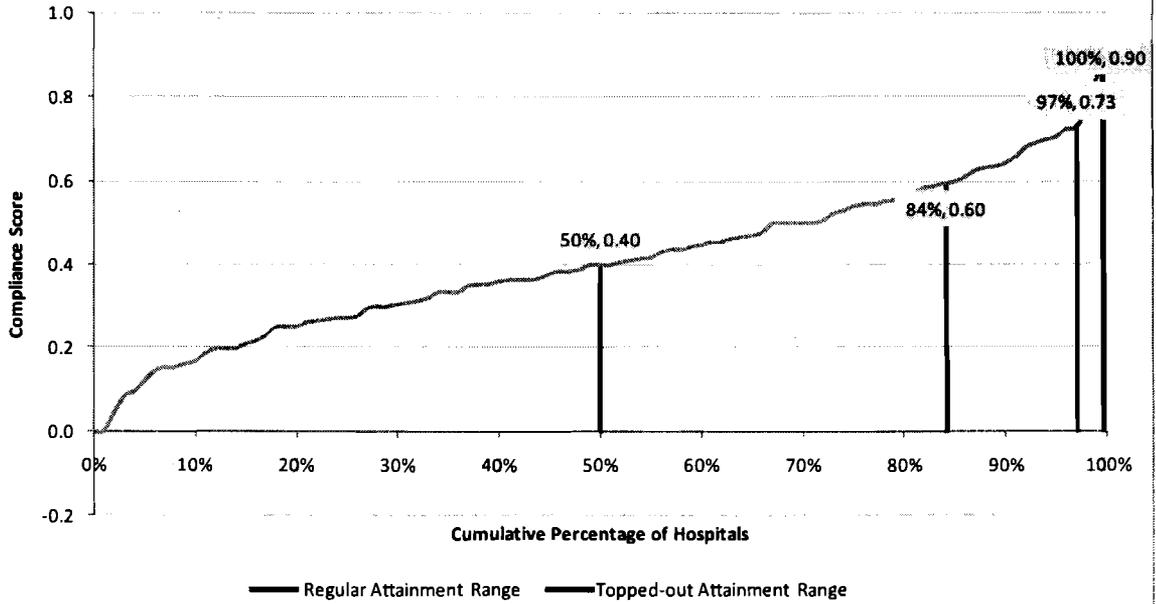
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AMI-5 Beta Blocker at Discharge Topped Out (per Options Paper): Yes



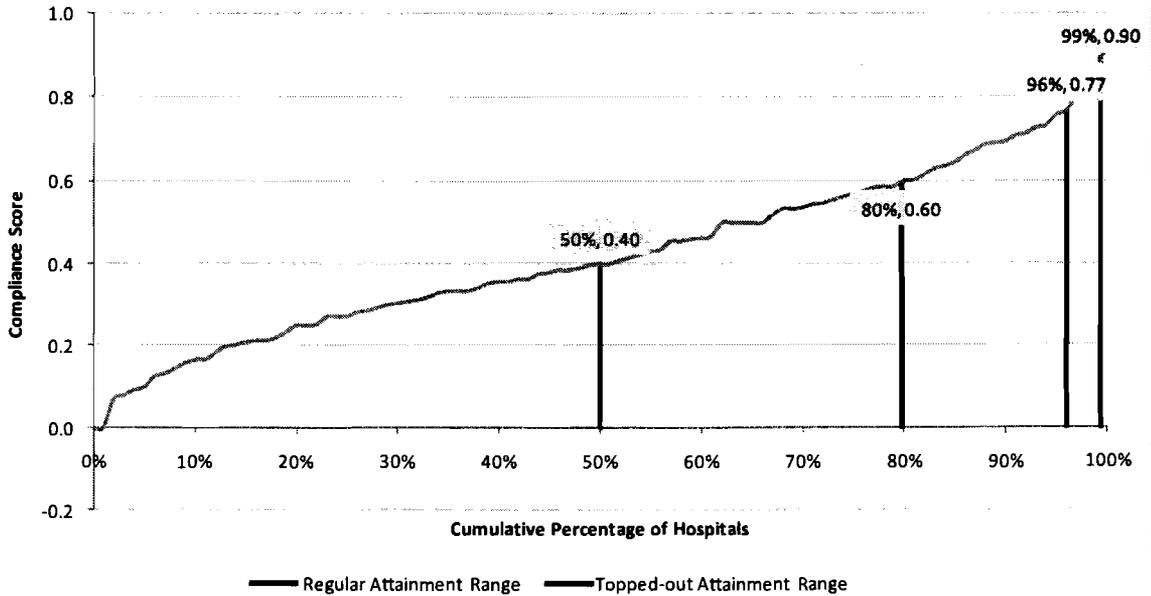
Database Release: 2006-03

AMI-7 Thrombolytic w/in 30min Topped Out (per Options Paper): No



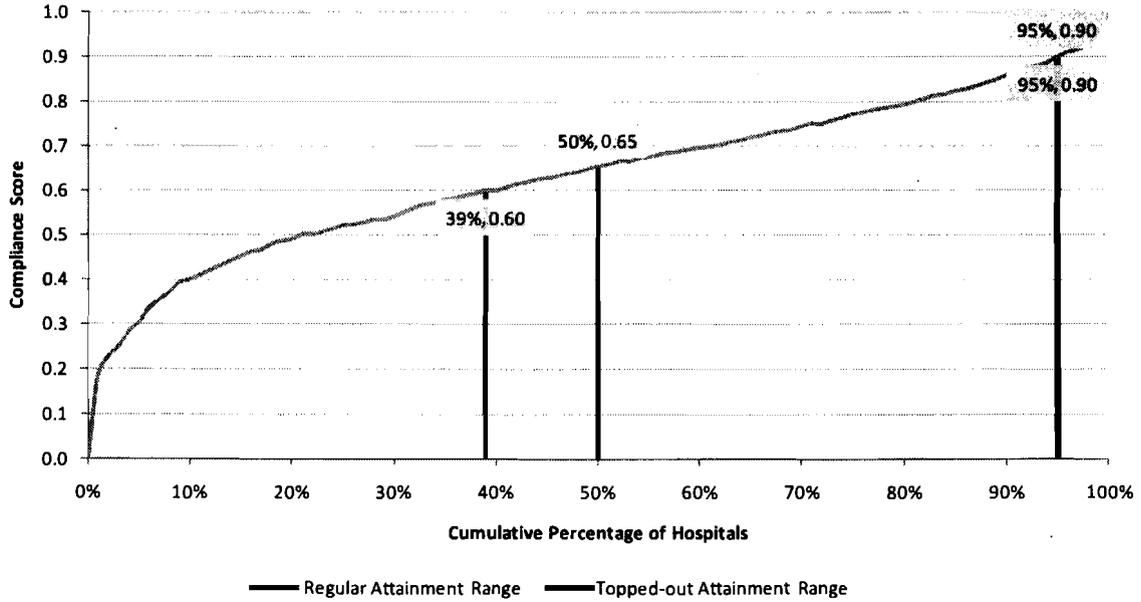
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AMI-7 Thrombolytic w/in 30min Topped Out (per Options Paper): No



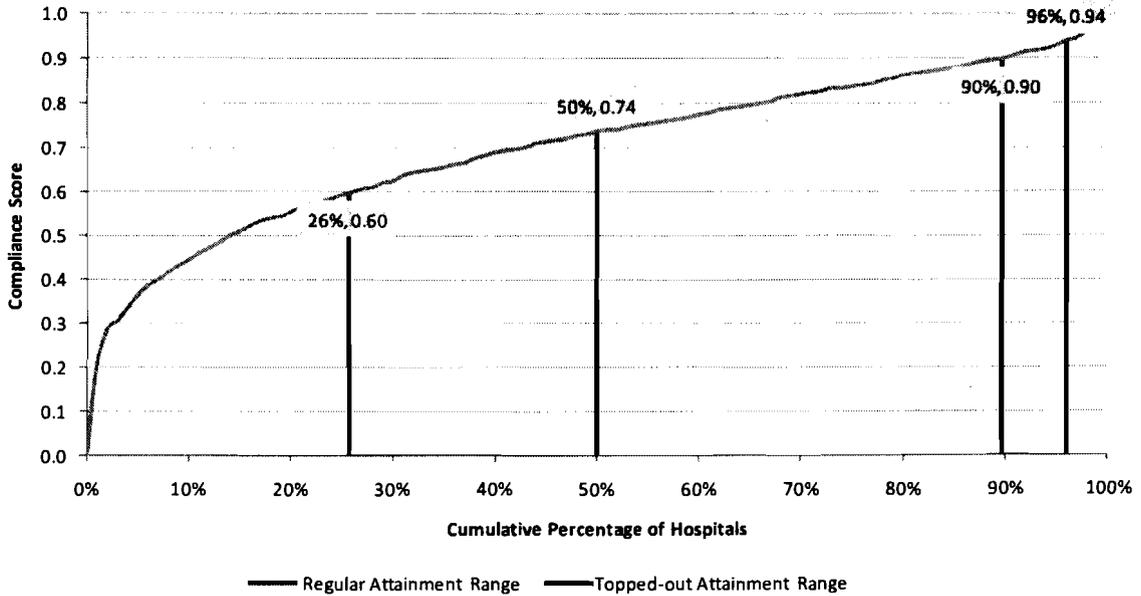
Database Release: 2006-03

AMI-8 PCI w/in 120min Topped Out (per Options Paper): No



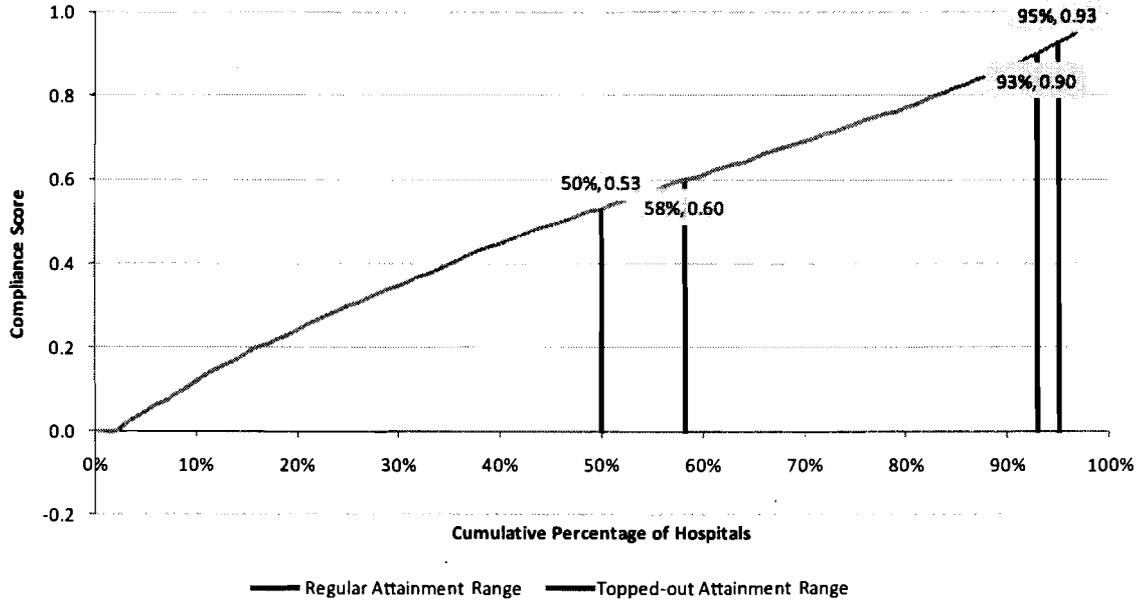
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AMI-8 PCI w/in 120min Topped Out (per Options Paper): No



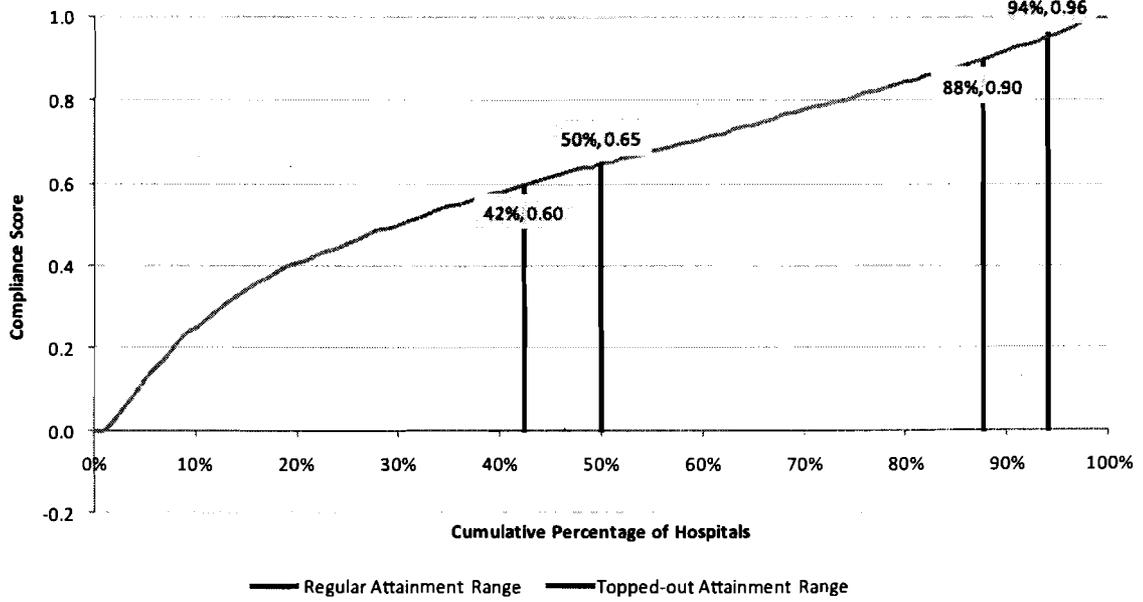
Database Release: 2006-03

HF-1 Discharge Instructions Topped Out (per Options Paper): No



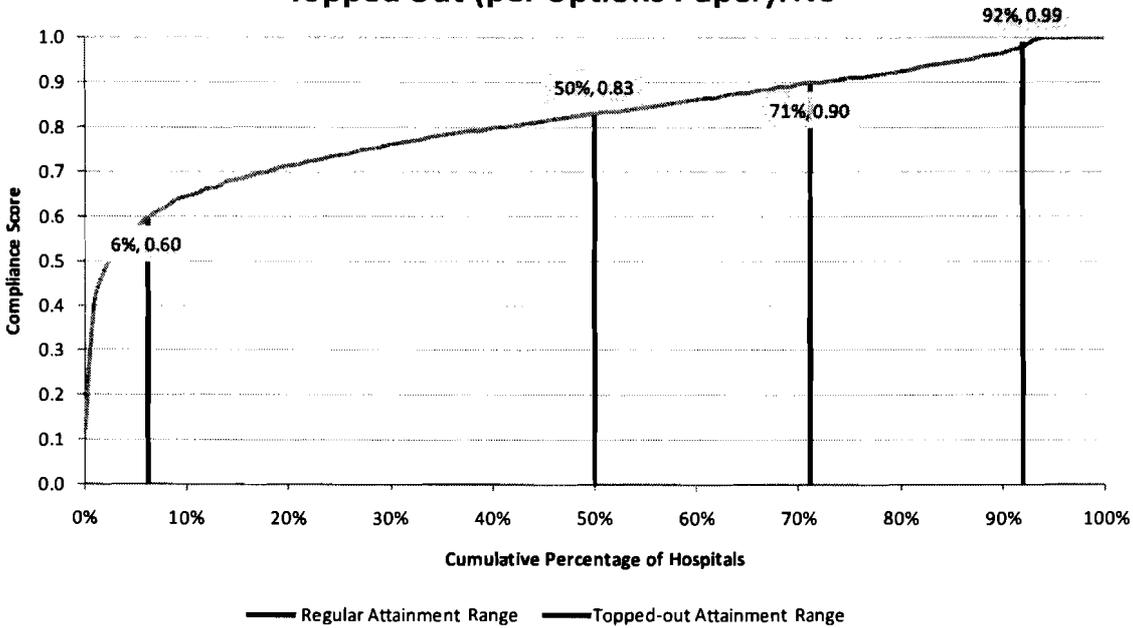
Database Release: 2007-03

HF-1 Discharge Instructions Topped Out (per Options Paper): No



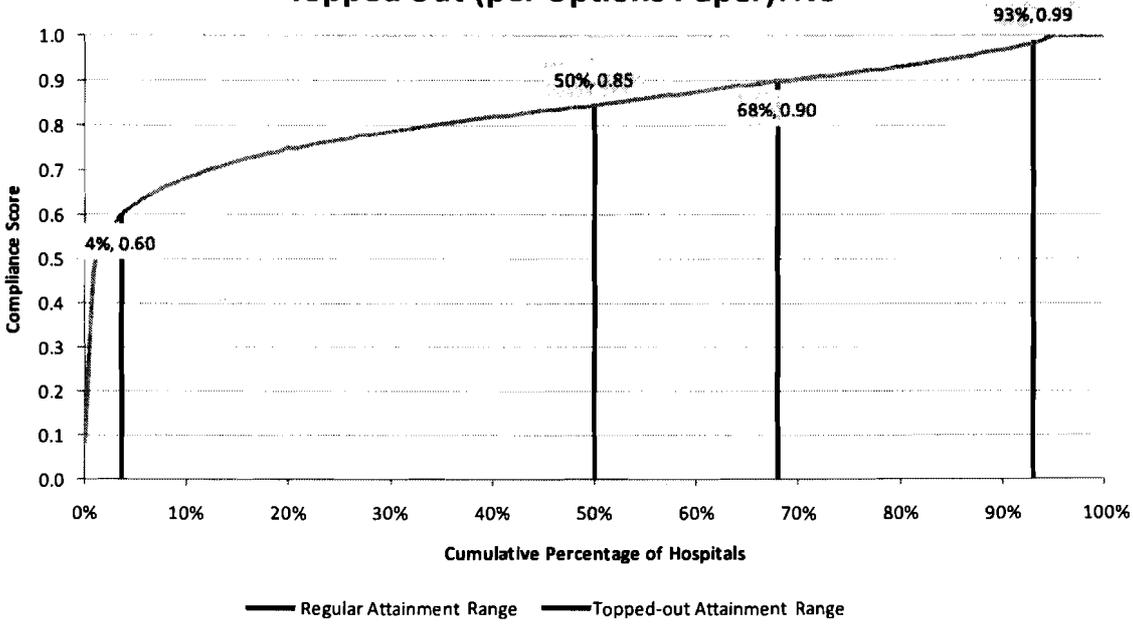
Database Release: 2006-03

HF-3 ACEI or ARB for LVSD Topped Out (per Options Paper): No



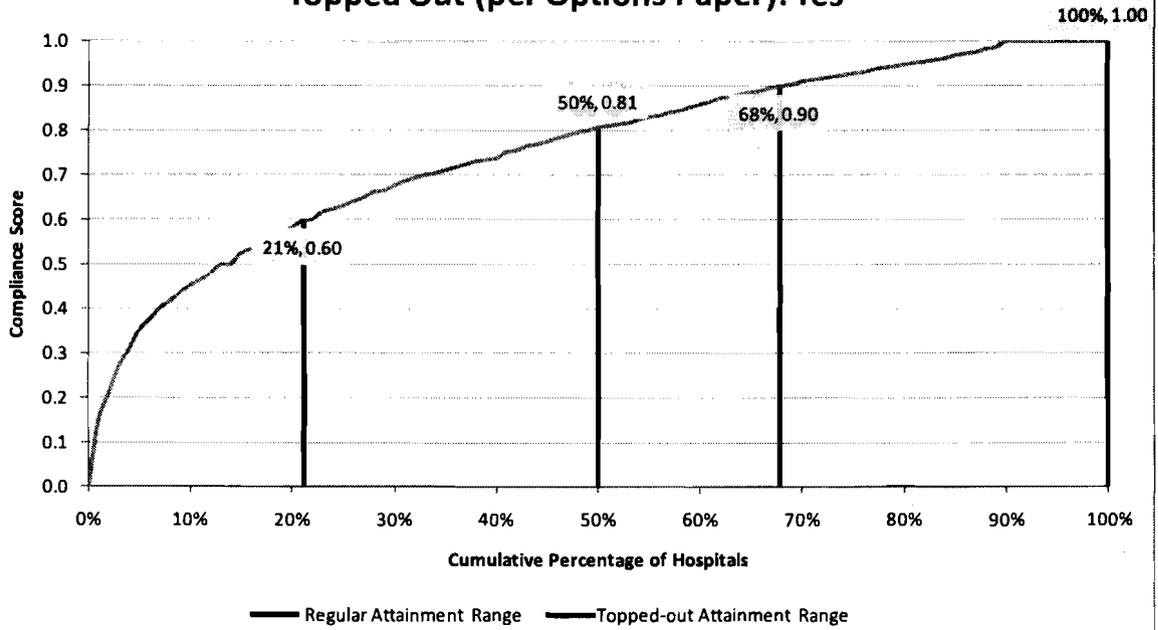
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HF-3 ACEI or ARB for LVSD Topped Out (per Options Paper): No



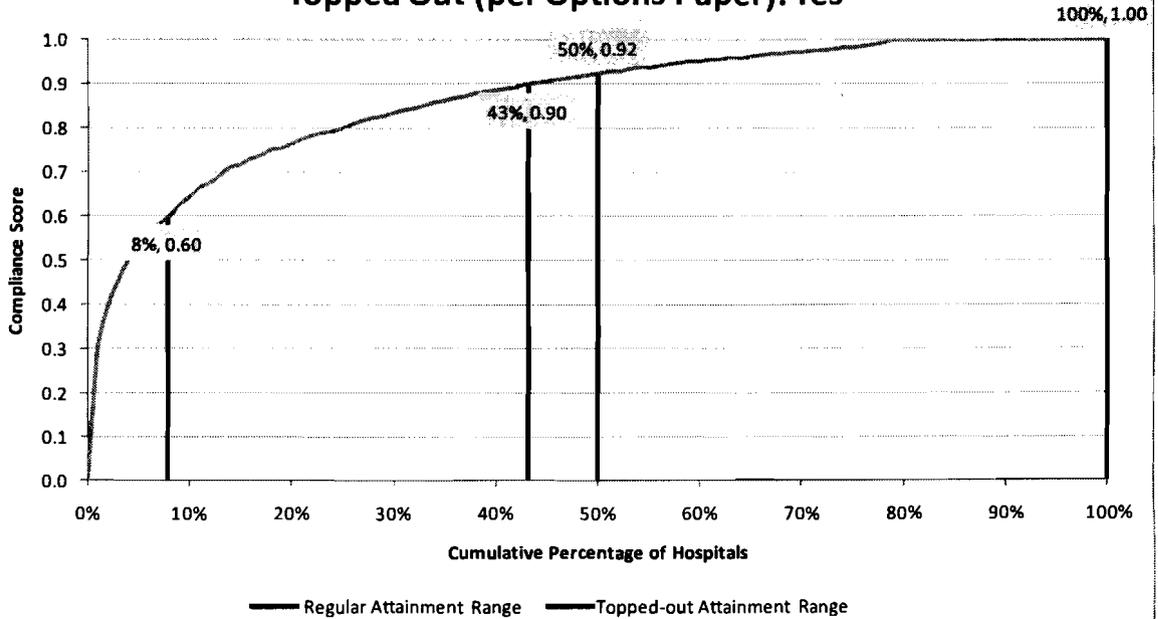
Database Release: 2006-03

HF-4 Smoking Cessation Topped Out (per Options Paper): Yes



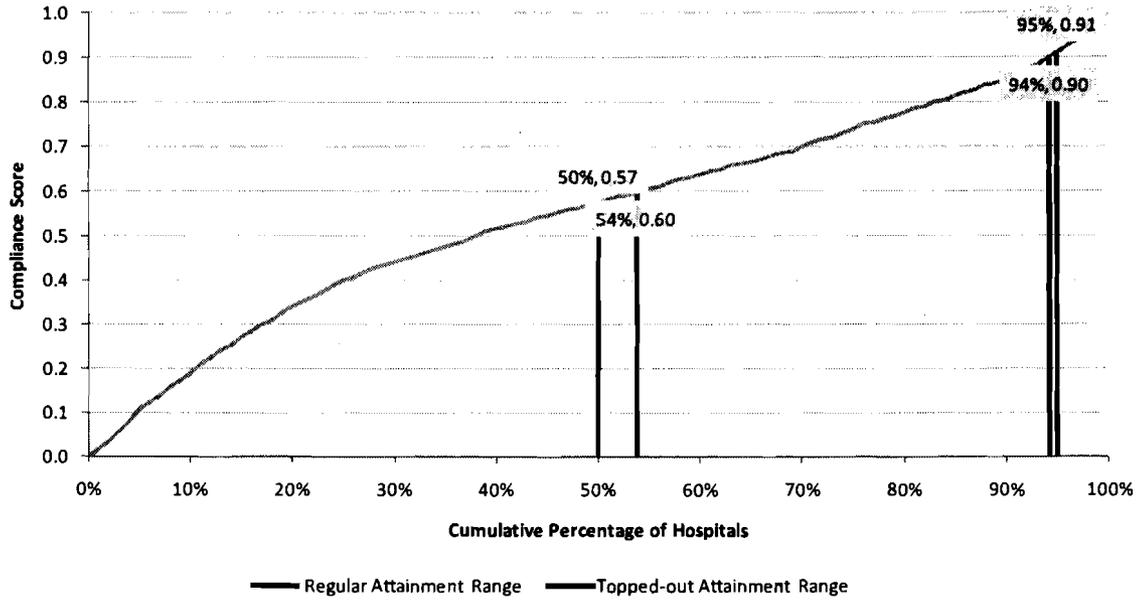
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HF-4 Smoking Cessation Topped Out (per Options Paper): Yes



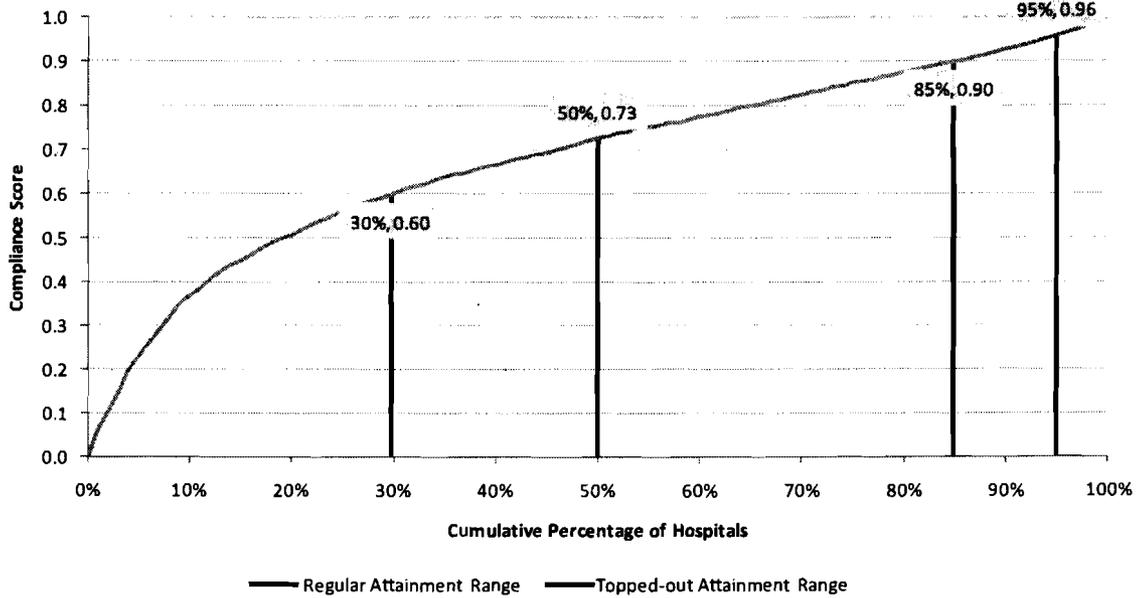
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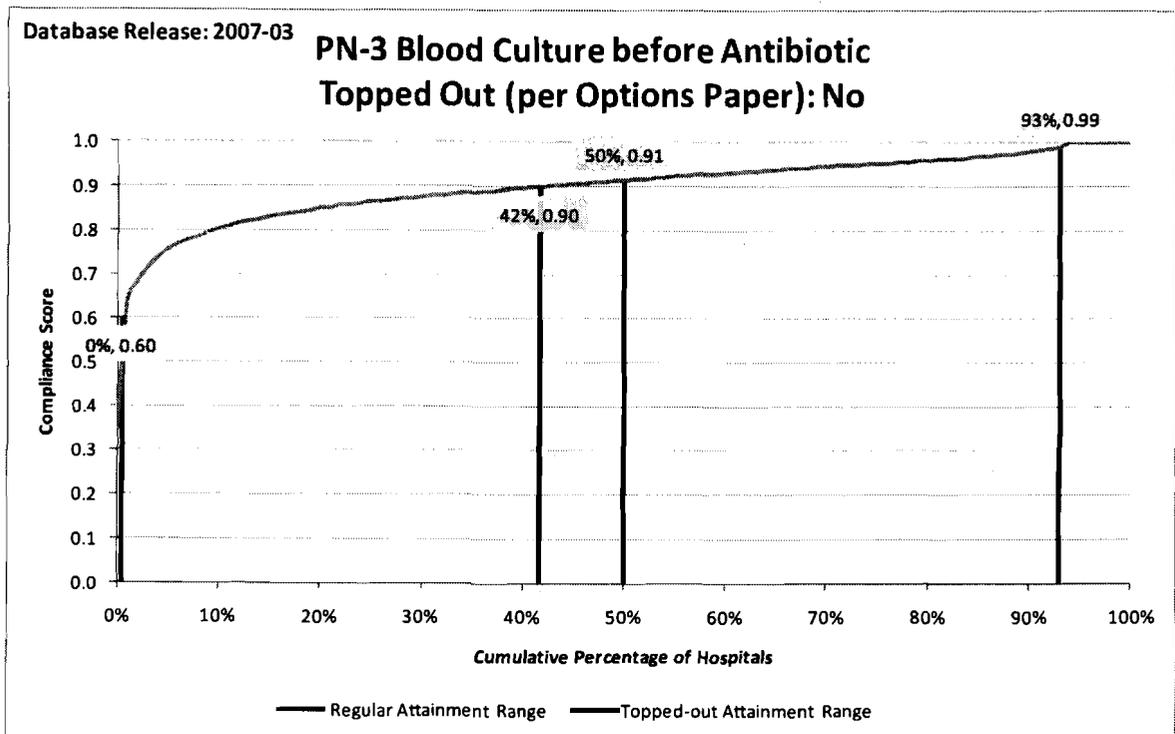
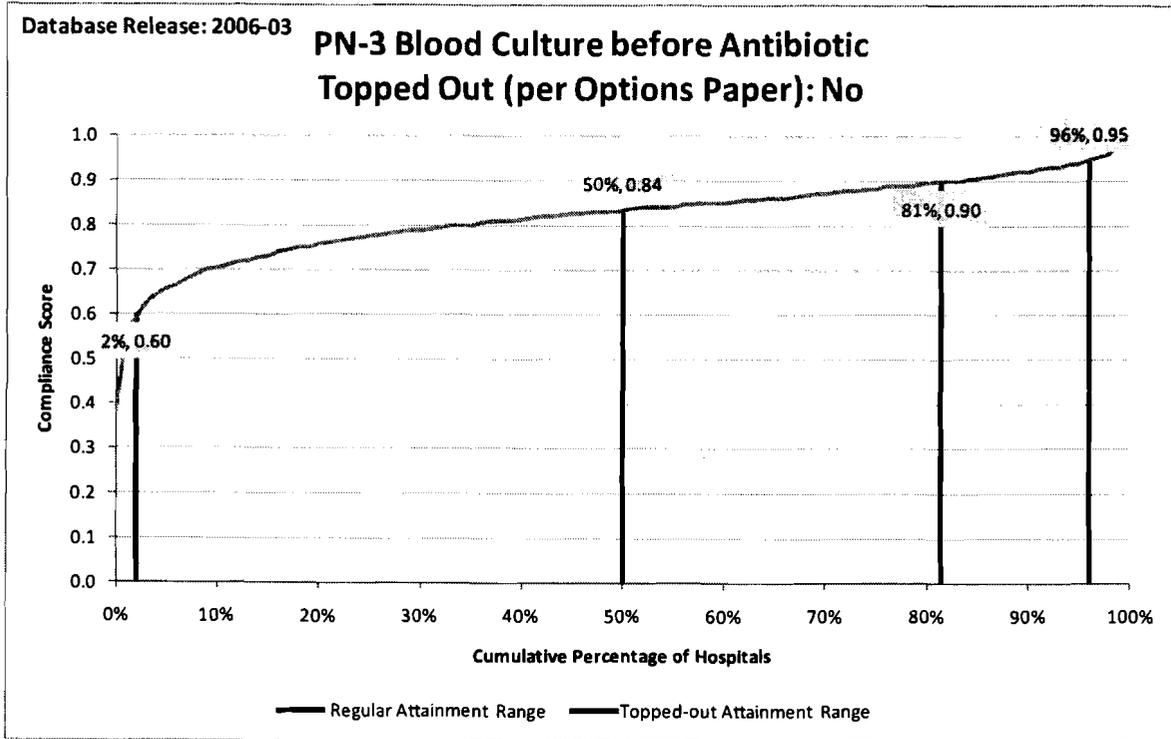
PN-2 Pneumococcal Vaccination Topped Out (per Options Paper): No



Database Release: 2007-03

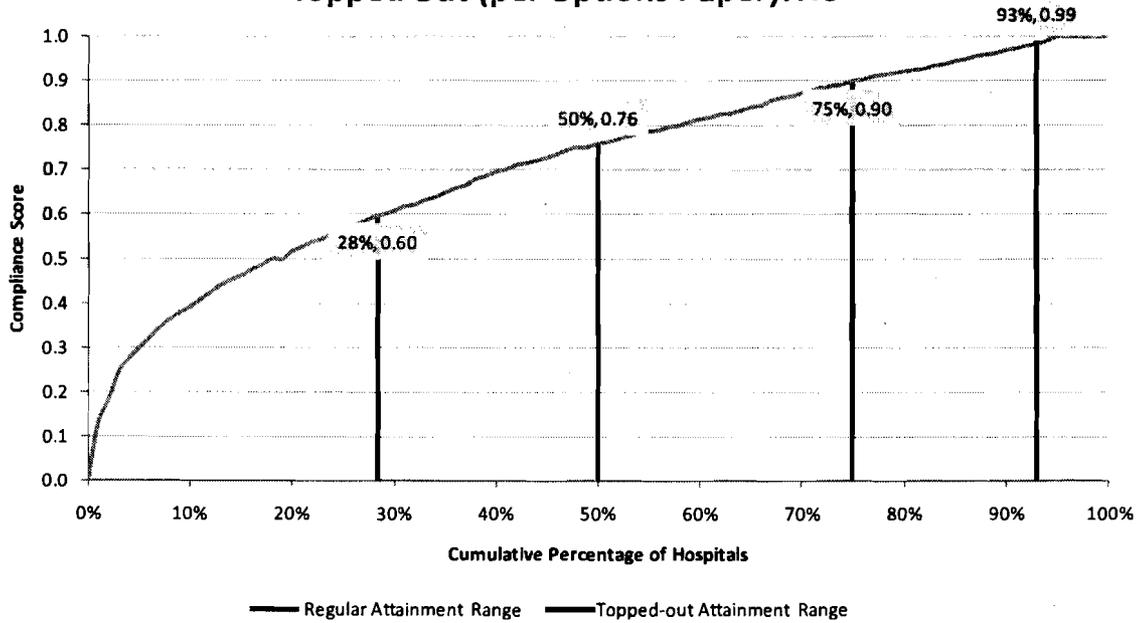
PN-2 Pneumococcal Vaccination Topped Out (per Options Paper): No





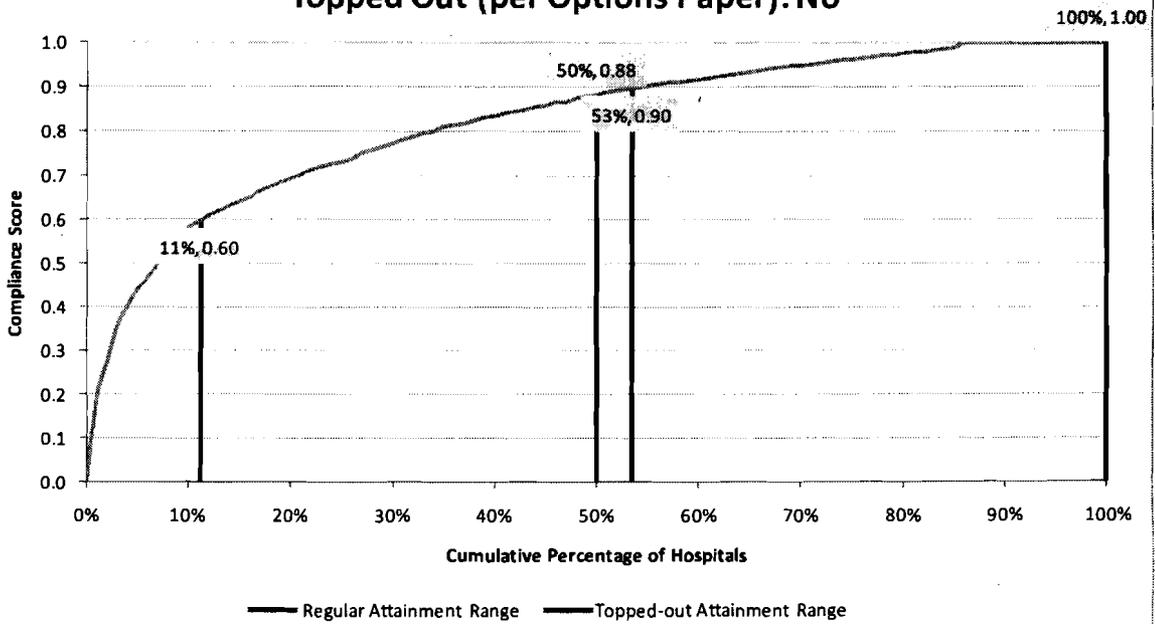
Database Release: 2006-03

PN-4 Smoking Cessation Topped Out (per Options Paper): No



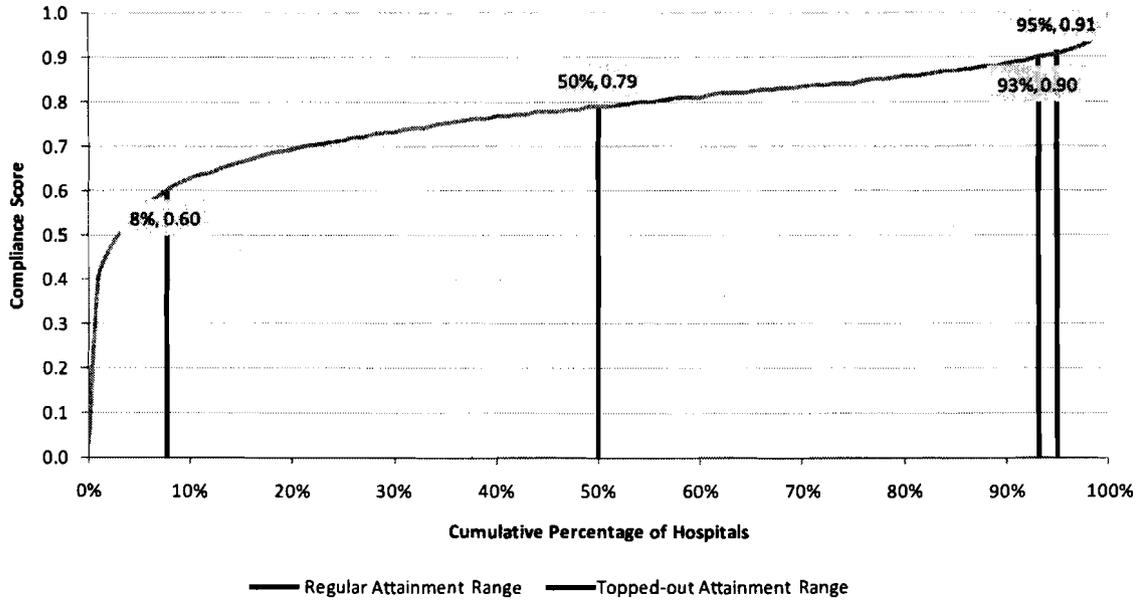
Database Release: 2007-03

PN-4 Smoking Cessation Topped Out (per Options Paper): No



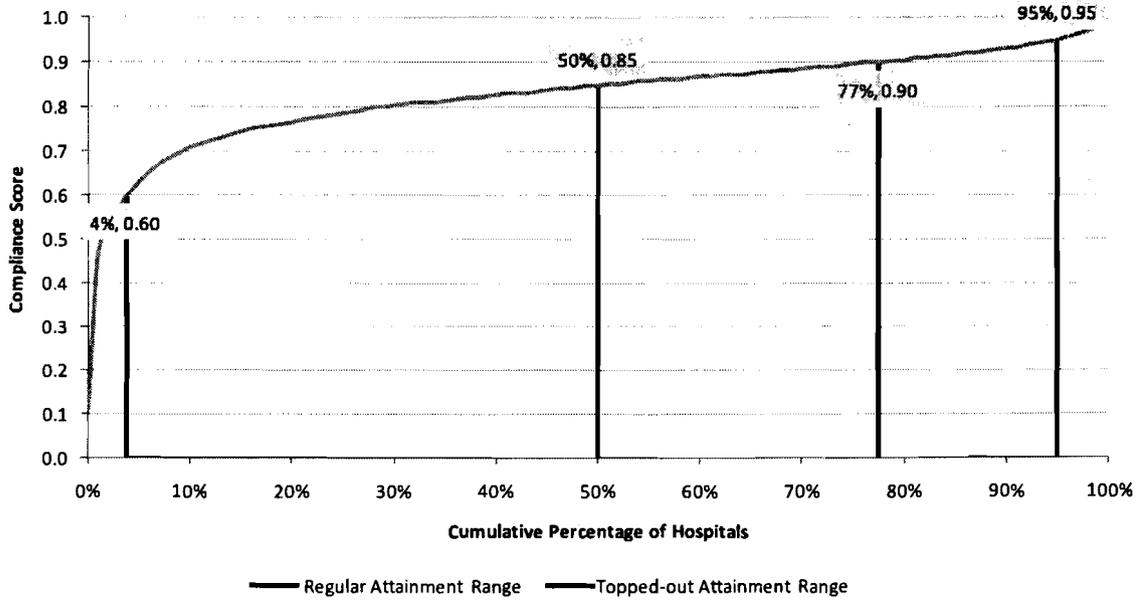
Database Release: 2006-03

PN-6 Appropriate Antibiotic Topped Out (per Options Paper): No



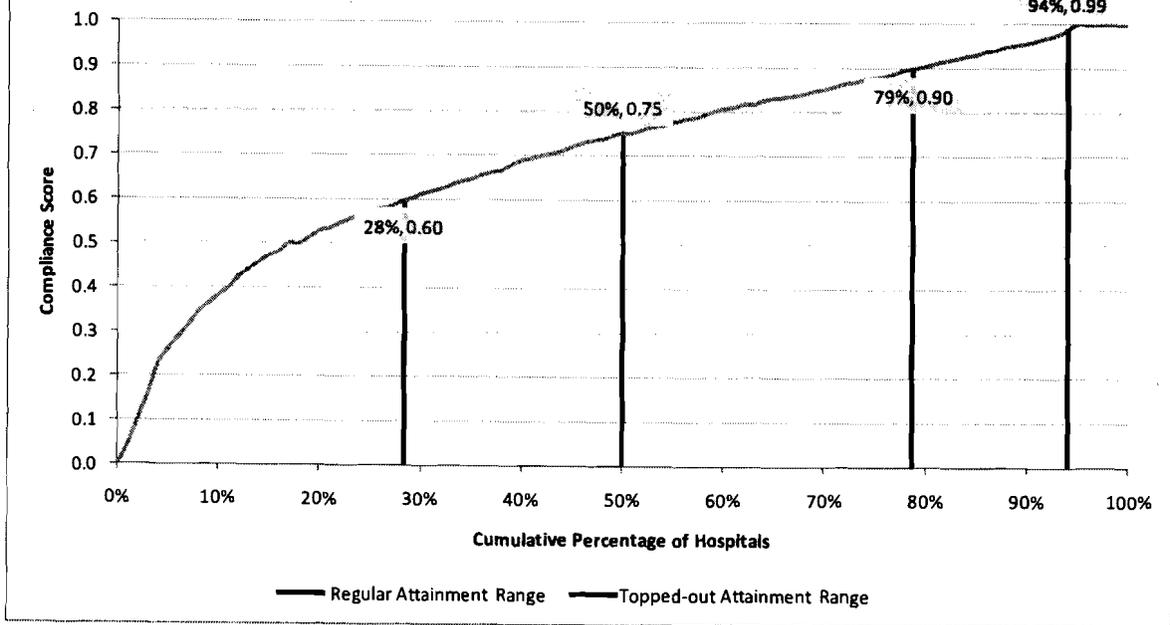
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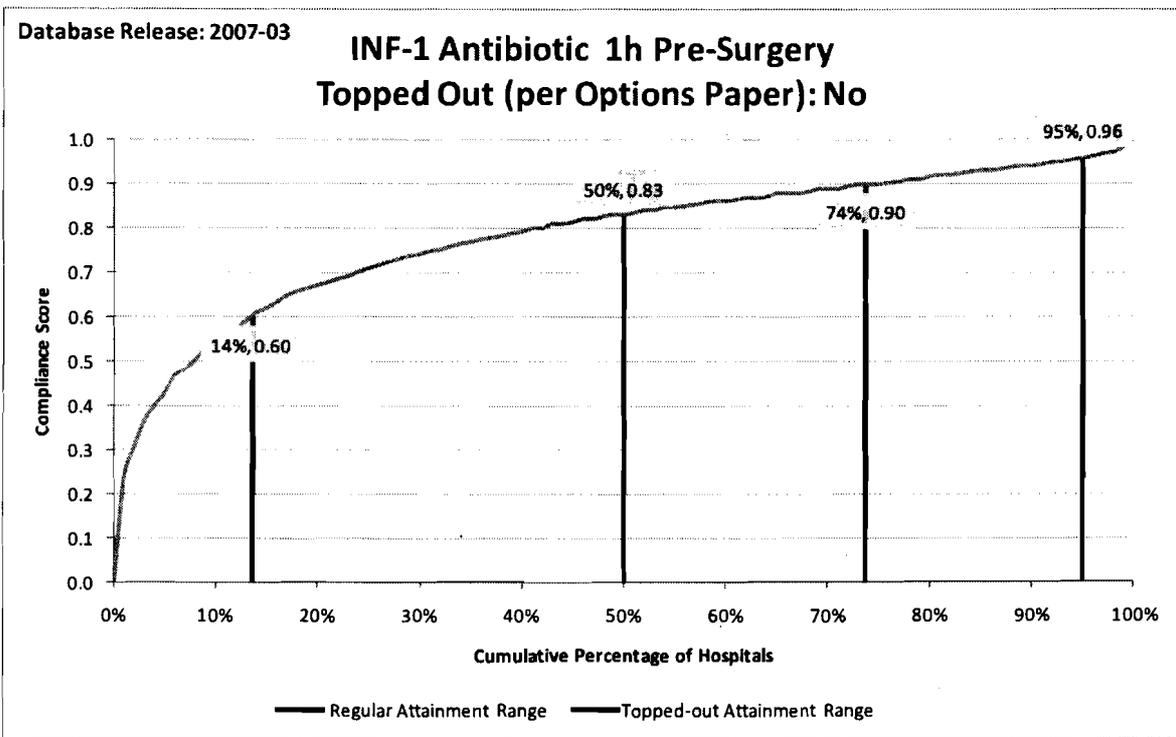
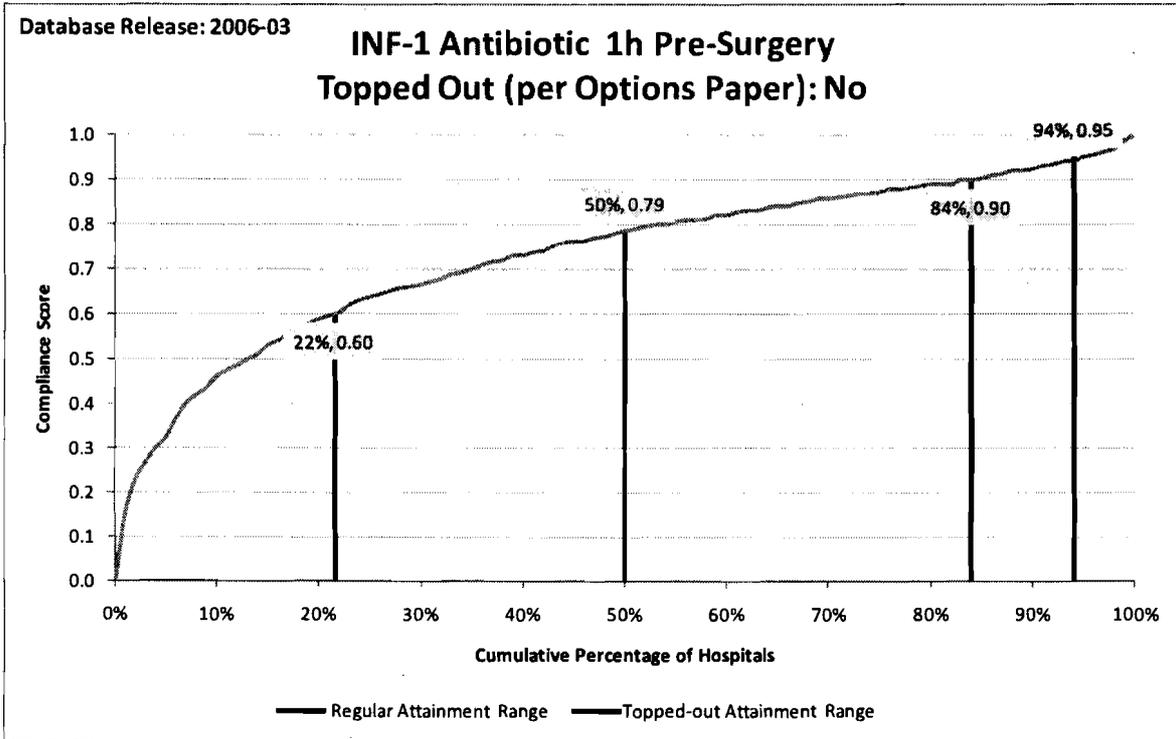
PN-6 Appropriate Antibiotic Topped Out (per Options Paper): No

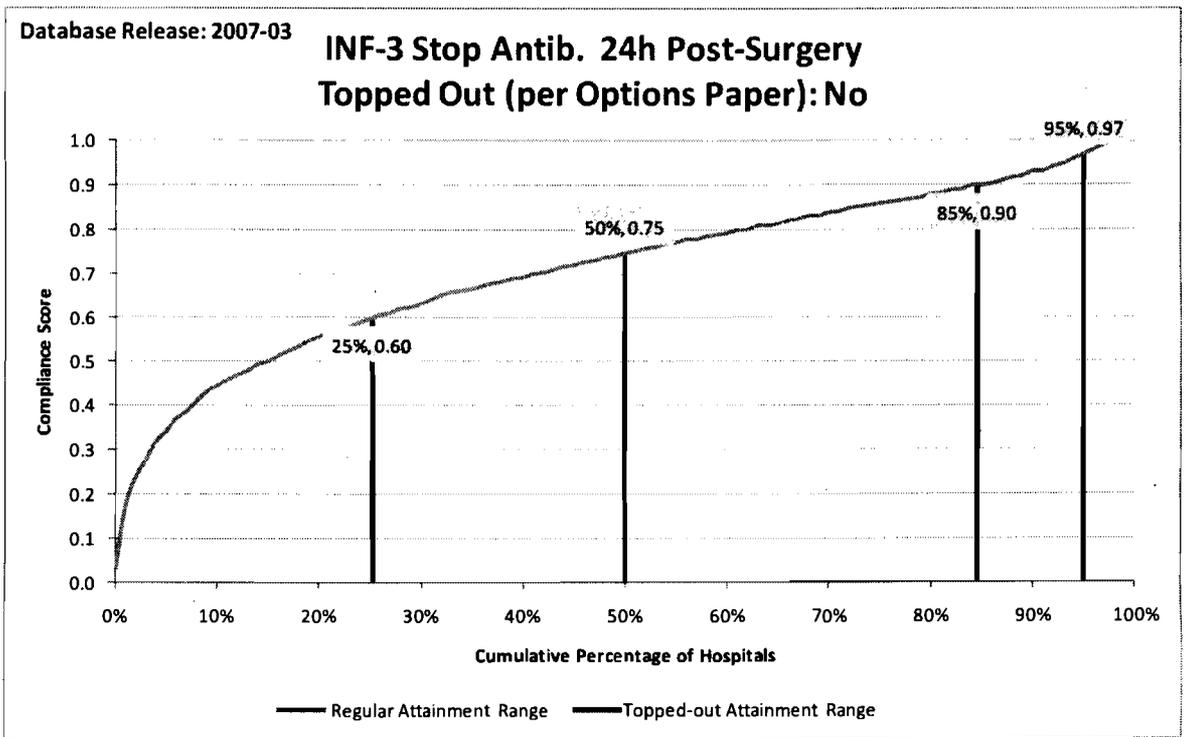
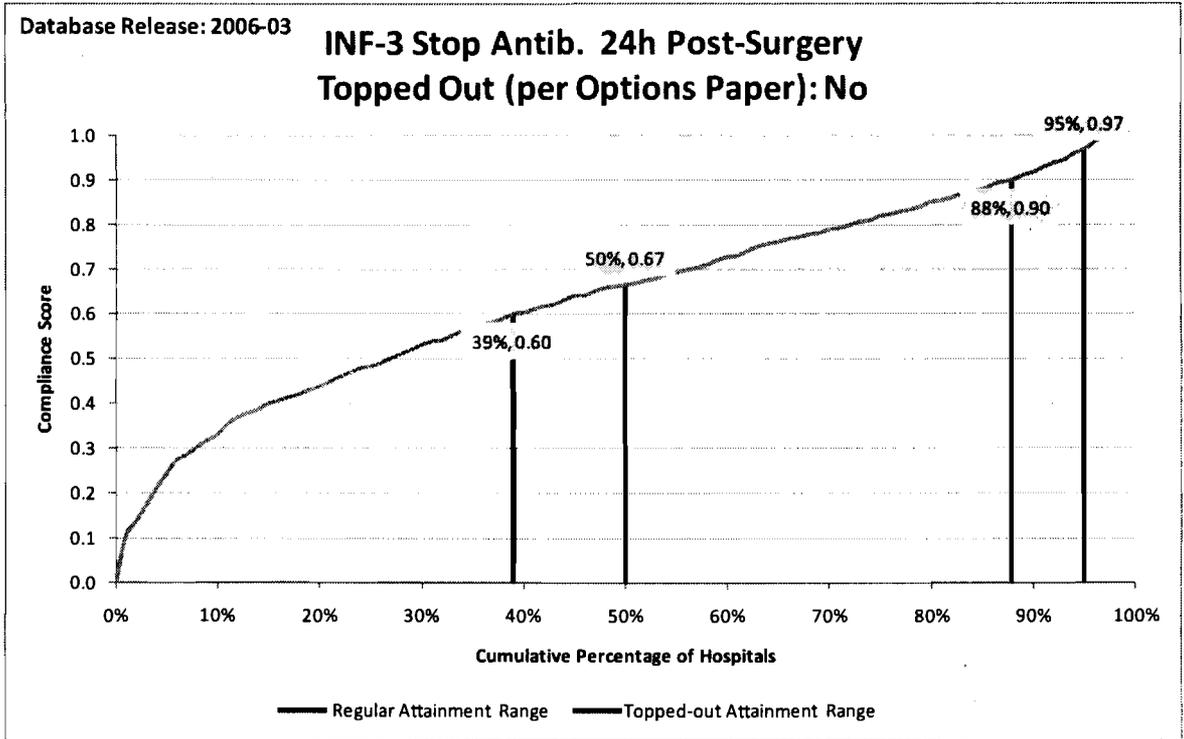


Database Release: 2007-03

PN-(New) Influenza Vaccination Topped Out (per Options Paper): n/a







**CMS-1533-P-219 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Dr. Barry Arbuckle

Date & Time: 06/08/2007

Organization : Memorial Health Services

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-219-Attach-1.DOC

 **MEMORIALCARE®**
MEMORIAL HEALTH SERVICES

June 12, 2007

Leslie 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

Via Electronic Mail

Dear Ms. Norwalk:

As President and Chief Executive Officer of MemorialCare Medical Centers (MemorialCare), a five-hospital, not-for-profit (NFP) health system in Los Angeles and Orange Counties, I welcome the opportunities to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates".

MemorialCare is an integrated health care system founded on the traditional values of not-for-profit community service. Our projected patient days for fiscal year 2007 are 380,396 on a base of 85,640 discharges. With over 217,100 visits to our Emergency Departments, including one Level II trauma center, we also served our communities by performing 47,000 surgeries and delivering 12,000 babies.

We feel it critical to the future of our system, and our ability to serve our communities well, that you address a number of important issues that will affect hospital financing in the coming year. I will offer our perspective on CMS's proposal to create 745 new Medicare Severity diagnosis-related groups (MS-DRGs) to replace the current 538 DRGs and the inclusion of a 2.4% 'behavioral offset' cut to both operating and capital payments; Physician ownership in hospitals; and I will conclude our comments on hospital acquired conditions.

DRG Changes

As in the past, MemorialCare stands with the hospital community in its support for meaningful, appropriate improvements to Medicare's inpatient PPS. Last year, we offered support for CMS's move to cost-based weights. The proposed 08 rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or comorbidity list. This proposed rule also includes a 2.4 percent cut to both operating and capital

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payments in both FYs 2008 and 2009 - \$24 billion over five years – to eliminate what you claim to be the effect of classification changes that do not reflect real changes in case-mix. **These changes alone will result in a loss of over \$800,000 to MemorialCare. As a NFP, MemorialCare cannot sustain such losses.**

CMS claims the 2.4 percent cut will eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. This 'behavioral offset' cut is based on the assumption that hospitals will fraudulently 'upcode' to higher paying DRGs. MemorialCare does not see any available data to support such an assumption. **Rather, MemorialCare believes that CMS is proposing this cut as a backdoor attempt at budget cuts. MemorialCare has communicated many times with CMS regarding appropriate methods of containing cost increases and unwarranted utilization. Cutting hospital reimbursement in this fashion is inappropriate and harmful to the healthcare delivery system.**

In addition, MemorialCare believes it is inappropriate for CMS to implement these cuts at the same time that it is implementing a new DRG system. Once the new MS-DRG system is implemented, CMS can then investigate whether payments have increased due to coding rather than the severity of patients, and **at that time** determine if an adjustment is necessary. **As currently proposed, CMS is assuming fraudulent activity, and MemorialCare strongly opposes these cuts in reimbursement.**

Physician Ownership in Hospitals

In FY 06, MemorialCare commended CMS for its leadership role in stating that certain physician-owned hospitals do not qualify under Medicare rules as a hospital. In the FY 08 rule, CMS is requiring all physician-owned hospitals at the beginning of an admission or outpatient visit to disclose to patients that physicians have an ownership interest or investment in the hospital, and offer to make a list of physician investors available upon request. **MemorialCare fully supports implementation of this physician-ownership disclosure requirement.**

In direct response to your request for comment on whether this requirement is located in the provider agreement or conditions of participation, **MemorialCare recommends that the ownership disclosure be incorporated into provider agreements.** Doing so will ensure the conditions of participation are focused on care delivery standards.

Further, **MemorialCare believes CMS should expand upon the proposal, and require that physician-owned hospitals provide patients with a list of physician investors immediately upon the patient's request, thereby ensuring a timely response.**

The proliferation of physician-owned, limited services hospitals will continue to erode any profitability for community-based hospitals. **MemorialCare strongly urges CMS to continue applying strategic limitations on physician-owned hospitals.**

DRGs: Hospital Acquired Conditions

MemorialCare highly supports all appropriate measures to reduce hospital-acquired conditions. To that end, MemorialCare has pioneered evidence-based, best practice medicine, by creating over one dozen Best Practice Teams. These interdisciplinary teams, coordinated by a physician leader, continue to develop guidelines, order sets and standards of practice utilizing data and resources from the latest evidence based medical literature. MemorialCare participates in national efforts such as 100K and 5M Lives Campaigns, Leapfrog and CHART (California Hospital Assessment and Reporting Task Force). Given this experience, MemorialCare has certain concerns related to CMS's proposed rules.

Since this proposal is based on coding, and although coders are expected to, and indeed, follow good coding principles, hospitals that appropriately code may be exposed to more penalties. This new coding system would need reasonable checks and balances, such as those in place in the random chart review process for QIO review of Core Measures, which ensure hospitals, are submitting data accurately and uniformly across the U.S. These checks and balances in themselves are expensive though and create another layer of cost to the entire system of care. MemorialCare does not see a provision for such in the language.

MemorialCare notes there is language providing for hospitals to submit a "present on admission" status for these complications. California has had this in place for a long time, but hospitals across the US would need ramp-up time to ensure such a system is operational and functional prior to payment changes taking place for FY'09.

From the list of potential complications, catheter-associated UTI, pressure ulcers and *Staphylococcus aureus* septicemia hospitals should be provided with specific exclusion definitions and provisions for patients who come in and are documented with those conditions when they enter our facilities.

The presence of an indwelling urinary catheter on admission is especially troubling as chronic foley catheter use has a very high likelihood of being chronically colonized with bacteria that may or may not represent an active infection.

Lastly, there does not appear to be language providing for situations where there are more comorbidities and complications than these scenarios that have

resulted in the selection of the higher DRG pairing. There are often many other issues that are patient and disease-progression related that occur during the normal hospitalization course of treating patients who enter our hospitals for care. Thus denying payment based on the presence of just one complication (if there are other issues contributing to the higher of the paired DRGs) would seem to over-penalize hospitals. If the only difference is one of these particular final chosen CCs that might be a cleaner approach.

MemorialCare urges CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have been reasonably prevented.

Thank you for the opportunity to present our views on these very important issues. The final disposition of the proposed rules will have a long lasting affect on MemorialCare and thousands of other not-for-profit hospitals. Our mission is to improve the health and well-being of individuals, families and our communities through innovation and the pursuit of excellence in all that we do. As proof of our commitment to serving our communities, MemorialCare contributed over \$108,000,000 in total quantifiable community benefits in FY 2006. **Any losses to our reimbursements for the care given to our Medicare patients will have a devastating affect on our ability to take care of those most in need.**

Deleted: this

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

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

Sincerely



Barry S. Arbuckle, Ph.D.
President and Chief Executive Officer
MemorialCare Medical Centers

CMS-1533-P-220 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Salvatore Cortese

Date & Time: 06/08/2007

Organization : Salvatore Cortese

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 542). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

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

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

Thank you for your consideration of this important matter!

Sincerely,
Salvatore Cortese

CMS-1533-P-221 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Robert A. Fink

Date & Time: 06/09/2007

Organization : Robert A. Fink, M. D., F.A.C.S.

Category : Physician

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

The use of chemotherapy-impregnated wafers (such as Gliadel) in the surgical treatment of malignant brain tumors has been effective in prolonging useful survival. The proposed changes in DRG for this procedure, because of decreased reimbursement for the wafers themselves will return us to the situation (before the present DRG was established) where patients will be denied the benefits of this useful treatment.

In my own practice, I have found that the use of Gliadel and similar modalities is an important portion of the standard of care for the treatment of malignant brain tumors; and this is supported by the medical literature.

Please do not deprive our patients of the benefits of this proven treatment of a dread disease. Thank you for your consideration.

Robert A. Fink, M. D., F.A.C.S.
Neurological Surgeon
Berkeley, California

CMS-1533-P-222 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : stephen coffman

Date & Time: 06/09/2007

Organization : stephen coffman

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please don't take away important treatment options for victims of brain tumors

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter

steve coffman
holland michigan 49423

CMS-1533-P-223 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter :

Date & Time: 06/09/2007

Organization :

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-224 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Anne Robillard

Date & Time: 06/09/2007

Organization : Anne Robillard

Category : Nurse

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

Anne Robillard

CMS-1533-P-225 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Lisa Libidinsky

Date & Time: 06/09/2007

Organization : Dr. Lisa Libidinsky

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-226 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Jen Chandler

Date & Time: 06/09/2007

Organization : Jen Chandler

Category : Health Care Professional or Association

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Gliadel is a wafer that is implanted into the tumor bed at the time of a brain tumor surgery, which slowly releases chemotherapy. Gliadel is now the standard of care for Glioblastoma Multiforme.

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

I am the friend of a young man and his wife, a brain tumor patient, He and his wife have 3 young children and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!
Jennifer Chandler MPT

CMS-1533-P-227 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : dennis greco

Date & Time: 06/10/2007

Organization : dennis greco

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

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

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

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

Thank you for your consideration of this important matter!

**CMS-1533-P-228 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Bill Ryan

Date & Time: 06/10/2007

Organization : Albert Einstein Healthcare Network

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

#228

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

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

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

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

CMS-1533-P-229 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. June O'Gara

Date & Time: 06/10/2007

Organization : Ms. June O'Gara

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

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

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

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

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

**CMS-1533-P-230 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. John Shaw

Date & Time: 06/10/2007

Organization : Next Wave

Category : Health Care Industry

Issue Areas/Comments

CC Exclusion List

CC Exclusion List

It is extremely time consuming to enter the exclusion list manually, or even one page at a time as a cut and paste. A machine readable format (Excel, Access, flat or delimited text, etc.) would allow more time to comment on substance rather than preparing data to be able to comment.

CMS-1533-P-231 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Amy Morais

Date & Time: 06/10/2007

Organization : Amy Morais

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am a dear friend of a brain tumor patient □ a young father with three beautiful and amazing children, all under the age of five - and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter! While my friend had private health insurance, I truly believe that all Americans should

have access to the same quality of health care, regardless of their income and station in life. I am incredibly grateful that he appears to have made a full recovery, and I wish for the same for others.

CMS-1533-P-232 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Teresa Accuntius

Date & Time: 06/11/2007

Organization : Ms. Teresa Accuntius

Category : Nurse

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

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

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

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

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

" These extremely harmful events have known methods of prevention.

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

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

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

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

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

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

" While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery bypass graft codes (without

valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

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

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

**CMS-1533-P-233 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Dr. Joshua Safer

Date & Time: 06/11/2007

Organization : Boston University Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please DO NOT make regulation changes that simply result in more administrative work. The additional work has a cost in the form of diminished training and fewer patients seen.

Thank you.

**CMS-1533-P-234 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Dr. David Bowton

Date & Time: 06/11/2007

Organization : Wake Forest University School of Medicine

Category : Physician

Issue Areas/Comments

**DRG Reform and Proposed
MS- DRGs**

DRG Reform and Proposed MS-DRGs

I commend CMS for their efforts to better align prospective payments with actual hospital costs. This may help financially stressed urban and academic hospitals who often see sicker, more costly patients. Further, we have long needed a septic shock or severe sepsis DRG code to more accurately categorize this patient subpopulation. However, I would urge CMS to be cautious in their calibrations of these DRGs so as not to reduce payments to hospitals for surgical patients who have preexisting major medical comorbidities who are, therefore, predisposed to serious adverse events (such as severe sepsis). It would be unfair to further reduce surgical prospective payments in such a situation (and I am NOT a surgeon). I recognize that budget neutrality must be maintained, but hope this is examined carefully such that routine surgical procedures in relatively healthy patients are appropriately valued less than surgical procedures in patients with multiple medical comorbidities who suffer foreseeable complications. Additionally, prolonged mechanical ventilation remains a very costly problem for most hospitals and the coding developed and reimbursement provided should permit the underlying diagnoses to be adequately represented (because there are MANY diagnoses that may require prolonged mechanical ventilatory support) and adequate payment to the hospitals to cover their costs, regardless of the etiology of the prolonged mechanical ventilation. The latter is needed to preserve hospital solvency, the former to permit a more accurate rendering of the epidemiology of costs and disease burden in the US. Thank you.

CMS-1533-P-235 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Janet Cremeens

Date & Time: 06/11/2007

Organization : Ferrell Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

As an APIC member and professional infection control nurse, I am in agreement with APIC and do not support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; 2 pressure ulcers and 6 Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes . Two states currently using POA codes report a minimum of two years needed to achieve reliability, much longer than the January 1,2008 time frame proposed by CMS. APIC requests CMNS to provide educational support needed to reliably determine POA codes. APIC does not believe conditions 1,2 and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented and each of these conditions carry with them unintended, far-reaching consequences. APIC recommends that CMS continue to address the coding challenges for ventilator associated pneumonia, vascular catheter associated infections and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital acquired conditions policy in the future, since they are important causes of healthcare associated mortality and morbidity. Current efforts and measureable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.

CMS-1533-P-236

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

Submitter : Karen Cain

Date & Time: 06/11/2007

Organization : Karen Cain

Category : Individual

Issue Areas/Comments

**DRG Reform and Proposed
MS- DRGs**

DRG Reform and Proposed MS-DRGs

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-237

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

Submitter : Mr.

Date & Time: 06/11/2007

Organization : Mr.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1533-P-237-Attach-1.PDF

June 7, 2007

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

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

Dear Sir:

Mercy Memorial Hospital System (MMHS) welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to update the Inpatient Prospective Payment System for Fiscal Year (FY) 2008. While the rule, which was published in the May 3, 2007, *Federal Register*, provides a 3.3 percent market basket increase for hospitals that submit data for the CMS quality measures, **we strongly oppose the CMS' 2.4 percent "behavioral offset" for anticipated changes in hospital coding.** We are also concerned about other significant policy changes included in the proposed rule that would negatively impact MMHS Medicare reimbursement.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of Monroe County Michigan's only hospital. Based on the latest data available, MMHS will experience an estimated negative 1.4% in operations payments in FY 2008 compared to our estimated 2007 FY payments. This is very concerning particularly since our service area population is aging and the number of Medicare beneficiaries is projected to increase significantly over the next decade.

MMHS believes it is important for the CMS to recognize that the proposed payment changes alone will severely impact the community's only acute care hospital. In addition, procedural modifications could not be adapted in the two months prior to Oct. 1.

Our key concerns include:

2.4 Percent "Behavioral Offset"

(Federal Register Pages 24708-24711)

A provision in the Benefits Improvement and Protection Act (BIPA) of 2000, provides the CMS authority to adjust the standardized amount to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix. **MMHS is strongly opposed to the proposed adjustment based on the assumption that the case mix index of hospitals will automatically increase. The CMS does not have any compelling evidence for this**

Corporate Connection
(734) 240-4150
Hospital
(734) 240-8400

Family Center
(734) 240-1760
Macomb Pharmacy
(734) 240-4100

Foundation
(734) 240-1802
Nursing Center
(734) 240-1820

HomeCare Connection
(734) 240-1717
Outpatient Surgery Center
(734) 240-1900

Hospice
(734) 240-8940
Rehabilitation Center
(734) 240-1950

proposed change. Mercy Memorial Hospital recommends that the CMS eliminate this reduction and provide hospitals with the full 3.3 percent market basket increase. Until the MS-DRGs are fully implemented and the CMS can document and demonstrate that any increase in case mix results from changes in coding practices rather than actual changes in patient severity, there should be no behavioral offset.

Medicare Severity (MS) DRGs

(Federal Register pages 24691 – 24712)

For FY 2008, the CMS is proposing to adopt Medicare Severity (MS) DRGs, which are the result of modifications to the current CMS DRGs to better account for patient severity. While the CMS proposes to implement the MS-DRGs on Oct 1, 2007, they believe that the MS-DRGs should be evaluated by RAND and have instructed RAND to evaluate the proposed MS-DRGs using the same criteria that it is applying to the other DRG systems.

While hospitals appreciate the CMS' recognition of the issues raised last year regarding its proposal to use Consolidated Severity (CS) adjusted DRGs, **we believe it is crucial that a system change of this magnitude have a transition period of four-years.** The change to MS DRGs is projected to result in reimbursement decrease of 1/2 percent for MMHS. In addition we would be unable to adapt to changes of this magnitude in two months, after release of the final rule. Furthermore, implementing these changes in coding and DRGs will add unfunded administrative costs to MMHS to provide care to Medicare beneficiaries. The American Health Information Management Association (AHIMA) has estimated that it will take twice the effort to correctly code an inpatient record under the MS-DRG guidelines. For MMHS, this means doubling the number of inpatient coding staff. In addition, MMHS will need to invest in additional technology to help apply the new codes accurately and completely.

As a result, MMHS recommends that in FY 2008, the emphasis be on preparation and testing of the new DRG classification system so that the CMS has adequate time to finalize data, introduce and test software for patient classification and payment and train its fiscal intermediaries. In addition, this will allow the CMS time for further analysis by hospital type to ensure the projected changes are consistent with the policy objectives the CMS desires to achieve. This would also give hospitals more time to implement and test the new system and adjust operations and staffing based on projected changes in Medicare revenues. **MMHS recommends a 4-year transition as follows:**

- In FY 2008, continue current DRG classification system;
- In FY 2009, DRG weights should be computed as a blend derived 1/3 from the MS-DRGs and 2/3 from traditional DRGs;
- In FY 2010, DRG weights should be computed as a blend derived 2/3 from MS-DRGs and 1/3 from traditional DRGs;
- In FY 2011, DRG weights should be derived using 100 percent of the MS-DRG

Hospital Quality Data

(Federal Register pages 24802 – 24809)

The Medicare Modernization Act (MMA) required hospitals to submit data on quality measures to the CMS, which this provision applied for three years (FY 2005-07). Participating hospitals were required to submit data on a set of ten quality measures and for their data to meet certain validation requirements. Hospitals that withdrew from the program or failed to submit valid data received the market basket increase minus 0.4 percent for FFYs 2005 and 2006.

The DRA extended and expanded this program, giving CMS greater authority. In the FFY 2007 IPPS final rule, the penalty for withdrawal from the program or failure to comply with its requirements was increased to 2.0 percent; some procedural changes were effected; and the set of quality measures was expanded to a total of twenty-one. For FY 2009, the CMS is proposing to add 1 outcome measure and 4 process measures to the existing 27 measure set to establish a new set of 32 quality measures to be used for the FY 2009 annual payment determination. **While MMHS is supportive of measuring and improving quality of care, we recommend that the CMS thoroughly evaluate whether quality has improved based on the measures that are currently being submitted and ensure that additional measures will result in meaningful quality improvements rather than merely additional reporting by hospitals.**

IPPS Capital Payments

(Federal Register pages 24818 – 24823)

Reimbursement for capital-related costs was implemented in FY 1992. Over a ten-year period, payments for capital were transitioned from a reasonable cost-based methodology to a prospective methodology. Beginning in FY 2002, all hospitals were paid based on 100 percent of the capital Federal rate, which is updated based on changes in a capital input price index (CIP) and several other policy adjustment factors. Since inception of the capital IPPS, urban and rural hospitals have received the same update to the capital Federal rate. For 2008, the CMS is proposing to give rural hospitals the full 0.8 percent update but no update for urban hospitals. MMHS opposes the CMS proposal to freeze urban capital rates and the CMS application of the 2.4 percent “behavioral offset” to capital rates. MMHS has already committed funds toward various capital projects with the expectation that Medicare funding would be available to cover a portion of the cost. **MMHS recommends that the CMS eliminate the 2.4 percent “behavioral offset” and provide all hospitals with the full 0.8 percent capital update.**

Cost Outliers

(Federal Register pages 24836 – 24838)

The CMS provides payments for outlier cases involving extraordinarily high costs when compared to average cases in the same DRG. To qualify as a cost outlier, a hospital’s cost for the case must exceed the payment rate for the DRG plus a specified amount called the fixed-loss threshold. The outlier payment is equal to 80 percent of the difference between the hospital’s

cost for the stay and the threshold amount. The threshold is adjusted every year based on CMS' projections of total outlier payments to make outlier reimbursement equal 5.1 percent of total payments.

The CMS is proposing to decrease the fixed-loss cost outlier threshold from the current \$24,485 to \$22,940, which represents a 6 percent decrease. Although a 5.1 percent pool was set aside each year for outlier payments, the CMS estimates that it spent 4.1 percent for outliers in FY 2005, 4.7 percent in FY 2006 and that only 4.9 percent will be spent in FY 2007.

We believe the CMS under-spent the funds set aside for outliers by an estimated \$3 billion over FYs 2004, 2005 and 2006. **This is a real cut in payments to MMHS that cannot be recouped.** While we appreciate the CMS' recognition of the need to reduce the outlier threshold, **we believe the CMS should consider a further reduction in the outlier threshold for FY 2008 to ensure that the entire 5.1 percent is paid to hospitals.**

Revision of the Wage Index Adjustment – FY 2009 Proposed Rule

(Federal Register page 24802)

Section 106(b)(1) of the Tax Relief and Health Care Act of 2006 requires MedPAC to review the current Medicare wage index classification system and recommend alternatives to the method of computing the wage index. MedPAC is required to submit a report to Congress on their findings by June 30, 2007.

In addition, the law requires the CMS, taking into account MedPAC's recommendations, to include one or more proposals to revise the wage index adjustment applied to the IPPS in the FY 2009 IPPS proposed rule. The law requires the proposal (or proposals) to consider the following:

- problems associated with the definition of labor markets for the wage index adjustment;
- the modification or elimination of geographic reclassifications and other adjustments;
- the use of Bureau of Labor of Statistics data or other data or methodologies to calculate relative wages for each geographic area;
- minimizing variations in wage index adjustments between and within MSAs and statewide rural areas;
- the feasibility of applying all components of CMS' proposal to other settings;
- methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality;
- the effect that the implementation of the proposal would have on health care providers on each region of the country;

- methods for implementing the proposal(s) including methods to phase in such implementations; and;
- issues relating to occupational mix such as staffing practices and any evidence on quality of care and patient safety including any recommendation for alternative calculations to the occupational mix.

To date, MedPAC has presented its preliminary findings regarding this issue. **MMHS opposes the CMS' use of the Bureau of Labor Statistics (BLS) data as a basis for future wage index calculations, particularly since the BLS fails to include fringe benefits, which are generally higher for hospitals compared to other industries. We believe the CMS should continue to collect hospital-specific data and evaluate other alternatives to minimize variation and volatility in the wage index.**

Additional Payments for New Technology

(Federal Register pages 24771 – 24776)

The CMS provides additional add-on payments for approved new technologies. To be approved for payment as a new technology, an item must be considered new, be inadequately paid otherwise and represent a substantial clinical improvement over previously available technologies. The cost threshold for new technologies to qualify for add-on payments is the lower of the following:

- 75 percent of the standardized amount (increased to reflect the difference between costs and charges)
- 75 percent of one standard deviation for the DRG involved

In FY 2008, the CMS proposes to discontinue reimbursement for the three technologies that are currently eligible for new technology payments. In addition, one technology is under review and may be approved for new technology payments in FY 2008. The CMS continues to review approval for: Wingspan® Stent System with Gateway™ PTA Balloon Catheter. **MMHS urges the CMS to approve and provide new technology payments for this new stent system in FY 2008.**

Development of Value-based Purchasing

(Federal Register pages 24809 - 24810)

The DRA required the CMS to develop a plan to implement hospital value-based purchasing (pay-for-performance) beginning in FY 2009. The plan must consider the following issues:

- measure development — the ongoing development, selection and modification process for measures of quality and efficiency in hospital inpatient settings
- data infrastructure and refinement — reporting, collecting and validating of quality data

- incentives — the structure of payment adjustments, including the determination of thresholds for improvements in quality that would substantiate a payment adjustment, the size of such payments and the sources of funding for the payments
- public reporting — disclosure of information on hospital performance

To date, the CMS has created an internal hospital pay-for-performance workgroup that is charged with preparing a set of design options, narrowing the set of design options to prepare a draft plan, and preparing the final plan for implementing VBP that will be provided to Congress. The workgroup is organized into four subgroups to address each of the required planning issues: measures, data collection and validation, incentive structure and public reporting. In addition, the CMS has hosted two “Listening Sessions” to solicit input from relevant affected parties on outstanding questions associated with development of the final plan. The CMS states in the proposed rule that, although the DRA authorized development of a VBP program, additional legislation will be required to establish and implement the VBP program. **MMHS encourages the CMS to continue its efforts in collaborating with a workgroup comprised of industry representatives, including physicians, to develop pay-for-performance measures that will work for all parties. MMHS has identified the following issues:**

- **Consistent measurement tools for all hospitals**
- **Demonstrated improvement to patient safety/quality – collecting and reporting data**
- **Some type of alignment with physicians in pay for performance, inclusive of published physician performance data.**

Hospital-Acquired Conditions

(Federal Register Page 24716 - 24726)

Complications such as infections acquired in the hospital can trigger higher payments in the form of outlier payments and/or higher DRG payments due to the presence of a complication or comorbidity (CC). The DRA requires the CMS to identify, by October 1, 2007 (FY 2008), at least two CC secondary diagnoses that:

- are high cost, high volume, or both;
- result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and
- could reasonably have been prevented through the application of evidence-based guidelines.
- For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases where one of the selected conditions was not present on admission, meaning the case would be paid as though the secondary diagnosis was not present. The law states that the CMS can revise the list from time-to-time, as long as the list contains at least two conditions. Additionally, the DRA requires

hospitals to report the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

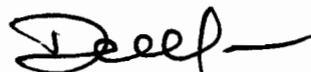
The CMS selected 13 conditions as possible candidates to satisfy the DRA provision for hospital-acquired conditions. According to the CMS' selection method, the conditions at the top of the following list best meet the statutory selection criteria, while the conditions lower on the list may meet the selection criteria but could present a particular challenge (that is, they may be preventable only in some circumstances, but not in others) and therefore, the first conditions listed should receive the highest consideration of selection among the initial group of hospital-acquired conditions.

MMHS participates with the Michigan Hospital Association (MHA) and other member hospitals in a joint project with Johns Hopkins, funded by a \$1 million grant from the U.S. Agency for Healthcare Research and Quality (AHRQ) to reduce ICU infections through the MHA Keystone Center. Over two years, 77 hospitals and 127 hospital ICUs voluntarily participated in this project to reduce infections in the ICU. After 18 months, the predictive model suggests that teams saved 1,574 lives, over 84,000 ICU days and over \$175 million dollars. Infections from central IV catheters plummeted. The median Catheter Related-Blood Stream Infection (CR-BSI) rate in participating ICUs has now been at zero for almost a year. Ventilator associated pneumonia rates in the ICUs have been cut by 40%. Forty six ICUs have gone for over six months with no ventilator associated pneumonias. Fifty seven ICUs have gone for over six months with no blood stream infections from IV catheters. MMHS believes proactive projects such as these will result in better patient safety and quality. However, hospitals need the training and funding in order to implement these changes.

MMHS believes the CMS proposal that complications are solely the result of hospital actions is fundamentally flawed. To reduce hospital payments for a condition present upon admission, but not documented, is too punitive. MMHS stands to see a \$500,000 reduction in reimbursement as a result of these changes, not because the patients are not receiving the needed care, but because of documentation deficiencies. In addition, there is good evidence to suggest that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Rather, MMHS recommends that the CMS expand demonstration projects such as the MHA Keystone Center to truly improve patient safety and quality for Medicare and all patients.

We believe our suggested modifications will result in positive changes for MMHS and the Medicare beneficiaries we serve. If you have questions on this comment letter, please contact me at (734) 240-8922.

Sincerely,



Daniel L. Wakeman
President and CEO

**CMS-1533-P-238 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. John Taylor

Date & Time: 06/11/2007

Organization : University Hospitals Health System

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-238-Attach-1.DOC

June 11, 2007

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

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

Dear Ms. Norwalk:

As Director of Reimbursement for the University Hospitals Health System in Cleveland, Ohio, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

While our system supports the creation of 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, we oppose the proposed "behavioral offset" cuts related to the transition to the proposed severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments. Our comments are as follows:

1. The documentation used to move from the current charge based system to the proposed cost based severity-adjusted system was apparently gleaned from grouping costs into 13 categories and reducing the charges to cost from cost-to-charge ratios (CCR) calculated from the Medicare cost reports for these same 13 categories. This methodology appears to be flawed in that line subscribing on the cost report is not uniform across all hospitals. Hospitals have some latitude in mapping their cost centers from their general ledgers to lines on the cost reports. By using non-standardized cost reports as a basis for the new DRG system, inappropriate groupings would be made due to the inconsistent subscribing. The Medicare cost report was not designed to be a cost accounting report and definitely was not designed to be used to ascertain costs at an individual DRG level.

If CMS is going to move to cost-based weights, regardless of the methodology, all hospitals will need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting. Additionally, if the intent was to use the audited cost report data, the larger teaching hospitals in North East Ohio are just now being audited for 2004 and 2005 Medicare cost reports and the 2003 cost reports were audited late in 2006. We recommend standardization of cost reporting mapping instruction before use of cost report data to determine costs.

2. The proposed rule includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 with the purpose of eliminating what you claim will be the effect of upcoding or "DRG creep" - classification changes that do not reflect real changes in case-mix.

In our initial review of the proposed system it appears that guides or prompts will be in place to help identify the correct mapping of a claim to the new

severity based DRG. This would appear to eliminate the opportunity for DRG upcoding since the documentation present within the medical records would indicate the assignment of the DRG. There does not appear to be any justification of the need for the 2.4% cut, other than an anticipation of the "possibility" of upcoding. We would recommend postponement of the 2.4% cut, or any cut, until the first year or two of the new system has been analyzed. At that time, adjustments can be made if it has been determined that upcoding has occurred. Additionally, CMS has not been required to make an adjustment at this time. *On a system wide basis, this anticipated reduction for upcoding, which is built into the base, decreases our reimbursement by approximately \$4.2 million per year.*

3. The proposed rule would eliminate the capital payment update for all urban hospitals (a 0.8 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). Additionally, cuts are proposed to eliminate the Teaching IME capital add-on and the Disproportionate Share capital add-on.

We are opposed to these unnecessary cuts, which ignore the capital needs of the urban teaching hospitals. By our very nature we are the safety net hospitals, treating a large portion of the Medicaid and uninsured population. Our aging hospitals come with many capital needs. Foremost are the need for increased maintenance and the needs for improvement of the hospitals' facilities and technology. Additionally, by embracing the directive from both the Administration and Congress to move forward with electronic health records, which is a major capital investment when done correctly, it does not make any logical sense to propose the arbitrary and unnecessary cuts to capital in this proposed rule.

Since Medicare does not include all capital related costs as allowable costs in the cost report, these additional and un-mandated budget cuts will further deplete scarce resources and increase the challenge we face in our ultimate mission of caring for our patients. We recommend that, CMS should not make any un-mandated cuts or other adjustments to the capital PPS. *The proposed reduction for capital issues decreases our reimbursement by approximately \$3.7 million per year. The elimination of the IME capital add-on would equal nearly \$2.6 million of the decrease, or the equivalent of the annual training cost for 33 FTE residents.*

4. The revised CC list is essentially comprised of significant acute diseases, acute exacerbation of significant chronic diseases, advanced or end-stage chronic diseases and chronic diseases associated with extensive debility. Many common secondary diagnoses have been removed from the CC list and we do not understand why they have been removed while other similar diagnoses remain on the CC list.

We would request that CMS make the final revised CC list publicly available as quickly as possible so that hospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.

We would request that CMS consider additional refinements to the revised CC list including addressing issues where the ICD-9-CM codes may need to be modified to provide the distinction between different levels of severity.

We request that CMS address the inconsistencies within the CC list identified by physicians and hospitals and recommend obtaining additional input from

practicing physicians in the appropriate specialties across the country to determine the standard of care and consequent increased hospital resource use. We also urge CMS to carefully consider the implications of its proposed MS-DRG changes on the inpatient psychiatric facility PPS, specifically, the DRGs for alcohol/drug use and the changes to the CC list.

5. The DRA requires CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a CC DRG. We ask CMS to carefully consider the criteria for selection along with the ability of hospitals to accurately identify and code for these conditions.

Three of the six conditions representing the serious preventable events identified by CMS - object left in during surgery, air embolism and blood incompatibility - are identifiable through specific ICD-9 codes and are easily coded by hospitals. These are events that can cause great harm to patients and there are known methods of prevention. As a system, we are committed to patient safety and strive to ensure that these events do not happen.

The other three proposed conditions - catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia - are difficult to identify upon admission without incurring additional testing up front and adding additional time to the admission process.

We urge CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections and staphylococcus aureus until after it has taken the necessary steps to educate physicians which will permit accurate identification of the relevant cases.

We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have been reasonably prevented. We are happy to work with CMS in helping to more accurately identify these patients.

We strongly encourage CMS to consider the additional testing that may be necessary to identify the hospital-acquired conditions. Also, the appeals process when a hospital disagrees with the CMS decision that a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment needs to be addressed.

6. The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures - four process measures and one outcome measure - to be included for the FY 2009 annual payment determination. We are pleased that CMS has proposed adding only measures that have been adopted by the Hospital Quality Alliance's (HQA) public reporting initiative, for patients discharged on or after January 1, 2008.

We urge CMS to carefully evaluate the value of the measures considered for future reporting. Measures should be evidence-based, contribute to the comprehensiveness of performance measurement, be under a hospital's control and account for potential unintended consequences. We urge CMS only to propose and select measures that meet all of these conditions and are measures that are NQF-endorsed and HQA-adopted; CMS can be assured that they meet these conditions.

7. As part of the DRA-required report to Congress, CMS also raised the issue of the safety of patients in physician-owned specialty hospitals. The State of Ohio is currently looking at the requirements regarding specialty hospitals including how emergencies are handled in specialty hospitals when the hospital does not have a physician available on the premises 24 hours a day, 7 days a week. Other issues that need to be addressed would be the required staffing competencies, certain equipment availability, and required 24-hour-a-day, 7-day-a-week ED availability.

The safety concerns that have been raised with physician owned specialty hospitals occur because these facilities operate outside the traditional network of care. They are free-standing facilities; most do not have transfer agreements with other hospitals and tend to specialize in one type of care delivery. This specialization challenges their ability to treat the unexpected event or emergency. We recommend applying the same standards of care requirements to specialty hospitals that small rural or critical access hospitals must meet as part of their conditions of participation.

8. In the FY 2008 proposed rule, CMS is addressing questions received regarding the treatment of vacation or sick leave time for interns and residents in the medical education program. While recognizing that this time is not devoted to patient care, we believe it should fall into the same category as orientation time and be fully counted. Medicare does not eliminate vacation and sick time for the standard hospital employee in the cost report so it doesn't make sense to isolate and exclude the vacation and sick time for another class of employee, namely the interns and residents.

Under the proposed rule, vacation and sick time would be removed from both the numerator and denominator of the FTE calculation. While this may seem like an easy task, the impracticality of the proposed change means that the hospitals would not only have to keep track of the leave for each resident, but they would somehow need to apportion the leave to each of the hospitals the residents' rotate through. Each of the hospitals within the rotation network has different vacation policies - there are not standard vacation policies. Under the proposed rule, each resident that rotates in or out of a hospital would need a multiplier of some sort that each hospital would use to calculate their allowable time spent. With over 700 residents, this will be an administrative and financial burden for our system. Compounding the problem would be the untold hours of manual auditing the Fiscal Intermediary would perform 2 or 3 years after the cost report is filed to ascertain whether rotations were correctly recorded. We recommend that CMS treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count. *The proposed reduction for resident and sick time could potentially decrease our reimbursement by nearly \$3.5 million per year, or the equivalent of the annual training of 45 residents.*

We appreciate the opportunity to comment on the proposed regulation changes.

Sincerely,

John E. Taylor
Director of Reimbursement
University Hospitals Health System
11100 Euclid Avenue
Mailstop LND 5022
Cleveland, OH 44106-5022

**CMS-1533-P-239 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Carolyn Scanlan

Date & Time: 06/11/2007

Organization : The Hospital & Healthsystem Association of PA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-239-Attach-1.DOC



#239

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

June 11, 2007

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

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

Dear Ms. Norwalk:

On behalf of Pennsylvania's nearly 250 member hospitals and health systems, The Hospital & Healthsystem Association of Pennsylvania (HAP), welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS), as published in the May 3, 2007, *Federal Register*. The proposed rule builds on efforts to implement the most significant revisions of Medicare's inpatient hospital rates since 1983.

As proposed, this rule includes changes to the reimbursement system that will have a considerable impact on Pennsylvania hospitals. The proposed operating payment and capital payment reductions, as well as the additional wage index decreases, and the adjustments to DRGs are disproportionately harmful to Pennsylvania hospitals. **The total estimated reduction in payment for Pennsylvania hospitals as a result of this proposed rule is \$67.5 million in federal fiscal year 2008, and an estimated \$1.6 billion over the next five years.** Such reductions and attempts at backdoor budget cuts will only further erode our scarce resources, and challenge our hospitals that much more with respect to caring for our patients.

Medicare-Severity Diagnosis-Related Groups

One of the most prevalent changes in the proposed 2008 rule is the implementation of MS DRGs for FFY 2008. As indicated in comments submitted last year, Pennsylvania hospitals support meaningful improvements to Medicare's inpatient PPS. While it is believed that the proposed MS-DRGs provide a reasonable framework for patient classification, **as proposed there would be a redistribution of approximately \$31 million in FY 2008 for Pennsylvania hospitals.**

HAP believes a transition period is necessary to afford hospitals the opportunity to incorporate the extensive classification system, address budgetary implications, etc. To that end, **HAP urges CMS to phase-in the MS-DRGs over a four-year period.**

In addition, HAP opposes the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) as well as the proposed cuts to capital payments. The proposed rule **includes a 2.4 percent reduction to both operating and capital payments in both FYs 2008 and 2009—\$1 billion over five years—to eliminate prospectively what is presumed by CMS to be classification changes that do not reflect real changes in case-mix.**

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
www.haponline.org

Leslie Norwalk, Esquire
June 11, 2007
Page 2

HAP contends that such a prospective reduction in payment is not justified and is a backdoor attempt at budget cuts.

Capital Payment Update

The proposed rule would eliminate the capital payment update for all urban hospitals (a 0.8 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). **These changes would result in a payment cut of \$27.5 million over five years to urban hospitals.**

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

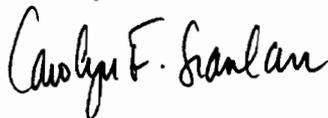
Wage Index

As proposed, most wage indices in Pennsylvania are projected to decrease. The only two regions in Pennsylvania experiencing an increase from the wage index are a result of falling below the rural floor and then being adjusted to that level. In addition, the expiration of the Section 508 provision, which had helped hospitals in Pennsylvania with significant wage index issues, causes further losses. **The combined impact on Pennsylvania hospitals of the changes to the wage index and the expiration of the 508 provisions is estimated to be a \$75 million loss.**

HAP has enclosed more detailed comments on the proposed rule, which further delineate our concerns and recommendations.

HAP appreciates the opportunity to submit these comments and recommendations. If you have any questions regarding our comments, please feel free to contact me or Melissa Speck, director for policy development, at (717) 561-5356 or mspeck@haponline.org.

Sincerely,



CAROLYN F. SCANLAN
President and Chief Executive Officer

Attachment

**The Hospital & Healthsystem Association of Pennsylvania
Detailed Comments on the Proposed Rule
FY 2008 Inpatient Prospective Payment System**

DRG REFORM AND PROPOSED MS-DRGS

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited-service hospitals, the Centers for Medicare & Medicaid Services (CMS) in fiscal year (FY) 2006 began significant efforts to reform the diagnosis-related groups (DRGs) and the calculation of the corresponding relative weights. While CMS adopted cost-based weights in FY 2007, it chose not to implement proposed adjustments to the DRG classification system to further recognize severity of illness. In FY 2008, CMS proposes continuing the transition to cost-based weights and offers a refinement to the current DRG system to better account for patient severity.

The hospital field supports meaningful improvements to Medicare's inpatient prospective payment system (PPS). We believe that HAP and CMS share the common goal of refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. We also believe that the system should be simple, predictable, and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions.

Another core feature of the PPS is clinically cohesive and meaningful DRGs that are intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. Ultimately, the inpatient PPS should foster innovation and best practice in care delivery. We believe that these are essential characteristics of a well-functioning PPS, and it is within these policy goals that we evaluate CMS' proposal.

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

Severity of Illness

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

Hospitals support meaningful improvements to Medicare's inpatient PPS. HAP believes that MS-DRGs represent a reasonable approach to DRG refinement. However, it is important for the field to be assured that CMS is committed to this system for the near future, and that because of

the extensive changes to the system, that CMS be willing to build in the time needed to ensure that both the agency and hospitals are adequately prepared for this significant change.

HAP urges CMS to adopt the MS-DRGs over a four-year transition period, as the implementation of the more extensive classification system, though budget neutral, would redistribute nationally, somewhere between \$800 million and \$900 million among hospitals. In Pennsylvania, this would equate to \$31 million among hospitals.

HAP recommends the following four-year transition (for FY 2008—2011):

FY 2008—The emphasis should be on preparation for and testing of the new classification system. This provides CMS with adequate time to finalize data and a CC list, introduce and test software for case classification and payment, including the definitions and instructions for case classification and payment, and train its fiscal agents. It also gives hospitals adequate time to implement and test the new system and adjust operations and staffing for predicted revenues. This also will allow vendors and state agencies time to incorporate such changes into their respective software and information systems.

FY 2009—DRG weights should be computed as a blend derived one-third from the MS-DRGs and two-thirds from traditional DRGs.

FY 2010 —DRG weights should be computed as a blend derived two-thirds from MS-DRGs and one-third from traditional DRGs.

FY 2011—DRG weights should be derived using only the MS-DRGs.

The weights would be established by CMS running the “old GROUPER” from 2008 without any changes to the CC list to establish where cases originated, and running the “new GROUPER” from 2009 with the new CC list, then blending the two weights based on the schedule above. Since there is not a perfect crosswalk from the old DRGs to the new ones, the weight used for payment in a given year would be established by blending the MS-DRG weight with a volume-weighted average of the CMS-DRG weights that feed into that particular MS-DRG. Thus, only one weight would be published in advance.

While there are many other ways to transition the system, we believe that this is easiest for CMS to implement, maintains the prospective nature of the system, is equitable across hospitals, does not require any sort of subsequent reconciliation, and does not require CMS or hospitals to run more than one GROUPER the entire year. We also believe that the length of the transition is appropriate given the large amount of money shifted within the system.

Behavioral Offset

Until MS-DRGs are fully implemented, and CMS can document and demonstrate that any increase in case-mix results from changes in coding practices rather than real changes in patient severity, there should be no “behavioral offset.”

The proposed rule includes a 2.4 percent cut in both FYs 2008 and 2009 to eliminate what CMS claims will be the effect of coding or classification changes that do not reflect real changes in case-mix. The 2.4 percent “behavioral offset” cut is based on assumptions made with little to no

data or experience, and cannot be justified in advance of making the DRG changes. **HAP opposes the “behavioral offset,” which will cut payments to hospitals in Pennsylvania by \$1 billion over the next five years. We do not believe that this cut is warranted—it is a backdoor attempt at budget cuts.**

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

The detailed comments below illustrate why the examples CMS uses to justify the coding adjustment are flawed. In addition, we also provide many reasons why we do not expect a significant increase in payment due to coding.

Maryland experience. In the rule, CMS uses the experience of Maryland hospitals moving to 3M’s All-Patient Refined DRGs (APR-DRGs) as a basis for the behavioral offset. However, MS-DRGs and APR-DRGs are two completely different ways to classify patients, and generalizing from one system to the other cannot be done. The existing classification rules will change only marginally with the introduction of MS-DRGs, whereas they are very different under the APR-DRG system. Differences include:

APR-DRGs consider multiple CCs in determining the placement of the patient and, ultimately, the payment. In fact, to be placed in the highest severity level, more than one high-severity secondary diagnosis is required. APR-DRGs consider interactions among primary and secondary diagnoses. Something that bumps one case type to a higher severity level might not affect another. This is not true for MS-DRGs. APR-DRGs consider interactions among *procedures* and diagnoses as well. MS-DRGs do not.

APR-DRGs have four severity subclasses for *each* base DRG, while MS-DRGs have three tiers, and this is only for 152 base DRGs—106 base DRGs only have two tiers, and 77 base DRGs are not split at all. Less than half the number of patient classifications in the MS-DRG system are dependent on the presence or absence of a CC—410 for MS-DRGs versus 863 for APR-DRGs.

All of these differences greatly reduce the possibility for changes in coding to affect payment and make the Maryland experience an invalid comparison.

IRF PPS experience. CMS also draws on the example of the inpatient rehabilitation facility (IRF) PPS to justify the coding adjustment. This is an appropriate comparison. The coding changes seen under the IRF PPS were the result of moving from a cost-based system to a PPS, not the marginal difference of moving from the existing CMS-DRGs to the refined MS-DRGs.

In addition, coding under the IRF PPS is driven by the Inpatient Rehabilitation Patient Assessment Instrument (IRF-PAI). This provides an incentive for IRFs to code in a way that differs from the inpatient PPS, which does not utilize a patient assessment instrument. Coding for

the IRF-PAI differs significantly from the long-standing coding rules that inpatient PPS hospitals have followed for the following reasons:

The IRF-PAI introduced a new data item into coding—namely “etiological diagnosis.” The definition of this new diagnosis and the applicable coding rules are significantly different than the “principal diagnosis” used to determine the DRG. More importantly, the Official Coding Guidelines that apply to all other diagnostic coding do not apply to the selection of the ICD-9-CM etiologic diagnoses codes.

The Official Coding Guidelines do not consistently apply to the coding of secondary diagnoses on the IRF-PAI. Several different exceptions to the guidelines have been developed by CMS for the completion of the IRF-PAI.

The definition of what secondary diagnoses may be appropriately reported differs under the IRF-PAI from the definition used by other inpatient coders.

Greater use of codes. Most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding CCs at high rates for many years. More than 70 percent of claims already include CCs, and more than 50 percent of claims have at least eight secondary diagnoses (the maximum number accepted in Medicare’s DRG GROUPER). Hospitals’ assumed ability to use even more CCs under MS-DRGs is very low.

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

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

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

Inpatient Psychiatric PPS

We urge CMS to carefully consider the implications of its proposed MS-DRG changes on the inpatient psychiatric facility PPS; specifically, the DRGs for alcohol/drug use and the changes to the CC list.

CAPITAL IPPS

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

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

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. According to MedPAC, overall Medicare margins will reach a ten-year low in 2007 at *negative* 5.4 percent. These cuts would amount to a decrease in capital payments of \$880 million nationally, and \$27.5 million for Pennsylvania hospitals, over the next five years. Hospitals cannot sustain in an already under-funded system, when faced with such reductions in payment.

Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties and amounts to Medicare renegeing on the full cost of caring for America's seniors and disabled.

HAP is opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology.

CMS justifies the cuts based on an analysis that purports to show that hospitals are experiencing substantial positive margins under the capital payment framework. The analysis, which averages hospital inpatient Medicare capital margins for the period from 1996 to 2004, is deficient in several respects. What hospitals experienced in 1996 is irrelevant to the operating environment today, 11 years later. Looking at a snapshot rather than a full capital cycle of 15 to 20 years is misleading. The averaging system is meant to balance the high spending cycles of some hospitals with the low spending cycles of others over time, but isolating any given portion of the cycle may not achieve this. In addition, the regression establishing the capital PPS was based on total costs, not just capital costs, so CMS should be looking at total margins. As noted earlier, MedPAC estimates an overall hospital Medicare margin in 2007 of negative 5.4 percent. Whether or not hospitals experience a narrow positive margin for their capital payments is of small consequence to the hospital losing money, on average, every time it treats a Medicare beneficiary. Moreover, this should not be discussed in isolation from the overall payment effect in an effort to mask the fact that these are significant capital cuts.

CMS' analysis concludes in 2004, the year when the margin dropped to its lowest point, 5.1 percent, in the time period CMS selected—34 percent below the 2003 capital margin and 41 percent below the 2002 capital margin. Extending that trend line projects that capital margins today are negative, which should not be a surprise because it is the very same overall Medicare

margin trajectory that MedPAC has documented—a sharp and steady decline since 2002—from positive 2.4 percent to an estimated negative 5.4 percent in 2007.

Hospitals must make a healthy positive margin in low spending years in order to access loans and take on large, long-term financial obligations. Yet, CMS is suggesting that a modest capital margin (5.1 percent in 2004, and likely lower today) is excessive. In 1991, CMS even stated that hospitals must accrue profits to supplement payments in high spending years.

In addition, CMS has not fully considered the ramifications of dramatic capital cuts on the use of technology and the quality of hospital infrastructure. Reduced capital payments would make buying the advanced technology and equipment that patients expect much more difficult for the nation's hospitals, and could have the effect of slowing clinical innovation. These changes disadvantage large urban and teaching hospitals, where much of the innovation and cutting-edge research is generated. These hospitals will be even more challenged to keep up with leading technology, facilities, and patient care. Moreover, for many hospitals, investing in information technology would become even more challenging. Without these facility and technological improvements, *all* patients will be deprived of these advances. At a time when the administration and Congress are pushing for such investments, this proposal may have the opposite effect of slowing needed adoption of health information technology.

HAP also opposes possible future cuts to the IME and DSH adjustments under the capital system. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications.

DRGS: HOSPITAL-ACQUIRED CONDITIONS

The DRA of 2005 requires CMS to identify by October 1, 2007, at least two preventable complications of care that could cause patients to be assigned to a CC DRG. The conditions must be either high cost or high volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG. That is, the case would be paid as though the secondary diagnosis were not present. Finally, the DRA requires hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding what is present on admission would be delayed until January 1, 2008, due to technical difficulties in software programming to accept the new information.

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

- Catheter-associated urinary tract infections
- Pressure ulcers
- Object left in during surgery

- Air embolism
- Blood incompatibility
- Staphylococcus aureus septicemia

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

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

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

Coding accuracy can only be achieved when physicians have been educated about the need to carefully identify and record, in an easily interpretable manner, whether pressure ulcers, urinary tract infections, or staphylococcus aureus are present on admission. To date, we are unaware of any efforts by CMS to initiate such an education process. Only after reasonable reliability in physician identification and recording of the complications that are present on admission are achieved can claims be coded in such a way that CMS could accurately identify those cases that should not be classified into the higher-paying DRGs. The two states that have undertaken the use of present-on-admission coding have reported that such educational efforts have taken 24 months or more, making it highly unlikely that CMS' plan to use present-on-admission coding for payment purposes less than a year after initiating the coding, and without any education of clinicians, would lead to the correct identification of the cases envisioned in the DRA. **We urge CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter-associated urinary tract infections, and staphylococcus aureus until after it has taken the necessary steps to permit accurate identification of the relevant cases.**

In addition, these conditions are high cost or high volume, but they may not always be reasonably preventable. There is good evidence to suggest that, even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. There is concern among infection control experts that the definitions of some of these conditions need to be reviewed and updated before they can be implemented successfully in a hospital reporting

program. Additionally, we believe that hospitals face significant challenges in diagnosing these conditions accurately on admission and coding for them at that time. Specific concerns with each of the three conditions follow.

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

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

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

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

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

Further, HAP feels that implementation of three of the six conditions representing the serious preventable events identified by CMS—object left in during surgery, air embolism, and blood incompatibility would align with our Pennsylvania Department of Public Welfare initiative for reduction in payment of preventable conditions.

Unintended consequences. HAP encourages CMS to consider the unintended consequences that might arise from implementing the hospital-acquired conditions policy. Trying to accurately

code for urinary tract infections that are present on admission may lead to excessive urinalysis testing for patients entering the hospital. The necessity to complete diagnostic tests before a patient is admitted to confirm present-on-admission status could lead to delayed admissions for some patients and disrupt efficient patient flow. In addition, HAP contends that there would likely be an increase in use of antibiotics for treatment, leading to antibiotic-resistant organisms.

Other technical clarifications. HAP would like clarification from CMS on how hospitals may appeal a CMS decision that a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.

HOSPITAL QUALITY DATA

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures—four process measures and one outcome measure—to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008.

New quality measures. HAP is in agreement with CMS proposing to add only measures that have been adopted by the HQA for public reporting in FY 2009. The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality—hospitals, purchasers, consumers, quality organizations, CMS and others—are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment. The measures proposed for FY 2009 are well-designed, represent aspects of care that are important to patients, and provide insights into the safety, efficiency, effectiveness, and patient-centeredness of care.

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to identify any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors.

Because we believe that all measures for public reporting should be adopted by the HQA, endorsed by the NQF, and tested in the field before implementation, we have concerns with some measures listed by CMS for possible implementation for FY 2009 or subsequent years because they do not fulfill these criteria. We urge CMS to carefully evaluate the value of the measures considered for reporting. Measures should be evidence-based, contribute to the comprehensiveness of performance measurement, be under a hospital's control, and account for potential unintended consequences. We recommend that CMS only propose and select measures that meet all of these conditions. **If the measures are NQF-endorsed and HQA-adopted, CMS can be assured that they meet these conditions. Therefore, CMS should only choose measures that have been selected by these two groups.**

The NQF currently is developing national quality goals. **We believe that CMS should look to the NQF goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should indicate its intent to follow the national goals as well.

We commend CMS for including in the proposed rule the measures that hospitals will be required to report to receive their full FY 2009 inpatient payments, as this early notice allows hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking to notify hospitals of the reporting requirements for the next fiscal year.**

Measure maintenance. HAP believes it is critical that the measures included in the pay-for-reporting program represent best clinical practice. Therefore, we are pleased that CMS recognizes that there may be a need to retire, replace, or revamp reporting measures. Currently, CMS and the Joint Commission have a process for reviewing measures and identifying modifications that should be made as a result of changes in scientific evidence. **As a process is developed to retire or replace measures for the pay-for-reporting program, we urge them to include hospitals, data vendors, and other stakeholders.** When amending measures, CMS and the Joint Commission should take into account the ability of hospitals, the data warehouse, and data vendors to successfully and quickly implement changes in reporting measures. In particular, to understand the effects that reporting changes have on hospitals, CMS should seek input from hospital data collection personnel as a part of the measure review process.

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

OCCUPATIONAL MIX ADJUSTMENT

By law, CMS must collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices—such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides—rather than geographic differences in the costs of labor.

Hospitals collected the hours and wages of employees from January 1 through June 30, 2006. CMS proposes to use these data in adjusting the FY 2008 area wage index. CMS also requested comments on what occupational mix adjustments to use for hospitals that did not turn in the data and whether to penalize such hospitals in the future.

For FY 2008, we believe that CMS' proposal to use the area's average adjustment for non-responsive hospitals and the national average adjustment for non-responsive counties is reasonable. For FY 2009 and beyond, because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. **We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals. We also encourage CMS to establish some sort of appeal process for hospitals with extenuating circumstances.**

WAGE DATA

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

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

CMS should fix the calculation and then reassess the impact on hospitals. In addition, a transition should be considered if the impact on any individual hospital is great.

WAGE INDEX

In FY 2009, CMS is required by law to consider changes to the area wage index. HAP agrees that the wage index is not functioning, and alternatives should be considered. There are some fundamental concerns with the wage index, as well as with MedPAC's recommendation which CMS should take into account as deliberation begins over the next year. AHA convened a workgroup, which was comprised of many state, regional, and metropolitan hospital association executives as well as other national hospital associations to rank concerns related to wage index. HAP concurs with the concerns listed below, in particular the apparent self-perpetuation in which hospitals with low wage indices are unable to increase wages to become competitive in the labor market.

Concerns related to wage index:

- ✓ Volatility of wage index year to year.
- ✓ Self-perpetuating—hospitals with low wage indices are unable to increase wages to become competitive in the labor market.

- ✓ Unrealistic geographic boundaries.
- ✓ Geographic boundaries create “cliffs” where adjacent areas have very different indices.
- ✓ Inaccurate measure of actual labor costs.
- ✓ Fiscal intermediaries are inconsistent in their interpretations.
- ✓ Hospitals can be penalized for erroneous data submitted by other hospitals in the same geographic area.
- ✓ Exclusion of some personnel from the wage index calculation—outsourcing of low-wage workers raises an area’s wage index.
- ✓ Regarding MedPAC’s recommendation, which will be released in its June report, the AHA workgroup had the following concerns.

Data source. MedPAC considered the use of Bureau of Labor Statistics (BLS) data rather than the hospital-reported data collected on CMS’ Medicare cost reports. While this approach may be significantly less burdensome for hospitals, there are critical differences between the two data sets that must be carefully evaluated. The new data source is the cornerstone of the MedPAC approach and represents a fundamental change. Many of the other aspects of the draft proposal possibly could be applied using hospital wage data as it is currently collected. Key differences between the CMS and BLS methodologies include:

Inclusion of non-hospital employers—The BLS wage data for a particular occupation are collected from *all employers*, not just short-term, acute-care hospitals participating in Medicare. Wage rates, however, vary depending on the type of employer (hospital, nursing home, physician office, insurance company, university, etc.), and the mix of employers varies by market. Thus, wage rates will be influenced by the specific mix of hospital vs. non-hospital employers of the same occupations. For example, the mean hourly wage of an RN working in a general medical and surgical hospital in 2005 was \$27.80 compared to \$24.76 for an RN working in a nursing care facility, according to BLS. Consequently, the BLS data may not be an accurate reflection of labor costs experienced by hospitals in communities with a higher proportion of other types of health care organizations.

In addition, section 1886(d)(3)(E) of the *Social Security Act* specifies that the wage index must be based on data from “subsection (d) hospitals.” The BLS data set would need to be altered to remove the wages and hours for non-inpatient PPS providers to satisfy this requirement, or the law would have to be changed to accommodate the use of BLS data.

Different treatment of certain types of personnel in wage data collection—Wages paid by companies that offer temporary employees to health care providers are included in the BLS sample. Thus, contract workers are included. However, their wages reflect the lower rate that the employees are paid *by* the agency as opposed to what the hospitals pay *to* the agency for the contract workers. This may understate labor costs in shortage areas with high use of registry nurses.

In addition, there are employee wages included in the current CMS data that are not included in the BLS data, such as Part A physicians' time unrelated to medical education. This may materially affect wage estimates in areas with a high penetration of teaching hospitals, particularly those that have provider-based clinics where employed physicians provide care not associated with teaching residents.

Process to review/verify data—Unlike CMS' public process for review and correction of wage data at the hospital level, BLS has a strict confidentiality policy that ensures that the sample composition, lists of reporting establishments, and names of respondents are kept confidential. Hospitals would be unable to verify the accuracy of the data.

Not designed to capture differences in wage growth between geographic areas—Every six months, BLS surveys 200,000 establishments ("a panel"), building the full sample of 1.2 million unique establishments over a three-year period. The data collected at each of these different points in time is combined on a rolling basis to create the annual estimate. For example, the May 2005 release of wage data is built from data collected in November 2002, May, and November 2003, May and November 2004, and May 2005.

Before estimates can be released, the five previous panels must be adjusted to the current reference period. Using the example above, the data collected in November 2002 and for each subsequent panel would need to be inflated to May 2005. This is done using a "single national estimate" of wage growth for broad occupational divisions, called the *Employment Cost Index*. This approach fails to account for any differences in wage growth between markets over the three-year period. As BLS notes, "*This procedure assumes that there are no major differences [in wage growth] by geography, industry, or detailed occupation.*"

Pay-period rather than full-year data—While CMS collects wage data for a 12-month period, the BLS survey captures only two payroll periods per year—one in May and the other in November—each capturing data from one-sixth of the total number of sampled establishments. (As noted above, data from six panels—with one survey every six months—are combined on a rolling basis over a three-year period to create the annual estimate.)

BLS excludes the cost of benefits – According to the HAP Annual Survey, benefits represent over 25 percent of hospitals' labor costs nationally. Looking across states, this percentage varies from a low of 18 percent to a high of 31 percent. Therefore, any adjustments made to include benefit costs would have to be market-specific. If benefits information is to be added, it would have to be collected on CMS' Medicare cost report in order to adjust the BLS data. This would negate the potential benefit of eliminating the collection of hospital-specific wage data.

BLS excludes pay counted by CMS—The BLS data excludes shift differentials, overtime pay and jury duty—all of which CMS includes. Overtime pay can be a cost associated with local labor shortages, and shift differentials can vary as well, depending on local labor market conditions.

Full-time and part-time employees are equally weighted—While CMS collects both wages and hours, BLS collects a count of workers within a series of wage ranges. The survey makes no distinction between full-time and part-time workers in estimating wage rates from the data collected. To the extent that the use of part-time versus full-time workers varies by market or

type of employer, this could distort the wage calculation if part-time hourly wages are lower than full-time wages.

Data subject to sampling error—Estimates using a sampling methodology like the BLS approach are going to be less reliable than using the entire universe of PPS hospitals, as is done by CMS. Both surveys would be subject to a non-sampling error (e.g., errors from respondents providing incorrect data). However, the CMS process allows for extensive public scrutiny of the data while the BLS approach does not.

Geographic boundaries.

Current geographic boundaries—The current wage index methodology, with the exception of some commuting pattern adjustments, assumes that there is no interrelationship between areas. By simply being on opposite sides of a geographic boundary, two hospitals can have very different reimbursement, even though they are competing for the same workforce. More refined areas—as in MedPAC’s proposal to vary wage indices by county—may be more realistic and less arbitrary. On the other hand, the “smoothing” approach, whereby wage index values or wages of neighboring areas are artificially constrained to allow only a 10 percent difference in wage indices, may mask actual variation in wages between areas. For example, there may be real, greater differences between outlying counties and an urban core.

In addition, MedPAC plans to use the decennial census to determine variation between the counties. So, for 2008, MedPAC would use the 2000 census data to establish the relationship between counties within a metropolitan statistical area until the 2010 census is available. Using data this old may create differences in wage indices that are inconsistent with the actual difference experienced in wages.

Single rural area wage index—While a single wage index for all rural areas of a state may be reasonable for small states, it may not adequately reflect wage variation in large states. While varying the wage indices within rural areas may make sense, we recommend further examination of MedPAC’s approach as to whether the decennial census data—now seven years old—produces accurate estimates of current area wage differences.

Year-to-year volatility—Volatility in wage indices from one year to the next makes it difficult for hospitals to estimate Medicare payments for budgeting purposes. While the three-year rolling average employed by BLS may reduce volatility, alternative approaches should be examined, including those that do not rely on BLS data.

RURAL FLOOR

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008. While it considered both an iterative process and a uniform reduction, the agency said the uniform reduction is operationally easier and results in the same wage indices.

HAP supports this move assuming that it removes the compounding effect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998. We believe that it was an unintended error to repeatedly apply the rural floor budget-neutrality adjustment without first reversing the prior year’s adjustment as is done with the outlier

calculation each year. We also suggest that CMS remove the effects of the adjustments made from 1999 through 2006 by increasing the positive budget-neutrality adjustment proposed to the standardized amount intended to just reverse the 2007 adjustment.

PHYSICIAN OWNERSHIP IN HOSPITALS

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

There are several specific aspects of the proposal that deserve comment:

Locus of requirement—CMS asked whether the requirement should be located in the provider agreement or conditions of participation. **We recommend that the ownership disclosure requirement be incorporated into provider agreements** because the conditions of participation should be focused on care delivery standards.

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

Definition of the beginning of an admission or outpatient visit—The “beginning of an inpatient admission or outpatient visit” specifically includes pre-admission testing and registration. **We recommend that the definition be clarified to include scheduling as well as pre-admission testing and registration.** Patients should receive these disclosures at the earliest opportunity so that they have an ability to act on the information if they choose.

Provision of list of physician investors—The proposal would require that physician-owned hospitals offer to provide patients with a list of the physician investors on request, but does not establish any time frame for doing so. **We recommend that the list be provided to patients at the time the request is made.** We believe providers should be able to provide the list immediately upon inquiry, so that patients would get the information in time to consider it.

PATIENT SAFETY MEASURES

As part of the DRA-required report to Congress, CMS also raised the issue of the safety of patients in physician-owned specialty hospitals. Recent events and media coverage of safety

concerns also have highlighted problems. The proposed rule would address these issues in several ways:

Require a written disclosure to patients of how emergencies are handled when the hospital does not have a physician available on the premises 24 hours a day, 7 days a week; and seek comment on whether current requirements for emergency service capabilities in hospitals both with and without emergency departments (EDs) should be strengthened in certain areas, including required staffing competencies, certain equipment availability, and required 24-hours-a-day, 7-days-a-week ED availability.

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

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

This is not the case with full-service community hospitals. Full-service community hospitals are part of a network of care in their community, involving referrals from local physician practices, reliance on local trauma support networks, participation in local emergency medical transport systems, and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted, and the patient's clinical information collected at one hospital goes with the patient to the next hospital. Small and rural hospitals also are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals. **Applying additional requirements for this group of hospitals is unnecessary and costly.**

The broader network of care delivery, of which full-service community hospitals are a part, is the best way to ensure that care is provided to patients at the right time and in the right setting.

The kinds of requirements discussed in the proposed rule can be used to assure that physician-owned facilities, in the absence of being a part of the broader care network, meet minimum standards for patient safety.

IME ADJUSTMENT

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

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

HAP appreciates CMS' efforts to clarify its policies, and its attempt to not penalize hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents rotate through. **We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count.** We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor effects, nationally speaking, while having major implications at the individual hospital level.

REPLACED DEVICES

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

Unlike the current outpatient PPS policy (which applies only when a device is provided at no cost), CMS proposes to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital or with full credit for the removed device. However, CMS proposes to apply the policy only to those DRGs under the inpatient PPS where the implantation of the device determines the base DRG assignment (22 DRGs), and situations where the hospital receives a credit equal to 20 percent or more of the cost of the device.

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

payment. In cases where the hospital receives a full or partial credit, the amount credited will be subtracted from the DRG payment.

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

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

However, if CMS implements this policy, we agree that it should limit the number of DRGs to which the policy applies. In addition, we agree that insignificant credits or refunds should not trigger this policy. However, CMS should consider raising the proposed threshold from 20 percent to greater than 50 percent or the majority of the cost of the device. Given the administrative burden of manually processing these claims, it is not worth the burden on the hospitals’ or FIs’ part if only a nominal portion of the cost of the device is at issue. In addition, inpatient PPS payments are often less than costs. If CMS implements this policy, **estimated costs should be calculated from the charges on the claims and only reduce the DRG payment by the device cost if the payment is greater than the cost of the case less the cost of the device.**

NEW TECHNOLOGY

Section 503 of the *Medicare Modernization Act* (MMA) provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS to ensure that the inpatient PPS would better account for expensive new drugs, devices, and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. **HAP also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology.**

HAP is also concerned about CMS’ ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

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

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000*.

To date, despite these recommendations, as well as the recommendations of several federal health care agencies and offices and health care trade and professional associations, the Department of Health and Human Services (HHS) has not yet moved forward to adopt the ICD-10 classification upgrades. Absent a switch to ICD-10 soon, hospitals will experience significant coding problems that will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede efforts to speed the adoption of electronic health records.

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

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

We strongly recommend that the Secretary expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. HHS should take the necessary steps to avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. It is imperative that the rulemaking process start immediately.

/dd

CMS-1533-P-240 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Dr. Gary Hullquist

Date & Time: 06/11/2007

Organization : J.A.Thomas

Category : Physician

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

We commend CMS for making the decision to choose their own severity-adjusted DRG system.

The goals of groupings that are "manageable, administratively feasible and understandable" appears, in our estimation, to have been exceptionally met. This is the only choice among the candidates presented in the proposed rule which offers a truly open data format and structure that is free of any proprietary interests.

The advantages for the proposed MS-DRGs are multiple:

" Grouping logic is a direct extension of the existing CMS DRGs making analysis and comparisons between data under these two systems straightforward and predictable.

" A smooth crosswalk exists between DRGs in both systems

" Monotonicity of linearly rising severity levels within DRG groups appears to be nearly universal.

Increasing the number of DRGs which recognize more complex or severe diagnoses from 115 to 410 (195 CCs + 215 MCCs), while increasing the available severity levels from 2 to 3, provides a very significant leap in severity-adjusted granularity, while elimination or consolidation of low volume DRGs improves the efficiency of the system.

Re-analysis of the existing CC list of diagnoses is welcome and long overdue. This update improves the list's ability to identify increased hospital resource utilization in today's healthcare environment.

We question, however, why this new system which will impose such a significantly increased restriction on identifying severity should need to have its weights adjusted to compensate for what CMS fears will be an enhanced emphasis on improved documentation and coding. Such a response appears to be in conflict with the stated goals of the Hospital Quality Initiative to improve documentation and performance.

CMS-1533-P-240-Attach-1.RTF

Comment for “DRG Reform and Proposed MS-DRGs”

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CMS-1533-P-241 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Karen Sher, RN, CIC

Date & Time: 06/11/2007

Organization : matagorda general hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

" These extremely harmful events have known methods of prevention.

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

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

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

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

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

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

" While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery bypass graft codes (without

valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

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

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

**CMS-1533-P-242 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Dr. Kent Palmberg

Date & Time: 06/11/2007

Organization : Stormont-Vail

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

#242

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

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

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

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**CMS-1533-P-243 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Phyllis Theriot

Date & Time: 06/11/2007

Organization : Jennings AMerican Legion Hospital

Category : Other Practitioner

Issue Areas/Comments

**DRGs: Hospital Acquired
Conditions**

DRGs: Hospital Acquired Conditions

see attachment

GENERAL

GENERAL

see attachment

CMS-1533-P-243-Attach-1.DOC

CMS-1533-P-243-Attach-1.DOC

Leslie Norwalk, Esq, Acting Administrator,
Center for Medicare & Medicaid Services

June 11, 2007

Dear Ms Norwalk,

I am an Infection Control Practitioner in a 60 bed hospital in rural Louisiana. I have concerns regarding the proposed "Present on Admission" that will be implemented in order to facilitate the identification of the three of the six serious preventable events.

First, my unease is centered on the introduction of new codes with the time frame to implement their usage by January 1, 2008. This is a major change and our staff will need to be educated and 6 months simply is not enough time when we do not know the rules yet!

My second concern is that although Hospital Acquired Infections are largely preventable, the fact is that all are not avoidable, even using the best practices guidelines. To list out the 3 serious preventable events that I have an issue with: #1 catheter-associated urinary tract infections; #2 pressure ulcers and #6 Staphylococcus aureus septicemia.

I would recommend that CMS continue to address the coding issues for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections. Perhaps these conditions should be included in the CMS's hospital-acquired conditions policy in the future. However, using current coding logic these conditions may not be readily identifiable.

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

For the surgical site infection identification, utilizing a high volume procedure such as coronary artery bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability. This is a well established procedure and code and can be readily identified. Consideration could also be given to of post-operative sepsis, using a specific procedure code such as CABG (with or without valve).

And finally I would like more details on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

Your attention to this matter is appreciated

Phyllis Theriot, MT(ASCP)

ICP

Jennings American Legion Hospital

1634 Elton Road

Jennings, LA 70546

337-616-7035

**CMS-1533-P-244 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Mr. Maynard Oliverius

Date & Time: 06/11/2007

Organization : Stormont-Vail HealthCare, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1533-P-244-Attach-1.DOC

Stormont-Vail HealthCare

June 5, 2007

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

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

Dear Ms. Norwalk:

I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' proposed rule for the fiscal year 2008 hospital inpatient prospective payment system (PPS).

While my colleagues and I support many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

We also believe that the 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 (\$24 billion over five years) will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoiding uninsured Medicaid and other low income patients.

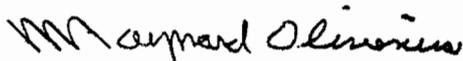
We also oppose the elimination of the capital payment updates for all urban hospitals and the large urban hospital capital payment add-on which contains an additional 3 percent cut). These changes would result in a payment cut of \$880 million over five years to urban hospitals. These unnecessary cuts ignore how vital capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology.

We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any further cuts or adjustments to the capital PPS.

These cuts will further deplete scarce resources, ultimately making the mission of hospitals to care for patients even more challenging.

We support the position taken by the American Hospital Association and urge your consideration of this position to help ensure the viability of the community hospital.

Sincerely,



Operating Committee Member

CMS-1533-P-245**Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates****Submitter :****Date & Time: 06/11/2007****Organization :****Category : Hospital****Issue Areas/Comments****DRGs: Relative Weight Calculations**

DRGs: Relative Weight Calculations

There is a definite need for an expanding level of reimbursement based on the acuity of a renal transplant. Currently, there is a national organ shortage, and the innovative ways of addressing this shortage are resulting in higher costs to transplant facilities. The OPTN has implemented an aggressive electronic organ offer system during 2007 - which has increased the use and acceptance of organs that historically would not have been transplanted. This new system has also increased the number of expanded criteria and deceased donor organs - which results in longer length of stays and increased use of inpatient induction therapy, both of which translates into increased cost to the facility. Additionally, is the option for facilities to perform incompatible transplants in an effort to increase organ availability. In the absence of a relative weight calculation, there is no mechanism for facilities to be reimbursed for their level services that they are performing. Commercial payors already distinguish between the transplants types and allow for additional reimbursement for deceased donor and high risk transplants in order to compensate for the increased cost of these transplants types. If the cost continues to rise, and reimbursement continues to decrease, it no longer becomes financially viable to perform these types of transplants - which would negatively impact the national efforts for increased donation and reverse the strides that have been made to date in the field of transplantation..

**CMS-1533-P-246 Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : Ms. Nancy Galvagni

Date & Time: 06/11/2007

Organization : Kentucky Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1533-P-246-Attach-1.DOC

June 7, 2007

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

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

Dear Ms. Norwalk:

On behalf of all hospitals in the Commonwealth of Kentucky, the Kentucky Hospital Association (KHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS).

Kentucky's hospitals support many of the proposed rule's provisions; however, they strongly oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGs

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or comorbidity list. Kentucky hospitals support meaningful improvements to Medicare's inpatient PPS. We believe that DRG categories should reflect clinically cohesive diagnoses with similar resource use and groupings that are intuitive for providers and coders to follow. It is also important that the system be simple, predictable and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to form their budgeting, marketing, staffing and other key management decisions. While we believe that the MS-DRGs provide a reasonable framework for patient classification, hospitals should be afforded a sufficient period of time to make adjustments to the redistribution of payments that will occur under the new DRG system. Therefore, KHA urges CMS to adopt the MS-DRGs over a four-year transition period. Specifically:

- In FY 2008, the emphasis should be on preparation for and testing of the new classification system. This provides CMS with adequate time to finalize data and a CC list, introduce and test software for case classification and payment, including the definitions and instructions for case classification and payment, and train its fiscal agents. It also gives hospitals adequate time to implement and test the new system and adjust operations and staffing for predicted revenues. This also will allow vendors and state agencies time to incorporate such changes into their respective software and information systems.
- In FY 2009, DRG weights should be computed as a blend derived one-third from the MS-DRGs and two-thirds from traditional DRGs.
- In FY 2010, DRG weights should be computed as a blend derived two-thirds from MS-DRGs and one-third from traditional DRGs.
- In FY 2011, DRG weights should be derived using only the MS-DRGs.

The weights would be established by CMS running the “old GROUPER” from 2008 without any changes to the CC list to establish where cases originated, and running the “new GROUPER” from 2009 with the new CC list, then blending the two weights based on the schedule above. Since there is not a perfect crosswalk from the old DRGs to the new ones, the weight used for payment in a given year would be established by blending the MS-DRG weight with a volume-weighted average of the CMS-DRG weights that feed into that particular MS-DRG. Thus, only one weight would be published in advance.

While there are many other ways to transition the system, we believe that this is easiest for CMS to implement, maintains the prospective nature of the system, is equitable across hospitals, does not require any sort of subsequent reconciliation, and does not require CMS or hospitals to run more than one GROUPER the entire year. We also believe that the length of the transition is appropriate given the large amount of money shifted within the system.

Behavioral Offset and Capital Cuts

The proposed rule also **includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009** to eliminate what CMS claims will be the effect of coding or classification changes as hospitals move to the new DRG system. **This “behavioral offset” would cut Medicare operating payments to Kentucky hospitals by \$416 million over the next five years.**

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a *refinement* of the existing system;

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

Maryland experience. In the rule, CMS uses the experience of Maryland hospitals moving to 3M’s All-Patient Refined DRGs (APR-DRGs) as a basis for the behavioral offset. However, MS-DRGs and APR-DRGs are two completely different ways to classify patients, and generalizing from one system to the other cannot be done. The existing classification rules will change only marginally with the introduction of MS-DRGs, whereas they are very different under the APR-DRG system.

Greater use of codes. Most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding CCs at high rates for many years. More than 70 percent of claims already include CCs, and more than 50 percent of claims have at least eight secondary diagnoses (the maximum number accepted in Medicare’s DRG GROUPER). Hospitals’ assumed ability to use even more CCs under MS-DRGs is very low.

Additionally, CMS is proposing to **freeze capital payments for all urban hospitals and eliminate the large urban capital payment add-on** (a 3 percent cut). **These actions would reduce payments by an additional \$ 45 million to Kentucky hospitals over the next five years.**

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. Capital cuts of this magnitude will disrupt hospitals’ ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America’s seniors and disabled.

Kentucky Impact

The combined action of the proposed behavioral offset and elimination of the capital add-on will reduce payments to Kentucky hospitals by \$461 million over the next five years.

Although the proposed rule provides for an inflationary update of 3.4 percent, the update is totally negated by CMS's unfair behavioral offset and capital payment cuts. Even though all of Kentucky's PPS hospitals are submitting quality data and are, therefore, entitled to receive a full market basket update, in the year 2008, the rule's overall impact will produce a real \$5 million cut to Kentucky hospitals.

Kentucky hospital Medicare margins are projected to be **negative 3.3 percent in 2008, and more than 40 percent of Kentucky's hospitals already have negative Medicare margins**. CMS's proposal would exacerbate this situation and continue the downward spiral of Kentucky hospitals' Medicare margins.

Accordingly, **KHA and all of Kentucky's hospitals urge CMS to drop the proposed "behavioral offset" at this time**. Once the MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment at this time, and should not do so without sufficient evidence and an understanding of the magnitude of any coding changes. **KHA also urges CMS to eliminate its proposed freeze in urban hospital capital payments** from the final regulation.

Recalibration of DRG Weights

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

However, the use of differing data sources (charges from MedPAR files and cost to charge ratios from the cost reports) as well as applying the same cost to charge ratio to items within the same cost center that have different mark ups can lead to distortion of the DRG weights.

The AHA, Association of American Medical Colleges (AAMC) and Federation of American Hospitals (FAH) convened a workgroup made up of state association, cost report and billing experts to discuss these issues earlier this year. KHA endorses the comments submitted by AHA on the cost-based weighting methodology that are an outgrowth of this group's recommendations,

Hospital Reporting and Payment for Preventable Hospital Acquired Conditions

KHA supports the comments and recommendations submitted by AHA that address quality data reporting and identification of hospital acquired preventable conditions that would not be paid for under as a result of the patient being assigned to a higher-paying DRG.

KHA is pleased that CMS has proposed adding only measures that have been adopted by the HCA for public reporting in FY 2009. We believe that CMS should only choose measures that have been NQF-endorsed and HCA-adopted. **A process should be developed to retire or replace measures for the pay-for-reporting program and CMS should develop a policy for suspending measures when there is a change in science or when an implementation issue arises during a reporting period that needs to be addressed immediately.** Finally, the proposed rule does not address the issue of data resubmission when the hospital or its vendor become aware of an error in the data that was sent to Q-Net exchange for posting on Hospital Compare. **KHA urges immediate adoption of an effective mechanism for allowing hospitals and their vendors to resubmit quality measure data if they discover an error as well as providing hospitals with a straightforward, transparent and timely process to appeal validation decisions.**

With regard to preventable conditions, CMS puts forward 13 conditions it is considering, but it recommends only six conditions for implementation at this time. The six conditions are:

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

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

Conditions to include for FY 2009. KHA believes that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are

appropriate conditions to include for FY 2009. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. Kentucky's hospitals are committed to patient safety and strive to ensure that these events do not happen.

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

Coding accuracy can only be achieved when physicians have been educated about the need to carefully identify and record, in an easily interpretable manner, whether pressure ulcers, urinary tract infections or staphylococcus aureus are present on admission. To date, we are unaware of any efforts by CMS to initiate such an education process. Only after reasonable reliability in physician identification and recording of the complications that are present on admission are achieved can claims be coded in such a way that CMS could accurately identify those cases that should not be classified into the higher-paying DRGs. The two states that have undertaken the use of present-on-admission coding have reported that such educational efforts have taken 24 months or more, making it highly unlikely that CMS' plan to use present-on-admission coding for payment purposes less than a year after initiating the coding, and without any education of clinicians, would lead to the correct identification of the cases envisioned in the DRA. **CMS should delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections and staphylococcus aureus until after it has taken the necessary steps to permit accurate identification of the relevant cases.**

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

and coding for them at that time. Our specific concerns with each of the three conditions follow.

- **Catheter-associated urinary tract infections** – Many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and prevention guidelines are still debated by clinicians.
- **Pressure ulcers** – It is difficult to detect stage I pressure ulcers on admission, as the skin is not yet broken, even though the tissue is damaged. The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. We also are concerned that the present-on-admission coding of pressure ulcers will rely solely on physicians' notes and diagnoses, per Medicare coding rules, and cannot make use of additional notes from nurses and other practitioners. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. There also is evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers because, in these cases, the condition may not be reasonably prevented.
- **Staphylococcus aureus septicemia** – Accurately diagnosing staphylococcus aureus septicemia on admission will be a challenge. Patients may be admitted to the hospital with a staphylococcus aureus infection of a limited location, such as pneumonia or a urinary tract infection. Subsequent development of staphylococcus aureus septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the proliferation of changes in coding guidelines for sepsis in recent years presents further challenges to hospital coding personnel to accurately capture present-on-admission status. Finally, there is still some debate among clinicians regarding the prevention guidelines for staphylococcus aureus septicemia.

Infectious disease experts have indicated that the category of staphylococcus aureus septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. **CMS should narrow this category to include only patients for whom it is reasonably clear that the hospital was the**

source of the infection and that it could have been reasonably prevented.

Wage Index

In FY 2009, CMS is required by law to consider changes to the area wage index. KHA welcomes the development of a new method to replace the problematic current wage index methodology and the many corresponding inequities. In particular, the current wage index fails to appropriately recognize the regional nature of the labor pool which does not conform to set geographic boundaries. Kentucky hospitals have been harmed by the self-perpetuating nature of the current index where hospitals with low wage indices are unable to increase wages to become competitive in the labor market and the "cliffs" that exist due to inappropriate geographic boundaries. We look forward to being part of the process in analyzing and developing a more appropriate method to adjust payments for labor costs.

Rural Floor

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008. While it considered both an iterative process and a uniform reduction, the agency said the uniform reduction is operationally easier and results in the same wage indices.

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

IME Adjustment

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

category, the proposed rule would treat vacation and sick time differently than it would treat orientation time. Orientation time would continue to be included as part of the full-time equivalent (FTE) count, as it always has.

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

KHA appreciates CMS' efforts to clarify its policies, and its attempt to not penalize hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through. **We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count.** We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor affects, nationally speaking, while having major implications at the individual hospital level.

Adoption of ICD-10

We strongly recommend that the Secretary expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. HHS should take the necessary steps to avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. It is imperative that the rulemaking process start immediately.

Physician Ownership in Hospitals

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

There are several specific aspects of the proposal that deserve comment:

- **Locus of requirement** – CMS asked whether the requirement should be located in the provider agreement or conditions of participation. **KHA recommends that the ownership disclosure requirement be incorporated into provider agreements** because the conditions of participation should be focused on care delivery standards.
- **Scope of requirement** – CMS asked whether the definition of a “physician-owned hospital” should exclude physician ownership or investment interests based on the nature of the interest, the relative size of the investment, or the type of investment (e.g., publicly-traded securities and mutual funds). **KHA recommends that the only exception to the definition of a “physician-owned hospital” be when physician ownership is limited to holding publicly-traded securities or mutual funds that satisfy the requirements for the exception under §411.356(a),(b). We oppose any exception based on the size of investment.** It is important for patients to know whenever there is a duality of interest on the part of their physician that could cause a conflict of interest in making decisions about their care. The size of that interest is immaterial to the fact that the conflict may exist.
- **Definition of the beginning of an admission or outpatient visit** – The “beginning of an inpatient admission or outpatient visit” specifically includes pre-admission testing and registration. **We recommend that the definition be clarified to include scheduling as well as pre-admission testing and registration.** Patients should receive these disclosures at the earliest opportunity so that they have an ability to act on the information if they choose.
- **Provision of list of physician investors** – The proposal would require that physician-owned hospitals offer to provide patients with a list of the physician investors on request. KHA believes that patients should not have to think to request this information; rather, **a printed list of physician investors should be immediately readily available for each patient to receive during the registration process** so that patients would receive the information in time to consider it.

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

changes to the self-referral statutes to close the loopholes on physician self-referral to all facilities that they have ownership in.

KHA appreciates the opportunity to provide these detailed comments, and we hope that the final regulation incorporates our recommendations.

Sincerely,

Nancy C. Galvagni
Senior Vice President

CMS-1533-P-247 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Leah Emerson

Date & Time: 06/11/2007

Organization : Ms. Leah Emerson

Category : Nurse

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

As a member of APIC Chapter 117, I wish to submit comments related to the proposed changes in the hospital prospective payment system related to hospital acquired conditions/infections.

CMS and APCI obviously have the same patient safety goals and agree that preventing infections and adverse events is of the highest priority.

However, implementation of the MS-DRG system with the determination of "present on admission codes" will be an overwhelming challenge in terms of educating clinical and coding staff.

APIC fully supports identifiable preventable events (#3) object(s) left during surgery, (#4) air embolism and (#5) blood incompatibility as these are clearly identifiable through the ICD-9 codes and these events are clearly preventable.

APIC does not support the remaining three preventable events as identified by CMS including (#1) catheter associated urinary tract infections, (#2) pressure ulcers and (#6) Staphylococcus aureus septicemia. These are much more difficult to properly identify and code and the time frame proposed is much too short. Additionally conditions 1, 2 and 6 are not always preventable even when the best practices are applied. Not all infections can be avoided particularly in light of diminished patient immune response related to a host of conditions.

APIC recommends that CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital acquired conditions policy in the future. It will be important that the approach to identifying all of these infections does not rely on POA codes

It is also important for CMS to clarify how hospitals may appeal a CMS decision if an error in coding occurs and if a patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity payment.

Thank you for the opportunity to comment on these proposed changes.

CMS-1533-P-248 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Mary Fulton

Date & Time: 06/11/2007

Organization : APIC

Category : Nurse

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

As an Infection Control Practitioner, I support the views of my professional organization, APIC, regarding the CMS POA initiatives. Below is APIC's stance on the initiative:

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

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

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

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

" These extremely harmful events have known methods of prevention.

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

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

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

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

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

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

" While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery bypass graft codes (without

valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

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

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

CMS-1533-P-249 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Ms. Denise Graham

Date & Time: 06/11/2007

Organization : Asso for Professionals in Infection Control

Category : Health Plan or Association

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

June 11, 2007

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

Dear Ms. Norwalk:

Thank you for taking the time to review the attached Word document sent along by the Association for Professionals in Infection Control and Epidemiology.

We applaud the foresight of CMS in this arena. Should you have any questions with the attached document, please reach out to me at 202-454- 2617 or at dgraham@apic.org.

Thank you.

Denise Graham
Vice President of Public Policy

CMS-1533-P-249-Attach-1.DOC



Association for Professionals in Infection Control and Epidemiology, Inc.

June 11, 2007

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

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

Dear Ms. Norwalk:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international professional association comprised of 11,000 infection prevention and control specialists, wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide additional input to the CMS proposed IPPS changes.

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

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

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

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

Six conditions proposed for consideration for FY 2009

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

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

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

Recommendations for FY 2009

Support

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

events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

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

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

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

We offer the following specific comments on each of these conditions

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

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control

Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

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

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

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

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

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

developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

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

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

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

Seven conditions mentioned but not recommended for consideration for FY 2009

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

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-

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

Potential FY 2009 recommendations

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

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

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

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

It is possible to:

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

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

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

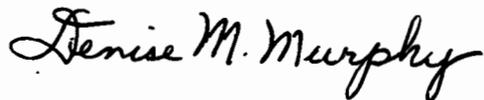
Although we agree with postponing consideration of surgical site infections at this time, we would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes - e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which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

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

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

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal. Should you require any follow up on our comments, please feel free to contact Denise Graham, Vice President of Public Policy at dgraham@apic.org or 202-454-2617.

Sincerely,



Denise Murphy, RN, BSN, MPH, CIC
2007 APIC President

References

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

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

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

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

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

CMS-1533-P-250 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : Mrs. Karen Bigley

Date & Time: 06/11/2007

Organization : Tattnall Community Hospital

Category : Hospital

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

I am an RN with a BSN and MHA, and have been certified in infection control (CIC) for 11 years. I would like to address Docket CMS-1533-P. Risk stratification is necessary whenever comparisons need to be made and benchmarks need to be chosen for any type of health data. It is necessary to risk stratify in order to compare infection rates between facilities, physicians, etc., since comorbidities of patients may determine whether or not an infection is acquired while in a hospital. It does not make sense to penalize one hospital that admits patients with cancer and who are on chemotherapy and then acquires an infection, and not another hospital whose patients have intact immune systems and therefore do not acquire infections. We, naturally, cannot pick and choose the healthiest patients to come into our facility. So, if everything is done right to prevent infection in the hospital, the patient with a compromised immune system may acquire an infection anyway, simply from his or her own flora and the body's inability to fight off bacteria. Payment for treatment of hospital-acquired infections should not be based on whether or not they were present on admission at this time. Until a solid system for identifying and risk stratifying hospital-acquired infections is developed, these changes should not be made. Thank you for your consideration.