

Submitter : Mr. Roland Goertz
Organization : Heart of Texas Community Health Center, Inc.
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical residency time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. Ronald Tachibana
Organization : Dr. Ronald Tachibana
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Ronald Tachibana, M.D.

Submitter : Dr. Joseph Gravel
Organization : Tufts Univ Family Med Residency at Hallmark Health
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Joseph Gravel, MD

Submitter : JAMES HORTON
 Organization : JAMES HORTON
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

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Submitter : Dr. Joane Baumer
Organization : JPShealthnetwork, Texas Academy of Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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See final paragraph

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JPS Healthnetwork, annually trains 72 family medicine residents and 10 fellows in sports medicine, geriatrics, obstetrics and ER. Implementation of this rule will be catastrophic to our program. We are already 30% over our cap. We would be required to cut our programs by 30% and will have major problems recruiting if we do so.

Texas is grossly underserved in over 1/2 of its counties with some having no docs. ALL of our activities are critical to the IOM and ACGME requirements for patient care -- Please do not do this.

Joane Baumer, MD
 Chair
 Department of Family Medicine

Submitter : Mr. James Shafer
Organization : Hamilton Healthcare System
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

DRG Reclassifications

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As a rural hospital that is very dependent on Medicare reimbursement I would request the CMS delay implementation of the proposed changes in the proposed Hospital Inpatient Prospective Payment Program until the full impact can be studied and understood as it can have very significant consequences on a rural hospital. I support the American Hospital Association's recommendations regarding the proposed study and phase in of changes in the current system to allow time for an institution to adjust.

Thank you for your consideration.

James R. Shafer FACHE
Hamilton Healthcare System
Hamilton, Texas

Submitter : Ms. Laura Bancroft
Organization : Ms. Laura Bancroft
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

DRGs: Severity of Illness

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I am greatly concerned that CMS is proposing we move to a proprietary system that is not transparent. This presents to me an appearance of impropriety between CMS and 3M and places an unnecessary burden of complication on the hospitals and their medical records departments. I am requesting that CMS re-evaluate this rule change and propose an alternative that is not proprietary. Thank you.

Submitter : Dr. Lakshmi Dodda
Organization : Jackson Park Hospital Family Medicine Residency Pr
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,

Lakshmi Dodda, M.D.
Program Director
Jackson Park Hospital
7501 S. Stony Island Avenue
Chicago, IL 60649

Submitter : Dr. Robin Winter
 Organization : Dr. Robin Winter
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Submitter : Dr. Jo Ann Brooks DNS, RN
Organization : Clarian Health Partners
Category : Nurse

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

On behalf of Clarian Health Partners, Inc., we are sharing the following concerns with proposed changes to the Hospital Prospective Payment Systems as described in CMS-1488-P. The proposed rule was not made public until April of 2006, but requires submission of the expanded measure set retrospectively for discharges beginning January 1, 2006.

Many hospitals were well into data abstraction of Q1 2006 cases by the end of April. For hospitals that have previously submitted only the 10 measure 'starter set', the proposed retrospective requirement places an unreasonable need to re-abstract previously abstracted records for the additional data elements.

In addition, hospitals not previously submitting Surgical Infection Prevention have been faced with the need to immediately locate and train qualified clinical chart abstraction nurses. It generally takes at least one quarter for new abstractors to fully learn the complex chart abstraction definitions and criteria for a new measure set. The retrospective requirement has not provided hospitals with sufficient time for training and inter-rater reliability testing for new data elements. This short preparation time also time places hospitals at unreasonable risk for subsequent loss of reimbursement related the increasingly stringent CMS validation process.

Hospitals, consumers, and regulatory agencies all have a common interest in accurate publicly reported hospital data. To provide hospitals with enough time to train and verify accuracy for the expanded measures, we would recommend that CMS defer the addition of the expanded measures into the RHQDAPU data set until July 1, 2006 discharges.

Submitter : Dr. Thomas Balsbaugh
Organization : UC Davis School of Medicine
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Thomas Balsbaugh, MD
Family Medicine Residency Program Director
UC Davis

Submitter : Dr. Ephraim Back
Organization : St. Clare's Family Practice Residency Program
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Ephraim Back, MD

Submitter : Dr. Philip Palmer
Organization : Dr. Philip Palmer
Category : Physician

Date: 06/09/2006

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Philip R. Palmer, MD

Submitter : Dr. Tom Houston
 Organization : Dr. Tom Houston
 Category : Physician

Date: 06/09/2006

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I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Tom Houston MD
 Clinical Professor of Family Medicine
 The Ohio State University College of Medicine

Submitter : Ms. Ann Langan
Organization : St. Cloud Hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRG Weights

DRG Weights

HSRV weights:

We are concerned about the grouping of the costs and charges associated with the high cost medical devices. We believe CMS has included the Medicare charges for medical devices in with the Medical Supplies cost center in determining the cost of these devices. We ask that CMS consider creating a separate cost center on the Medicare cost report for medical devices. By creating this separate cost center, CMS would create a method of gathering consistent data on the costs and charges associated with medical devices for future DRG cost-based weight computations that will be performed annually. Medical devices should not be considered to be medical supplies. The installation of a medical device is usually the main reason for the procedure to be performed. The high cost of the medical device is not being computed in method used by CMS in determining the cost-based DRG weights since medical devices are not like items compared to medical supplies (e.g. a stent is not comparable to a bandaid). Technology has increased the use of medical devices over the years however, the Medicare cost report cost centers have not been updated to include a cost center to record the costs and charges of the medical devices. This has lead to an inconsistency among providers and intermediaries as to where to record the costs and charges of the medical devices on the Medicare cost report. Without a consistent method of recording the cost and charges of medical devices, CMS can not make the assumption that all Medicare cost reports have the cost and charges of medical devices recorded in the Medical Supplies cost center.

We ask CMS to create a separate cost center on the Medicare cost report for medical devices and provide the definition of the medical devices to be included in this cost center in order to properly account for the cost and charges of medical devices for all providers.

In the proposed rule, CMS asked for comments on various alternatives on implementing the cost-based DRG weights. We ask that CMS consider phasing in the cost-based DRG weights over three years in order to lessen the severity of this change in the DRG weights. During this three year transition period, the DRG weights would be a product of a blend of the charge-based DRG weights and the cost-based DRG weights.

DRGs: Severity of Illness

DRGs: Severity of Illness

DRGs: Severity of Illness:

We ask that CMS consider implementing the consolidated severity-adjusted (CSA) DRGs effective October 1, 2006. The reason we ask for this is that the simultaneous implementation of the change in DRG weights and the CSA DRGs will help neutralize the impact of both changes.

By implementing only the DRG weight changes effective October 1, 2006 and delaying the implementation of the CSA DRGs until sometime before or on October 1, 2007, our hospital will experience an approximate 2% reduction in inpatient Medicare reimbursement. Our hospital provides cardiac services to the residents of central Minnesota. We support CMS effort to refine the DRG system to better reflect the severity of illness. However, by delaying the implementation of the CSA DRGs and proceeding forward with the DRG weight changes effective October, 1, 2006, our cardiology DRG reimbursement will be reduced until CSA DRGs are implemented.

Our hospital treats the severe cardiology cases and we feel that under the CSA DRG system we would be able to accurately report patients comorbidities and complications and thereby receive the accurate compensation for the services we provide to our Medicare patients. We believe our request for a simultaneous implementation of the change in DRG weights and the CSA DRGs is consistent with MedPac's recommendations.

If CMS is unable to administratively implement CSA DRGs effective October 1, 2006, we ask that CMS not delay the implementation of CSA DRGs until October 1, 2007 but rather implement CSA DRGs as soon as administratively possible during FY 2007.

If CMS is unable to implement CSA DRGs prior to October 1, 2007, then we ask for a one year delay in the implementation of the change in the DRG weights from charge-based weights to cost-based weights.

In the final rule, we ask that CMS include a table of a listing of the CSA-DRGs similar to Table 5 regardless of whether the CSA-DRGs will be implemented effective October 1, 2006. This listing of CSA-DRGs should include the DRG weight, the geometric length of stay and a yes/no as to whether the CSA-DRG will be subject to the transfer rule. Without the geometric length of stay and an indication of which CSA-DRGs will be subject to the transfer rule, the complete impact of the CSA-DRGs can not be determined.

We also ask that CMS expand the number of diagnosis codes and procedure codes the GROUPER will use to determine the CSA-DRG in order to capture the full severity of the patient. Currently, the GROUPER uses nine diagnosis codes and six procedure codes to determine the CMS-DRG. In the future, the modernized ICD-10 coding system will probably be in use which makes it all the more important for CMS to expand the number of codes the GROUPER will use to determine the CSA-DRG. This is consistent with MedPac's desire that the refinements to the DRG definitions and weights would substantially strengthen providers incentives to accurately report patients comorbidities and complications.

Submitter : Dr. Pamela Farmer
Organization : Dr. Pamela Farmer
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBridé, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Pamela L. Farmer, M.D.

Submitter : Dr. Barbara Atkinson
Organization : University of Kansas Medical Center
Category : Academic

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

See attachment

CMS-1488-P-767-Attach-1.RTF

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

Attn: **CMS-1488—P** "Resident Time in Patient-Related Activities"

Dear Administrator McClellan:

On behalf of the residency programs at the University of Kansas Medical Center, I appreciate the opportunity to comment on the CMS proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" 71 Federal Register 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in this proposed rule that sets up an artificial divide between resident training time in didactic activities and time in patient-care activities. In effect, this rule would exclude all medical resident time spent in didactic activities from calculations for Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

I would argue that almost no resident experience is unrelated to patient care activities. The learning model used in graduate medical education is delivering care to patients under the supervision of fully-trained physicians. Everything a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident's educational development into an autonomous practitioner.

In addition to the financial difficulties this rule would cause in my institution, compliance with this rule would also place on us an unreasonable administrative burden. Separating out CMS's newly defined patient-care time from didactic sessions - which often become discussions of particular patients and thus more related to patient care than didactic - seems to be an exercise in futility.

This proposed change, coming at a time when the financial viability of a significant number of graduate medical education programs is already in question, places many more programs at risk. Unless the payments which help cover the stipend and benefit payments to resident physicians are maintained, teaching institutions will be forced to down-size or eliminate graduate medical education programs, ultimately reducing the number of fully trained physicians available to provide care to an aging population.

I urge CMS to reconsider this rule and realize the integral nature of so-called didactic activities to the patient care experiences of resident physicians.

Sincerely,

/s

Barbara Atkinson, M.D.
Executive Vice Chancellor, University of Kansas Medical Center
Executive Dean, University of Kansas School of Medicine

Submitter : Dr. Douglas Rose
Organization : East Tennessee State University
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Douglas Rose M.D.

Submitter : Dr. Christine Jacobs
Organization : Dr. Christine Jacobs
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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Background

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Residency Program Activities and Patient Care

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Christine Jacobs MD

Submitter : Dr. Benjamin Leavitt
Organization : Cox Family Medicine Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Benjamin Leavitt, MD

Submitter : Michael Fortunato
Organization : Michael Fortunato
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

To alter the GME payments in the manner proposed would hurt primary care training program. It is VITAL that we support these programs or face a shortage of primary care doctors.

Submitter : Dr. Gregg Mitchell
Organization : UT Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 Gregg Mitchell M.D.

Submitter : Dr. Chris Kuhlman
Organization : Northridge Family Practice Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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Background

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Residency Program Activities and Patient Care

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Chris Kuhlman, MD

P.S. During a residency day, there is no time spent that is not related, in some way, directly to patient care. Even didactic teaching is directly related to patient care.

Submitter : Dr. Martha Illige
Organization : Rose Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care." I strongly disagree! Learning medicine is directly related to patient care and to patient safety!

This would reverse the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," all residency experiences are related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Martha Illige, MD

Teaching and practicing family medicine for 26 years

Submitter : Ms. Deborah Windish
Organization : Michigan Academy of Family Physicians
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

I am writing on behalf of the Michigan Academy of Family Physicians. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

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This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, the Academy believes this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

We urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Deborah Windish, Manager
 Government Relations & Communications

Submitter : Dr. Holbrook Raynal
Organization : Dept of Fam and Prev Med, USC-SOM
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Holbrook Raynal, MD, DHA
Director of Quality and Clinical Care
Department of Family and Preventive Med.
School of Medicine
University of South Carolina
Columbia, SC 29325

Submitter : Dr. Martin Rodriguez-Porcel
Organization : mayo clinic
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

HSRV Weights

HSRV Weights

Comments to Proposed Rule 71 FR 23995, Medicare Program: I agree with increasing payment accuracy of claims, but on the other hand I disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. Following are some of the points that should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007: the proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in its methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing the implementation of the new DRGs will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. In addition, implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. I thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-1648.

Submitter : Dr. Michael Johns
Organization : Woodruff Health Sciences Center
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-778-Attach-1.PDF



EMORY
UNIVERSITY

Michael M.E. Johns, MD
Executive Vice President for Health Affairs
CEO, Robert W. Woodruff Health Sciences Center
Chairman of the Board, Emory Healthcare

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Administrator McClellan:

The Woodruff Health Sciences Center (WHSC) at Emory University welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.*" 71 Fed. Reg. 23996 (April 25, 2006).

The two components of the rule with the greatest potential impact on the WHSC are the proposed changes in the DRG system (HSRVcc weighting methodology and CS-DRGs) and the "clarification" related to inclusion of didactic time in calculating resident FTE's for direct and indirect medical education payments.

To the extent that changes are offered that are intended to improve the payment system, we ask for your careful analysis. While it is unclear what an appropriately devised new DRG classification and weighting system might look like, it is obvious that such a change will involve the redistribution of hundreds of millions of dollars. Because Medicare is a critical revenue source for our hospitals, changes resulting in significant payment reductions must be carefully evaluated in order to prevent unexpected disruptions to operations.

In addition, we strongly urge CMS to withdraw its clarification in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care." However, this is contrary to CMS' earlier position as stated in September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute



The Robert W. Woodruff Health Sciences Center
Emory University
1440 Clifton Road NE, Suite 400
Atlanta, Georgia 30322

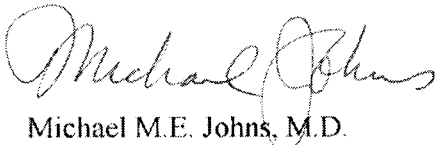
An equal opportunity, affirmative action university

Tel 404-778-3500
Fax 404-778-2100
mmcjohn@emory.edu

Care to Scott McBride, Vinson & Elkins. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs.

The WHSC estimates that it will lose \$9 million annually if this rule goes forward. We hope that you will take our comments, as well as the economic impact this rule presents, into serious consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Johns". The signature is fluid and cursive, with the first name "Michael" written in a larger, more prominent script than the last name "Johns".

Michael M.E. Johns, M.D.
CEO of the Woodruff Health Sciences Center
Executive Vice-President for Health Affairs
Chairman, Emory Healthcare

cc: Senator Saxby Chambliss
Senator Johnny Isakson
Congressman John Lewis
Congresswoman Cynthia McKinney

Submitter : Dr. Cynthia Herzog
Organization : Long Beach Memorial Family Medicine Residency Prog
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician and a family medicine residency faculty member, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Cynthia Herzog, MD
 Associate Program Director
 Long Beach Memorial Family Medicine Residency Program

Submitter : Dr. Kate Gunnell

Date: 06/09/2006

Organization : Dr. Kate Gunnell

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Kate Gunnell, MD

Submitter : Dr. Oladapo Adewuya
Organization : University Of Texas Houston, Fam. Med Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

I rather think that Family Medicine residencies should have more funding. This is because we are an important part of the first responders of the health care system. An example is our versatility in disaster situations that can call for medical specialities that are multi trained like family docs.

Submitter : Dr. Stewart Brown
 Organization : Dr. Stewart Brown
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Stewart C. Brown M.D.

Submitter : Dr. Daniel Sontheimer
Organization : Cox Family Medicine Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 Daniel Sontheimer

Submitter : Michael Huppert
Organization : University of Massachusetts Medical School
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

June 9, 2006

To Whom It May Concern:

As a family medicine residency faculty member, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In addition, I cannot conceive of how a residency program would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. The documentation requirements that this would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Michael E. Huppert, M.P.H.
 Associate Dean and Director
 Office of Community Programs
 UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
 222 Maple Avenue, Chang Building
 Shrewsbury, MA 01545

Submitter : Mrs. Starr West
Organization : Texas Hospital Association
Category : Health Care Provider/Association

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

See attached

Value-Based Purchasing

Value-Based Purchasing

See attached

CMS-1488-P-785-Attach-1.DOC



TEXAS HOSPITAL ASSOCIATION

June 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Sent electronically

RE: CMS-1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates - Proposed Rule

Dear Dr. McClellan:

The Texas Hospital Association, on behalf of its 450 member hospitals, is submitting the following comments on the proposed rules published in the April 25, 2006 *Federal Register*.

ISSUE: Reporting of Hospital Quality Data for Annual Hospital Payment Update

The proposed Medicare inpatient prospective payment system (IP-PPS) regulations for fiscal year 2007 put forward new quality reporting requirements for hospitals to receive the full annual payment update (APU). The new reporting requirements implement a number of the changes made by the Deficit Reduction Act of 2005 (DRA). As provided in that Act, the regulations would reduce the market basket update by 2.0 percentage points for any hospital that does not submit the 10 quality measures starter set plus additional measures for acute myocardial infarction, heart failure, pneumonia and surgical infection prevention.

In addition, the proposed rule would require that hospitals submit data on the expanded measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2006 (January through March discharges). The proposed deadline for hospitals reimbursed under the CMS prospective payment system to submit their data for the first quarter of 2006 would be Aug. 15, 2006. Failure to submit the data on these additional measures in the proposed time frame would result in those hospitals receiving the full market basket update minus 2 percent.

The proposed rule was published in the *Federal Register* on April 25, 2006, after hospitals were already in the process of abstracting and transmitting data for first quarter 2006 discharges. At the time of rule publication, most Texas hospitals were abstracting and transmitting data for only the 10 starter measures, and many were unaware that proposed rules would so dramatically change the reporting requirements for the APU.

As written, the proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files adds burden and cost to the health care system, and may penalize hospitals that are reluctant to collect data that may not be included in the final rule.

RECOMMENDATION: THA recommends that CMS make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to further expand the measures that must be reported to qualify for full market basket update in future years. THA strongly urges CMS to select measures only from those used by the Hospital Quality Alliance (HQA) for public reporting. To choose different measures would thwart efforts to streamline quality reporting, add to the “babble” of quality measurement that currently exists in health care and dilute efforts to create a single source to share solid reliable information with the public. In addition, whenever the Secretary intends to expand the set of measures linked to payment, CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year. This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

ISSUE: Value-Based Purchasing

The DRA required 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;
- Public reporting – disclosure of information on hospital performance; and
- Incentives – the structure of payment adjustments, including the determination of thresholds for quality improvements that would substantiate a payment adjustment, the size of such payments and the sources of funding for the payments.

RECOMMENDATION: Hospitals remain committed to providing safe, effective, patient-centered, timely, efficient and equitable care to all patients. It is critically important that a value-based purchasing system for Medicare be well thought out.

Significant resources already have been invested in the HQA effort and the *Hospital Compare* Web site by all of the participants. More than 300 Texas hospitals – representing more than 99 percent of all eligible Medicare PPS hospitals in the state – have committed to this process, leading the way by sharing data with their communities and the public. This is a solid foundation on which we must continue to build, and it should be the foundation for any pay-for-performance program included in legislation. To

base the pay-for-performance initiative on the work of a group other than the HQA would be duplicative, wasting significant knowledge and expertise.

ISSUE: Considerations Related to Certain Conditions, Including Hospital-Acquired Infections

In the proposed rule, CMS has asked for ideas about how to effectively implement the DRA provision requiring the agency to identify instances in which the reliable application of science and appropriate processes of care should prevent infections, and to ensure that Medicare does not pay more for the hospital care of patients who becomes infected as a result of their care than it does for patients who are infection free. The DRA requires the Secretary to identify, by Oct. 1, 2007, at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines.

In the April 2006 issue of *Infection Control and Hospital Epidemiology*, Sherman et al., report that to their knowledge no standardized method using claims data to find cases of hospital-acquired infections has been validated. Sherman's study found that targeted active surveillance carried out by trained infection control practitioners was the most accurate method of identifying true hospital-acquired infections. The poor positive predictive value for identifying cases of hospital-acquired infections through administrative data – coupled with the inevitable coding changes that will result from the proposed changes to DRG weights and reclassifications – makes the DRG system problematic for the purposes outlined in the DRA.

RECOMMENDATION: THA recommends that more study be done to consider what conditions, procedures and circumstances should be targeted for this change. The ICD-10 coding system may provide the necessary specificity to accomplish the purposes of the DRA; however, HHS has not yet moved forward to adopt ICD-10. Additional time is needed to identify the impact of changes in the DRG weights and reclassifications. The proposed rules would eliminate the complication or comorbidity splits in the current DRG system and would potentially replace the current DRGs with a consolidated severity adjusted DRG system. The impact of a new severity adjusted system on coding practices is unknown. Expertise on coding and the DRG changes adopted under the final rule is needed to address questions of what data are helpful and readily available to determine which infections were acquired in the hospital versus the community, and which codes actually lead to enhanced payments.

A starting point for this work is to build off CMS' investment in the Surgical Care Improvement Project (SCIP). Surgical wound infections are among the most common and hazardous hospital-acquired infections. The existing SCIP partners' expertise can help identify a few surgical procedures that might be most appropriate for the change Congress envisioned. 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. Therefore, THA suggests that by utilizing the SCIP program as the basis for responding to the congressional mandate, CMS could choose not to penalize a hospital if, despite best efforts, an infection occurs. For example, if a hospital's performance on the SCIP surgical wound infection prevention measures show that it reliably performs the necessary infection prevention steps all or nearly all of the time, CMS might not make any change to the current payment system for that hospital.

Thank you for the opportunity to provide comments on these rules. If you have questions or wish to discuss THA's comments, please contact me at 512/465-1042 or swest@tha.org.

Sincerely,

A handwritten signature in black ink that reads "Starr West". The signature is written in a cursive, flowing style.

Starr West
Director Policy Analysis

Submitter : Dr. Jeanne Spencer
 Organization : Conemaugh
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

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The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 Jeanne P Spencer, MD

Submitter : Dr. Allen Shaughnessy
Organization : Tufts University Family Medicine Residency
Category : Other Practitioner

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As an educator of family physicians, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

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Sincerely,

Allen F. Shaughnessy, PharmD

Submitter : Mr. Jeremy Crisp
Organization : Mr. Jeremy Crisp
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a medical student and future family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates., 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

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Sincerely,
Jeremy Crisp

Submitter : Dr. James McKinley
 Organization : UTHCT
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Peter Rives

Date: 06/09/2006

Organization : Dr. Peter Rives

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

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Submitter : Ms. Barbara Allen
Organization : Northern Michigan Hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRG Weights

DRG Weights

Northern Michigan Hospital, a 243-bed Sole Community Hospital located in the northern tip of Michigan's Lower Peninsula, is pleased to offer our comments on the proposed changes to the Hospital Inpatient Prospective Payment System and fiscal year 2007 rates and our concerns about the negative impact these changes will have on our ability to provide services to our patients with highly complex medical conditions.

As a regional referral center, Northern Michigan Hospital handles high complexity cases in our 24-county service area, including cardiac and orthopedic care, from smaller, critical access hospitals in the region. These hospitals are not equipped to treat these complex cases and the next closest hospital would require considerable travel in often harsh weather conditions.

The proposed changes to the Hospital Inpatient Prospective Payment System's DRG weightings, if implemented as written, will have a significant adverse effect on our capacity to continue to treat patients with these complex conditions.

For example, let's take the case of a patient needing an implantable defibrillator (DRG 515, 535 and 536). The current Medicare payment for the cost of this procedure is not keeping pace with the innovation. We provide our patients with this device as part of a comprehensive cardiac program. The proposed rule reduces the payment for this procedure by 25 percent in one year.

While some hospitals may offset losses in the surgical DRGs with gains in the medical DRGs, Northern Michigan Hospital does not have that option. We would have to make the undesirable decision of whether we can afford to continue to provide this service to our patients if the payment doesn't even cover the cost of the implant.

We believe that the proposed DRG payment weights are fundamentally flawed. By using two-year-old data to determine the cost for procedures performed today, it does not take into account the advances in these devices over the past couple of years. With wireless technology, patients receiving these advanced capability devices may be monitored and adjustments made from their home, avoiding a trip to the physician's office or the nearest Emergency Department. Substantial cost-savings are achieved and improved patient outcomes are a result. Our ability to provide the best technology and the best patient care will be severely impacted if CMS uses out-of-date cost analysis in determining the payment structure.

In regards to part two of the proposed rule dealing with the APR-DRGs, we are not in a position to comment as we have been unable to find anyone who can quantify the impact on our hospital.

In summary, the proposed changes to the Hospital Inpatient Prospective Payment System and fiscal year 2007 rates would have a detrimental impact on regional referral hospitals such as Northern Michigan Hospital and significantly impair our ability to provide healthcare services to patients in northern Michigan. We urge the Centers for Medicare and Medicaid Services to delay implementation to allow for a complete analysis and the use of updated data. To do otherwise, will result in what we are sure are unintended outcome for our patients and the hospital.

Northern Michigan Hospital is available to assist you in any way in providing data on the impact of this proposed rule on regional referral centers and sole community hospitals. Please do not hesitate to contact us.

Thomas C. Mroczkowski
 President and CEO
 Northern Michigan Hospital
 416 Connable Avenue
 Petoskey, Michigan 49770
 231.487.4005
 tmroczkowski@northernhealth.org

Submitter : Dr. Joseph Horan
 Organization : Dr. Joseph Horan
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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Sincerely,

Joseph F. Horan, MD

Submitter :

Date: 06/09/2006

Organization :

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-793-Attach-1.DOC

June 9, 2006

By Electronic Mail

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
7500 Security Boulevard
Baltimore, MD 21244-1850



Dear CMS Officials:

Thank you for this opportunity to comment. Since 1991, Princeton Reimbursement Group (PRG) has provided reimbursement consulting services to the medical technology industry. We have helped hundreds of clients, from start-up device manufacturers to some of the world's largest medical products companies, successfully address their reimbursement issues. This wide range of experience has positioned PRG to help various stakeholders deal with today's dynamic healthcare reimbursement environment. As active participants in the healthcare system and future consumers of the Medicare program we would like to use this opportunity to voice our observations and comments, specifically about the HIPPS proposed rule and payment policies in general. We realize our comments deviate from the norm; we offer no tactical comments on refinement but rather state what we view as the obvious: a need for economic incentives beyond an episode of care and the need for an improved working relationship between CMS and industry.

We support CMS's attempts to develop methodologies that provide equitable payment for medically necessary services. Our concern is that the payment per episode of care, whether CMS DRGs, APR DRGs or consolidated severity-adjusted DRGs fails to reward or provide economic incentives for services that negate the need for downstream services. Often the value of a new technology is realized because it prevents the need for additional services or it extends life or improves quality of life or a combination of the aforementioned. Unfortunately the episode per care method focuses only on the cost of care – not the added benefit. Further, whether intentional or unintentionally it seems that the manufacturers of technology are viewed in a negative light: "base DRGs formed based on the use of a specific technology would result in the payment weight for the DRG being dominated by the price set by the manufacturer for the technology."¹ If the manufacturer has proven the value of the technology why does it matter that the DRG is dominated by the price of the technology?

We submit our comments in the spirit of improving the healthcare reimbursement system. We believe that trust and respect are basic fundamentals to any successful endeavor. We realize that this "fix" requires efforts by a multitude of stakeholders and is beyond CMS's authority to change in isolation. We hope that our comments are received in the spirit in which they were given. Thank you for allowing us this venue for expression.

Sincerely,

Judith Hickey
President Princeton Reimbursement Group
9801 Dupont Avenue, Suite 295
Minneapolis, MN 55431

¹ Federal Register, Vol. 71, No. 79, 4/25/06, p. 24014

Submitter : Mr. vaughn gower
Organization : lehigh valley hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRG Weights

DRG Weights

i leave it to the aamc and aha to provide analysis and feedback regarding the technical and methodological issues of the proposal. key points: 1) need more time to evaluate impact and methods. the objective should be fair and correct changes , not fast changes. this is especially true when viewed against the fact that major revamping's to medicare's payment structure occurs on average every 20 years. 2) implement all drg changes at one time. 3) phase the changes in over 3 years; old system 75%, 50%, 25%, 0% annually.

DRGs: Severity of Illness

DRGs: Severity of Illness

i leave it to the aamc and aha to provide feedback and analysis on technical and methodological issues. key points . 1) allow more time to evaluate the methods and impacts of the proposals. include industry rep's in that review. the objective should fair and correct changes , not fast changes. this is important when viewed against the fact that major changes to medicare's payment structure occurs on average every 20 years. 2) implement all drg changes at one time. 3) phase in the effect of the changes over 3 years: old system 75%, 50% , 25% , 0% annually.

FTE Resident Count and Documentation

FTE Resident Count and Documentation

please drop the exclusion for didactic work. medicare policy currently recognizes didactic activity broadly as part of patient care activities. keep this policy. it is virtually impossible to accurately determine resident activity for didactic and for patient care as they are inherently integrated.

Submitter : Miss. Stacey Malakoff
Organization : Hospital for Special Surgery
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

In concept, we support both Cost Based Weights and the stated goals of the HSRV weights:

" Using costs addresses bias caused by current differential charge mark-ups across cost centers, hospitals, and states.

" HSRVs intend to implicitly adjust for hospital level differences in wage levels, commitment to teaching, and provision of services to underserved populations

In practice, however, the proposal needs significant change to correct new bias introduced by how the proposed methodologies aggregate across hospitals and DRGs:

" Compression of the weights is caused by the HSRV methodology. Although the goal is to address the differences above, the reality is that it only works if there is NO correlation between costs and the factors involved. Since higher cost, difficult patients are appropriately and systematically referred to teaching hospitals located in urban areas that are designed as regional centers to treat these patients, the calculations will systematically under-price those DRGs where these difficult patients group, introducing new bias and perverse incentives.

" All nursing costs per day are assumed to be the same for every patient, regardless of the nursing needs of each patient. This will also provide a perverse incentive to admit only simple patients.

" A single set of RCC values are used across all hospitals. This introduces new bias, unless case mix is randomly distributed across hospitals. Charges should be converted to cost at each hospital prior to any aggregation.

" A single set of cost center weights (% of cost) is used across all hospitals and all DRGs. Table H in the proposal itself shows that this is an invalid assumption. Patient level charges should be converted to cost in each DRG at each hospital prior to any aggregation.

" There are some technical concerns regarding charge mapping between cost reports and MEDPAR designation available at the DRG level.

Due to the major inaccuracies in the proposals, and the significant perverse incentives implementation would introduce, we recommend:

" Delay of implementation until these concerns can be corrected.

" Full evaluation and validation of any methodologies that redistribute multiple millions of dollars of Medicare funds. This analysis should include a specific assessment of whether new bias is introduced while attempting to correct old bias.

Please see attached letter for more details.

CMS-1488-P-795-Attach-1.PDF

HOSPITAL
FOR
**SPECIAL
SURGERY**



June 7, 2006

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

<http://www.cms.hhs.gov/eRulemaking>

**Specialists
in Mobility**

Re: File code CMS-1488-P.

Comments: "HSRV Weights"

- In concept, we support the intended goals of both Cost Based weights and Hospital Specific Relative Values (HSRVs):
 - Cost Based Weights theoretically address the issue of bias caused by generally higher charge mark-ups over cost for ancillary services than for routine services. This practice thereby overvalues ancillary services and undervalues routine services, which in turn overvalues surgical care relative to medical care in DRG weights, since surgical patients use more ancillaries.
 - HSRVs intend to implicitly adjust for hospital level differences in location, wage and fringe levels, commitment to teaching, charges, and provision of disproportionate services to underserved populations when determining relative weights between patients. This reduces the reliance on the accuracy of the explicit adjustments for these factors under the current methodology.

- In practice, the proposal needs significant changes to correct compression of weights and three NEW distortions introduced in attempting to correct current bias. This is due to implicit assumptions in cost conversion using simple versus weighted averages and single sets of national averages across hospitals for RCC factors and across DRGs for cost center mix:
 - **Proposal Assumption 1:** CMS applied the same amount for nursing services to all patients. This implies that the costs of routine nursing services that patients need and receive are the same per day across all patients and all DRGs.
 - For example, nursing cost for a surgical patient just returning from the Operating Room after bi-lateral hip replacement or coronary bypass surgery, or a patient with a tracheostomy or on ventilator support is treated the same as the nursing cost for a patient with simple medical back or chest pain or a patient with laparoscopic cholecystectomy or urinary stones.
 - This assumption introduces a new distortion that understates inherently higher nursing needs for surgical patients and overstates medical care patient nursing costs.

- **Proposal Assumption 2:** CMS applied the same RCC value across all hospitals for a given cost center. This implies that all hospitals have the same mark-up on their charges for a given cost center.
 - A brief review of cost reports for several hospitals will show this assumption to be untrue. In fact, variability in charge mark-ups are a major reason to shift from charge based weights to cost based.
- **Proposal Assumption 3:** CMS applied the same % mix of services by cost center to all DRGs. This implies that the % mix of services by cost center is the same across all DRGs.
 - The proposal itself shows this assumption to be untrue – Table H on page 24020 of the April 25, 2006 Federal Register shows that the % mix of services by cost center is significantly different for Medical and Surgical patients. Medical patients have much higher proportions of routine daily costs and the costs of Lab, X-ray, and Therapy, while surgical patients have much higher proportions of Supplies and Equipment and O.R. The %mix of services by DRG is even more variable.

- **Recommended Solutions**

- **Delay Implementation Until Data and Methodology Concerns Addressed**
 - We understand that there are major charge “mapping” inconsistencies between MEDPAR designations and cost reports for many hospitals - that need to be corrected before moving to cost based DRG weights.
 - Methodologies need to be fully evaluated and validated for accuracy prior to use to re-distribute millions of dollars of Medicare funds. This should include identifying reasons/causes for observed “weight compression” and the following specific methodology recommendations.
- **Adjust for relative daily nursing needs by DRG**
 - CMS has approved Medicaid DRG rates for payment incorporating Nursing Intensity Weights in New York’s State Plan for almost 20 years. These weights could easily be implemented for Medicare to adjust DRG daily costs for relative nursing intensity (i.e. use nursing intensity weighted days to allocate routine costs to DRGs.)
 - Other CMS payment systems currently recognize that patient nursing needs vary widely per day between patients. A significant portion of Skilled Nursing Facility rates are based upon on relative daily nursing needs (which combined with relative rehabilitation needs form the basis for the Resource Utilization Group (RUGS) weights.)
- **The calculation order needs to be reversed (Now=HSRV first then convert to Cost; change to: convert to Cost first, then compute HSRV)**
 - The current proposal does the hospital specific relative value calculation using unadjusted charges first, then converts it to cost using national average assumptions for sets of RCC values and for % relative cost center mix. Reversing the calculation order to convert charges to cost first for each hospital and DRG, and then computing hospital specific relative values accommodates cost center mix and charge mark-up differences across hospitals and across DRGs – without introducing new bias.

Thank you for the opportunity to respond to these proposed Medicare payment policy changes. If you need any clarifications of these comments, please contact Mr. Brian Fullerton of our staff, (212) 774-2926.

Sincerely,

Stacey L. Malakoff
Executive Vice President and Chief Financial Officer

Submitter : Dr. James Lundy
Organization : North Mississippi Family Medicine Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely,

James R Lundy, MD

Submitter : Dr. David Lehmann
Organization : SUNY Upstate Medical University
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

Blood Clotting Factor

Blood Clotting Factor

June 9, 2006

Centers for Medicare and Medicaid Services

RE: NCD for administering blood-clotting factors

To Whom It May Concern:

The State University of New York-Upstate Medical University Hospital is submitting a formal request for reconsideration of the National Coverage Determination for administering blood-clotting factors to Medicare beneficiaries who are acute care hospital inpatients. Specifically, we are writing to request Medicare to include intracerebral bleeding in the coverage for the administration of activated coagulation factor seven. Conditions that cause intracerebral hemorrhage (ICH) are medical emergencies that are associated with very poor clinical outcomes. The current standard of care for management of ICH is supportive care that includes correction of any underlying coagulopathy combined with judicious surgical intervention. Since outcomes are directly related to the extent of the bleed over time, any intervention that produces immediate hemostasis at the bleeding site improves outcomes.

A recent randomized trial has documented that activated factor seven given to patients within four hours from the onset of symptoms limits bleeding extension, reduces mortality, and improves the 90-day functional outcome by 20%. (Mayer, et.al., N Engl J Med 2005;352:777-85.) Accordingly, at University Hospital, we consider withholding the drug from patients who present with this condition within its time window of efficacy to constitute substandard medical care. Since Medicare expenses from an adverse outcome due to an expanding clot far outweigh the high cost of activated factor seven, any financial impediments for this use should be removed.

Unfortunately, although the documentation for its beneficial effect in ICH is robust, activated factor seven, although widely marketed, is not yet a covered diagnosis for additional payment by Medicare. Despite our considerable out-of-pocket expense, and driven solely for interests of quality, we have made the decision to move activated factor seven into the role of first-line therapy for these patients. As a result, our financial liability has already reached several hundred thousand dollars. This drain on our hospital budget impedes our further attempts to address quality in other areas. Furthermore, the lack of reimbursement for this agent limits the availability of this compound at smaller regional medical centers without emergency neurosurgical services, where its administration would have an even greater salutary impact during the period of stabilization prior to transport.

Lastly, I would like to state that no one at University Hospital involved in the care of patients with ICH has a relationship with the manufacturer of activated factor seven that could serve as a source of bias or influence. Our opinions and the policy of University Hospital are based solely on the interests of maintaining the highest quality of patient care.

David Lehmann M.D., Pharm.D.
Professor of Medicine & Pharmacology
Chair, Pharmacy & Therapeutics Committee for
SUNY UMU
University Hospital

Submitter : Dr. Matt Brown
Organization : UIC/Advocate Christ
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Matt Brown, MD

Submitter : Dr. Andrea Gordon
Organization : Tufts Family Medicine
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Submitter : Dr. David Lehmann
Organization : SUNY Upstate Medical University
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

Blood Clotting Factor Payment Rate

Blood Clotting Factor Payment Rate

June 9, 2006

Centers for Medicare and Medicaid Services

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David Lehmann M.D., Pharm.D.
Professor of Medicine & Pharmacology
Chair, Pharmacy & Therapeutics Committee for
SUNY UMU
University Hospital

Submitter :

Date: 06/09/2006

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1488-P-801-Attach-1.DOC



Aurora Medical Center®

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June 9, 2006

Mark McClellan M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan,

Aurora Medical Center wishes to comment on the April 25th Federal Register entitled, Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

In particular, Aurora Medical Center would like to comment on the changing of the DRG weight calculation from a charge based to a cost based system removal of offsite non-patient care time for Indirect Medical Education reimbursement, the movement to severity adjusted DRG's, the expansion of number of quality measures to report on, and non payment for infections not present at the time of admission.

DRG Reclassification

Aurora Medical Center takes issue in the re-weighting of the Medicare inpatient DRG's based upon costs rather than billed charges. Our main issues are as follows:

- Not all hospitals have the same cost to charge ratios. In fact, in order to remain competitive, many urban facilities do not mark up expensive surgical supplies such as drug eluding stents and pacemakers very much at all to keep managed care companies from not authorizing a potentially life saving surgery. These supplies in the CMS calculation are marked up based upon overall department markup, which may not reflect actual supply mark-up.
- Two hundred sixty very large hospitals representing twenty five percent of the total charges were excluded from the cost center cost to charge ratio calculation. However, these hospitals were not exempt from the effects of the DRG weight change, even though the data from their hospital(s) were not included in the calculation of the DRG weights.

- Large hospitals offer cutting-edge technology services such as Cardiology, and Neurosurgery. Excluding these hospitals from the cost to charge ratio calculation does not give an accurate national cost to charge ratio for modeling purposes.
- Hospitals do not consistently group costs in the same manner on the Medicare cost report. This will lead to cost to charge ratio inaccuracies for the calculation of the DRG payments.
- The cost to charge ratio data used in the calculation is based upon cost report information from 2003. Current technology such as drug-eluting stents, and bi-ventricular pacemakers were in its infancy in 2003, and does not accurately reflect the utilization of these services as it exists today. This leads to inaccuracies in the way these DRG's are proposed to be reimbursed by CMS compared to the actual costs the Hospital incurs for the inpatient stay.
- Cardiology related services will be hit unusually hard in this proposal. As a result of these changes the proposed DRG's for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers reduced 12 to 14%. Drug eluting stents cost \$3,000 a piece. The average number of stents per patient is 1.65. Cost for drug eluting stents per patient is \$4,950. With the average reimbursement for DRG 558 being \$7,200, this leaves \$2,250 to cover the surgery, all of the other supplies, drugs, and the patient stay of two days. This will not even cover the direct costs much less the overhead it takes to run a hospital. The payment shortfall will have a devastating impact for Cardiology programs across the country, and will potentially cause access problems due to programs not being able to recover the cost of the leading edge technology. This is clearly not the intent of what CMS wanted to do.

With DRG's being a payment system of gains on some DRG's and losses on others, recalculation of the DRG weights based upon costs, will cause a lot more losers than gainers. This could cause hospitals not to invest in expensive life saving treatments due to lack of adequate payment, and therefore inhibit potentially life saving patient care.

Due to the drastic financial effect this has on hospitals, at a minimum this change should be delayed for one year, or be phased in over a four year period of time to allow hospitals to adjust to the new payment.

DRG's: Severity of Illness

Aurora Medical Center supports CMS's concept of paying claims more accurately by having severity payment levels within each DRG. However, there needs to be a lot more work done before severity DRG's can be implemented.

- More time is needed before implementation for coding staff training.
- The severity of illness DRG grouper needs to be released to the public so other information system vendors can perform the necessary programming for medical records and business office software systems. Having 3M maintain control of the grouper software limits access by other software vendors to begin reprogramming of the many computer systems that need to have the severity adjusted grouper software and are not compatible with the 3M grouper. This needs to happen well before

implementation so hospitals can test their systems, and study the impact on their facilities.

- The new version of the UB-92 needs to be released, so the additional ICD-9 codes beyond nine can be accepted by claims processing system. Without this change hospital providers may not get paid accurately under the severity adjusted system.
- ICD-10 codes need to be implemented in order to obtain an accurate patient diagnosis.
- The effect the severity adjusted payment system has on outliers needs to be studied more closely to make the sure payment is accurate for the resources consumed by the patient.

CMS also needs to take the additional time to implement this so their systems operate smoothly and not create accounts receivable problems for the hospitals.

Hospital Quality Data

Aurora Medical Center supports CMS's effort to expand the number of quality measures hospitals report on in order to receive the full market basket payment increase. However, more time is needed in order for hospitals to implement the expansion. With the final notice not coming out until the beginning of August, and the quarterly data that CMS wants providers to report the expanded data is due on August 15th. That is not enough time for providers to implement the change. Many hospitals use external vendors to compile and submit the data to CMS. Vendors need adequate time to deal with the programming changes necessary to implement the revised quality measures after the regulation is final. Software testing at the hospital needs to be completed to make sure the data is complete and accurate. Aurora Medical Center proposes delaying this provision for at least six months to allow for a smooth implementation.

Value Based Purchasing

Aurora Medical Center is opposed to CMS's recommendation to not pay additional payments for infections acquired while the patient is in the hospital. Hospitals, most of the time, have no control over what patient complications arise when they are in the hospital. Many visitors who may come to the hospital have drug resistant staph infections, and not even realize it. This can be passed along to the patient quite easily.

Hospital's infection control departments have measures in place to prevent infections as much as they can. However, they cannot possibly control all of the infections all of the time. Hospital's still need to be paid adequately for taking care of the patient, especially the complex hard to treat patient with acquired infections.

FTE Resident Count and Documentation

Aurora Medical Center remains opposed to CMS's interpretation of Public Law 105-33 requiring only patient care time spent be allowed in the FTE count calculation when the Intern or Resident is training outside of the Hospital.

Interns and Residents, in order to obtain proper training must spend significant non-patient care time out of the hospital. Time spent at external seminars, reviewing clinic patient charts, researching patient symptoms for related diseases, virtual learning (practice suturing etc.) and documentation coordination with the physician in their clinic, are just a few of very important functions the Intern or Resident spends doing activities outside of the hospital. These are very essential roles for the education of future

Physicians. Residents are bound to train for a maximum of 80 hours per week, so wherever the resident may have down time, they spend their time on these non-direct patient care functions. Without these functions, the training programs cannot exist.

CMS has made a commitment to fund Graduate Medical Education programs. Without adequate funding by CMS for these programs, many programs will not be able to survive and forced to shut down.

Aurora Medical Center would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call Steve Kowske at 414-647-3429.

Sincerely,

A handwritten signature in black ink, appearing to read "Robin Pedersen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robin Pedersen
Vice President Finance
Aurora Health Care

Submitter : Dr. Sean Bryan
 Organization : Phoebe Putney Memorial Hospital
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. Background: The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient Care! firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. Jeannette South-Paul
Organization : University of Pittsburgh
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

Impact Analysis

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Submitter : Mrs. Theresa Noel
Organization : ROCKDALE MEDICAL CENTER
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

I think that this has not been well thought out-We need another year to determine SIP Accuracy

Submitter : Dr. John Carper
Organization : Alameda Family Physicians
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

John Carper, MD

Submitter : Dr. Gregory Hindahl
Organization : Deaconess Family Medicine Residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Greg Hindahl, MD
Associate Director
Deaconess Family Medicine Residency
Evansville, IN 47710
812-450-2931

Submitter : Dr. Amy Thomas
 Organization : Dr. Amy Thomas
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

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Submitter : Dr. Franklyn Babb
 Organization : Dr. Franklyn Babb
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : *BARR, JOHN D.*

Date: 06/09/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

ICD-9-CM DRG assignment
See attachment

CMS-1488-P-809-Attach-1.WPD

June 9, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attn: CMS-1488-P

Dear Dr. McClellan:

On behalf of the American Society of Interventional & Therapeutic Neuroradiology (ASITN), I would like to commend the Centers for Medicare and Medicaid Services (CMS) for the creation of new ICD-9-CM procedure code, 39.74 Endovascular removal of obstructions from head and neck vessel(s), and for assigning this new code to the following DRGs:

- DRG 001 – Craniotomy, Age Greater than 17 with CC
- DRG 002 – Craniotomy, Age Greater than 17 without CC
- DRG 003 – Craniotomy, Age 0-17
- DRG 543 – Craniotomy with Implantation of Chemotherapeutic agent or Acute complex Central Nervous System Principle Diagnosis
- DRG 442 – Other O.R. Procedures for Injuries with CC
- DRG 443 – Other O.R. Procedures for Injuries without CC
- DRG 486 – Other O.R. Procedures for Multiple Significant Trauma

CMS' action in creating this new procedure code and assigning it to clinical coherent DRGs will help to ensure access to clinically appropriate surgical interventions for the 700,000 individuals in the United States who suffer a stroke each year, of which 88 percent are ischemic in nature.

The ASITN recommends that CMS move forward with these DRG assignments for ICD-9-CM procedure code 39.74 in the Inpatient Prospective Payment System Final Rule for FY 2007.

Background

Ischemic stroke patients who are treated with endovascular thrombectomy are typically more ill than the average stroke patient, judging by their higher baseline NIH Stroke Scale (NIHSS) scores. Specifically, patients treated with endovascular thrombectomy typically have NIHSS scores of 8 or greater, with a median score in the MERCI trial of 19, representing a moderate-to-severe stroke. Patients treated with IV tPA typically have a "measurable deficit." The median NIHSS score in the NINDS trial was 14, which represents a significantly less severe stroke population than treated in the MERCI trial. Also, for patients treated with endovascular thrombectomy the usual time from stroke onset is already past 3 hours or there are other compromising clinical factors such as

#809

recent surgery, long-term current use of anticoagulants, or the patient has already failed intravenous tPA therapy.

Patients treated with endovascular thrombectomy experience additional CT, MR, and MRA imaging studies, approximately 2 hours of operating room time, an additional CT angiogram, and an average length of stay that is two days longer than an ischemic stroke patient treated with IV tPA. This level of service intensity is clinically similar to other endovascular procedure codes assigned to DRGs 543 and 001.

An analysis of the 2004 MedPAR data that we presented at a meeting with CMS staff on February 22, 2006 also demonstrated that the standardized charges and average length of stay for ischemic stroke patients treated with endovascular thrombectomy was similar to the overall standardized charges and average length of stay for DRGs 543 and 001.

2004 MedPAR Analysis – Endovascular Thrombectomy Patients

	Standardized Charges (Mean)	Length of Stay (Mean)	Total Payment (Mean)
Endovascular Thrombectomy Cases	\$54,960	9.4	\$21,405
DRG 001	\$54,545	10.3	\$23,213
DRG 543 (using 2004 amounts)	\$66,543	12.0	\$23,296

In closing, the ASITN has enjoyed the opportunity to work with CMS in creating ICD-9-CM procedure code, 39.74 Endovascular removal of obstructions from head and neck vessel(s), and in providing data and information regarding assigning this new code to the appropriate DRGs. Please feel free to contact Marie Williams, ASITN Executive Director at 703-691-2272, if you have any questions or if there are areas where the ASITN can be of assistance.

Sincerely,

John D Barr, MD

John D. Barr, MD
President

Submitter : Dr. Irene Hamrick
Organization : East Carolina University
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a geriatrician I am concerned about CMS' proposal to separate resident training time into "didactic" and "patient care activities". Patients and learners benefit from bedside teaching. And patient examples are used in didactics to increase relevance and retention. The two are tightly interwoven and cannot be extricated. Furthermore, it would add undue administrative burden of separating one from the other.

Academic centers are currently functioning in the red and further decrease in funding in addition to the title VII cuts, may make it untenable to educate residents. Particularly in primary care this will worsen the already existing shortage. Currently 20,000 geriatricians are needed and 9,000 are available and in the future (2030) even greater discrepancy of 36,000 is needed and 11,000 available. (<http://www.uoworks.com/pdfs/feats/GERIATRICS.pdf>), (JAMA 2001;286:1095-1107) The discrepancy in academic geriatrics is even greater, with 2,400 currently needed but only 700 available. There is a crucial need to attract physicians into the profession, but reducing funding to teaching hospitals by separating didactic teaching from patient care will severely jeopardize the ability of teaching institutions to survive. Please feel free to contact me with questions. Sincerely,

Irene Hamrick, MD
Assistant Professor of Family Medicine
Director, Geriatric Fellowship Program
Brody School of Medicine at East Carolina University
Brody 4N-72A, 600 Moye Blvd.
Greenville, NC 27834
Office: (252)744-2597 Fax: (252)744-2623
Voicemail: (252)744-2450
New e-mail: hamricki@ecu.edu

Submitter :**Date:** 06/09/2006**Organization :****Category :** Physician**Issue Areas/Comments****GME Payments**

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. David Bomback
Organization : CT Neck and Back Specialists, LLC
Category : Health Care Provider/Association

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter re: X STOP IDP

CMS-1488-P-812-Attach-1.DOC

Connecticut Neck & Back Specialists, LLC

20 Germantown Road
Danbury, CT 06810
Tel: 203 744 9700
Fax: 203 744 9701

David L. Kramer, M.D.
David A. Bomback, M.D.
Jennifer Madonia-Barr, PA-C

www.ctneckandback.com

June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP Interspinous Decompression System
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I believe that the X STOP Interspinous Decompression System (X STOP IPD) should be available to Medicare patients that have no surgical alternatives. In the past year, I have implanted the X STOP in four elderly comorbid patients (aged 67 to 82 years), and three-quarters have experienced significant improvement in physical function and reduce symptoms. Post-operative x-rays show significant improvement in motion, lateral bending, and axial rotation.

About 80 percent of my lumbar stenosis patients are Medicare beneficiaries. All too often, these patients have comorbidities that prevent me from recommending a laminectomy. Also, the patients with scoliosis, which represents a significant portion of my caseload, have no surgical options. I would estimate that about half of my non-surgical candidates might be candidates for X STOP IPD.

Clinically, I have seen some startlingly good results. Patients who could walk only 100 feet pre-operatively can now walk two miles. Patients who were in wheelchairs pre-operatively are now ambulatory. Two patients have doubled or tripled the distance they can walk. Pain scores have dropped from an average of 9 (with 10 being the most intense) to about 2-3. I have been amazed that patients are mobile the day after surgery, most of my laminectomy patients often require short term rehabilitation for gait assistance.

I urge Medicare to pay for the X STOP IPD procedure, as I think it should be offered as first line treatment for LLS patients who cannot benefit from a laminectomy.

Sincerely,

David A. Bomback, M.D.

David A. Bomback, M.D.
Connecticut Neck and Back Specialists, LLC

Submitter : Dr. Neil Oslos
Organization : Florida Academy of Family Physicians
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. James Gardner

Date: 06/09/2006

Organization : Cook Group

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Cook Group will be submitting three separate comments via attachments

CMS-1488-P-814-Attach-1.DOC

CMS-1488-P-814-Attach-2.DOC

CMS-1488-P-814-Attach-3.DOC

COOK[®]

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Comments to CMS-1488-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

The Cook Group, Inc. ("Cook") is pleased to comment on the conditions and evidence-based guidelines that should be selected to implement the new, incentive-based payment policy for reducing hospital-acquired infections ("HAIs") in response to the Proposed Rule, "CMS-1488-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." As a manufacturer of diagnostic and interventional products, Cook shares the Department of Health and Human Services' ("HHS") commitment to reducing HAIs through the use of evidence-based guidelines.

Cook is a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. We pioneered the development of products used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. The company sells over 15,000 different products worldwide.

These comments focus specifically on the section of the Proposed Rule pertaining to "Considerations Related to Certain Conditions, Including Hospital-Acquired Infections." As you know, by October 1, 2007, Section 5001(c) of the Deficit Reduction Omnibus Reconciliation Act of 2005 ("Deficit Reduction Act"), "Quality Adjustment in DRG Payments for Certain Hospital Acquired Infections," requires the Secretary of HHS to select diagnosis codes associated with at least two conditions that: (1) describe cases that are high in number and/or cost; (2) result in the assignment of a case to a diagnosis related group ("DRG") that has a higher payment when the selected code is present as a secondary diagnosis; and (3) describe conditions that are reasonably preventable through the use of evidence-based guidelines.¹

The purpose of this policy is to reduce HAIs, to lower government costs, and to develop financial incentives for hospitals to enhance patient quality. Cook supports this provision and believes it can be implemented most effectively if HHS includes codes associated

¹ Pub. L. No. 109-171.

with bloodstream infections (“BSIs”) related to central venous catheters (“CVCs”) when it makes its selection. BSIs result in higher costs per episode than any of the other most frequent HAIs. Additionally, the rate of BSIs is rapidly increasing, and CVC-related BSIs are reasonably preventable through the use of evidence-based guidelines.

Currently, there are two codes associated with CVC-related BSIs that result in assignment of a case to a DRG that has a higher payment when the selected code is present as a secondary diagnosis: (1) ICD-9-CM Code 996.62, “Infection and Inflammatory Reaction Due to Other Vascular Device, Implant, and Graft”; and (2) ICD-9-CM Code 038, “Septicemia” (used in conjunction with 996.62 when the CVC-related infection results in sepsis). As both of these codes meet the three conditions set forth above, the Secretary should utilize them to implement the provisions of Section 5001(c).

Selecting BSI codes as part of this Deficit Reduction Act policy is particularly important given the Centers for Disease Control and Prevention’s (“CDC”) efforts to reduce catheter-related associated events. Significantly, in its “7 Healthcare Safety Challenges,” the CDC’s Division on Healthcare Quality Promotion lists its number one challenge as reducing catheter-associated adverse events by fifty percent among patients in healthcare settings.² Further, the Institute for Healthcare Improvement’s “100k Lives Campaign” includes preventing central line infections as one of six changes in care it seeks to implement; these six changes are all proven to prevent avoidable deaths.³ Accomplishing these goals will become more feasible if the codes referenced above are included under this new, incentive-based payment policy.

Each year, HAIs result in approximately 2 million infections, 90,000 deaths, and \$4.5 billion in excess costs.⁴ The most frequent HAIs include urinary tract infections (“UTIs”) (usually catheter-related), surgical-site infections (“SSIs”), BSIs (usually related to the use of an intravascular device), and pneumonia (usually ventilator-associated).⁵ BSIs account for only fifteen percent of hospital acquired infections, but are associated with higher costs than the other most frequent infections and an incidence rate that is rising much more rapidly than the rate of UTIs and SSIs.⁶

Most of the serious catheter-related infections arise from the use of CVCs.⁷ In intensive care units, CVC-related BSIs result in an estimated \$34,508 to \$56,000 in additional

² CDC, *7 Healthcare Safety Challenges* (2001), available at http://www.cdc.gov/ncidod/dhqp/about_challenges.html.

³ Institute for Healthcare Improvement, Leaflet, *100k Lives Campaign* (2006), available at <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=1>.

⁴ Linda McKibben, MD, et al., *Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee*, 33 AM. J. INFECTION CONTROL 217, 218 (2005).

⁵ John P. Burke, MD, *Infection Control—A Problem for Patient Safety*, 348 NEW ENG. J. MED. 651 (2003).

⁶ Id.

⁷ CDC, *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, 51 MORBIDITY & MORTALITY WEEKLY R. 1, 2 (2002).

costs per episode.⁸ Across entire hospitals, the additional costs amount to as much as \$25,000 per episode.⁹ The yearly cost of treating patients with CVC-related BSIs ranges from \$296 million to \$2.3 billion.¹⁰

Although CVC-related BSIs result in significant costs per episode and are increasing at a rapid rate, they are reasonably preventable through the use of evidence-based guidelines.¹¹ For example, the Agency for Healthcare Research and Quality (“AHRQ”) recommends several guidelines for preventing intravascular catheter-associated infections, such as (1) restricting the duration of catheterization; (2) stringently complying with proper handwashing and proven infection control principles; (3) using maximum barrier precautions during CVC insertion; and (4) using CVCs coated with antibacterial or antiseptic agents.¹²

Along with the use of maximum sterile barriers during catheter insertion, AHRQ specifically cites to the use of antibiotic-impregnated catheters as a patient safety practice with the “greatest strength of evidence” regarding its impact and effectiveness in addressing the problem of CVC-related BSIs and notes that the cost and complexity of implementing this patient safety measure is low. AHRQ, *Summary, in MAKING HEALTH CARE SAFER* at 10 tbl. A-3. In fact, many studies over the past ten years have proven that using antibiotic-impregnated CVCs, rather than unimpregnated catheters, can drastically reduce the occurrence of BSIs associated with CVCs.¹³

⁸ Id.

⁹ Id.

¹⁰ Id.

¹¹ Sanjay Saint, MD, MPH, *Prevention of Intravascular Catheter-Associated Infections*, in EVIDENCE REPORT/TECHNOLOGY ASSESSMENT NO. 43, MAKING HEALTH CARE SAFER: A CRITICAL ANALYSIS OF PATIENT SAFETY PRACTICES (AHRQ Publication No. 01-E058) [hereinafter MAKING HEALTH CARE SAFER]; CDC, 51 MORBIDITY & MORTALITY WEEKLY R. 1.

¹² Saint, MAKING HEALTH CARE SAFER

¹³ A study published in the American Journal of Infection Control determined that minocycline/rifampin catheters are clinically and economically superior to chlorhexidine/silver sulfadiazine catheters for patients catheterized for longer than one week. Kristin D. Marciante, MPH, PhD (candidate), et al., *Which Antimicrobial Impregnated Central Venous Catheter Should We Use? Modeling the Costs and Outcomes of Antimicrobial Catheter Use*, 31 AM. J. INFECTION CONTROL 1, 5 (2003). The authors of the study noted that its findings are conservative because it considered only the direct costs of catheter-related outcomes. *Id.* at 7. The study determined that for patients catheterized for eight days, the probability that minocycline/rifampin catheters were cost-effective was 91% and costs in the reference case were reduced by \$67; in patients catheterized for thirteen or more days, the probability increased to 97.4% and costs in the reference case were reduced by \$203. *Id.* at 5. Accordingly, by selecting codes associated with CVC-related BSIs, CMS will help to encourage hospitals to implement the use of CVCs impregnated with antibiotics and reduce HAIs and related costs.

Additionally, a study comparing two different types of antimicrobial-impregnated CVCs found that the anti-infective efficacy of the CVCs impregnated with minocycline and rifampin were superior to those impregnated with chlorhexidine and silver sulfadiazine. Rabih O. Darouiche, MD, et al., *A Comparison of Two Antimicrobial-Impregnated Central Venous Catheters*, 340 NEW ENG. J. MED. 1, 5 (1999).

See also Issam Raad, MD, et al., *Central Venous Catheters Coated with Minocycline and Rifampin for the Prevention of Catheter-Related Colonization and Bloodstream Infections*, 127 ANNALS OF INTERNAL MED. 267 (1997).

Mark B. McClellan, M.D., Ph.D.

June 9, 2006

Page 4

Cook supports the Deficit Reduction Act's policy goals of reducing HAIs and enhancing patient quality. To achieve these goals, the Secretary should select the codes that will be most effective in assisting the CDC to attain one of its top public health priorities: reducing catheter-associated adverse events by fifty percent among patients in healthcare settings. Accordingly, we urge HHS to utilize ICD-9-CM Code 996.62, "Infection and Inflammatory Reaction due to Other Vascular Device, Implant, and Graft," and ICD-9-CM Code 038, "Septicemia," (when used in conjunction with 996.62) to implement the requirements of Section 5001(c).

Thank you for your efforts to implement this new, incentive-based payment policy for reducing HAIs. Please contact us if you have any questions regarding our comments. Thank you in advance for your consideration of this submission.

Respectfully submitted,

James Gardner, M.D., M.B.A.

Medical Science Officer & Director of Reimbursement

jgardner@cook-inc.com

COOK[®]

June 9, 2006

The Honorable Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, Maryland 21244-1850

**Re: Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems & Fiscal Year 2007 Rates**

Dear Dr. McClellan:

This comment is filed on behalf of the Cook Group, Inc. ("Cook"), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells over 15,000 different products.

Cook has reviewed with interest the proposed inpatient prospective payment system rule. We have tried as best we can to analyze the impact of this very complex proposal on the welfare of patients, and we are concerned that it may significantly reduce patient access to medical technologies. In separate letters Cook submitted broad comments on the proposed changes to the Medicare 2007 Inpatient Prospective Payment System, along with specific comments related to quality-adjusted DRG payments. In this letter, we would like to submit comments on the proposed rules' effect on two specific procedures --endovascular repair of abdominal aortic aneurysms (EVAR) and endovascular repair of thoracic aortic aneurysms (TEVAR) -- and how the proposed rules could inhibit Medicare beneficiaries' access to these very important, life-saving procedures.

Mark McClellan, M.D., Ph.D.

June 9, 2006

Page 2

As background, EVAR and TEVAR offer minimally invasive treatment options for the life-threatening conditions of abdominal aortic aneurysm and thoracic aortic aneurysm, respectively. Historically, open surgery was the treatment of choice for both these diseases. Open surgery was (and remains) highly invasive, major surgery with significant morbidity and mortality, long hospital stays, and extended periods of recuperation. In the late 1990's, the first endovascular grafts for repair of abdominal aortic aneurysm (AAA) received FDA approval in the U.S., followed by the first FDA approval in 2005 of an endovascular graft to treat thoracic aortic aneurysms (TAA). These devices allow a minimally invasive option to treat these diseases. Not all patients have anatomy suitable for endovascular repair, but for those that do EVAR and TEVAR offer treatment options that result in less peri-operative mortality, fewer significant peri-operative complications, and shorter hospital stays.¹ In fact, for patients too sick or frail to undergo major surgery, EVAR and TEVAR may offer the only definitive treatment options for their life-threatening aneurysms.

With an EVAR (and TEVAR) repair, small incisions are made in the patients' groin(s) to expose the femoral arteries. Catheters containing the endovascular stent-grafts (synthetic graft materials, such as Dacron or PTFE, attached to a tubular metal framework) are then passed through the femoral arteries to the site of the aneurysm. Once positioned to exclude the aneurysm from the flow of blood, the stent-grafts are released from the catheter, and allowed to expand within the aorta. The device provides a new channel for the blood to flow through, preventing flow into the aneurysm, thereby reducing the risk of aneurysm rupture, which is the goal of aneurysm treatment.

I. Current Medicare IPPS Reimbursement for EVAR

The EVAR procedure for treating AAAs is coded with ICD-9 procedural code "39.71 Endovascular implantation of graft in abdominal aorta." Claims submitted to Medicare containing this procedural code in conjunction with the primary diagnosis code "441.4 Abdominal aneurysm without mention of rupture" will most often result in the assignment of the patient's admission to one of the following two major cardiovascular procedure DRGs:

DRG 110: Major cardiovascular procedure with complications or comorbidities

DRG 111: Major cardiovascular procedure without complications or comorbidities

¹ Lifeline Registry of EVAR Publications Committee, "Lifeline Registry of endovascular aneurysm repair: Long-term primary patency outcomes measures"; Journal of Vascular Surgery; Vol 42, no. 1, July 2005

2004 Medpar data reveals the following distribution of DRG assignments for Medicare claims submitted with procedure code 39.71 and primary diagnosis 441.4 (along with other procedural and diagnostic codes relevant to that hospital admission):

2004 Medpar data; CMS-DRG Assignments: Procedure code 39.71; Diagnostic code 441.1

DRG	Descriptor	Relative Weight	% of 2004 Discharges
110	Major CV procedure with CC	3.9587	66%
111	Major CV procedure without CC	2.4488	33%
Weighted Average Relative Weight:		3.4208	

For comparison sake, the following table contains a similar summary of 2004 Medicare claims for open surgical repairs of AAA (Procedure code "38.44 resection of vessel with replacement, aorta, abdominal" and primary diagnostic code 441.4):

2004 Medpar data; CMS-DRG Assignments: Procedure code 38.44; Diagnostic code 441.1

DRG	Descriptor	Relative Weight	% of 2004 Discharges
110	Major CV procedure with CC	3.9587	85%
111	Major CV procedure without CC	2.4488	15%
Weighted Average Relative Weight:		3.7322	

II. Medicare IPPS Reimbursement for EVAR Under the Proposed "Consolidated" APR-DRG (cAPR-DRG) System

For fiscal year 2008, CMS is suggesting a change from its current DRG classification system to the cAPR-DRG system. With no clear crosswalk from the current system to the proposed system, it is challenging to anticipate the net effect of this change for any particular patient, hospital, or procedure. However, the 3M grouper software for the proposed DRG system has been made available, allowing one to run different combinations of diagnostic codes and procedural codes through the grouper to assess DRG assignment(s) under the proposed cAPR-DRG system.

Using Medicare's supplemental 2004 Medpar file, claims with primary procedure 39.71 and primary diagnosis 441.4 were identified, along with the cAPR-DRG

assignment. The weighted average Relative Weight was then calculated; the results of this exercise are as follows:

2004 Medpar data; cAPR-DRG Assignments: Procedure code 39.71; Diagnostic code 441.1

cAPR-DRG	Descriptor	Relative Weight	% of Discharges
234	Other vascular procedure, SOI 1	1.5918	44%
235	Other vascular procedure, SOI 2	2.0045	44%
236	Other vascular procedure, SOI 3	3.1716	7%
205	Vascular procedures, SOI 4	6.7708	2%
Weighted Average Relative Weight: 1.9957			

Again, for comparison the same exercise was performed for 2004 claims containing, at a minimum, the open repair procedural code (Procedure code "38.44 resection of vessel with replacement, aorta, abdominal") and primary diagnostic code 441.4:

Medpar 2004; cAPR-DRG Assignments: Procedure code 38.44; Diagnostic code 441.1

cAPR-DRG	Descriptor	Relative Weight	% of Discharges
225	Major thoracic and abdominal vascular surgery, SOI 1	1.9777	10%
226	Major thoracic and abdominal vascular surgery, SOI 2	2.6456	50%
227	Major thoracic and abdominal vascular surgery, SOI 2	3.8085	27%
205	Vascular procedures, SOI 4	6.7708	13%
Weighted Average Relative Weight: 3.4269			

III. Comparison: EVAR reimbursement under the current CMS-DRG system vs. the proposed cAPR-DRG system

As displayed in the sections above, EVAR patients as a group had DRG assignments resulting in a weighted average relative weight of 3.4208 under the current CMS-DRG system. Assuming an OSA of \$4731, that would result in an average hospital reimbursement of approximately \$16,200 (Of course, individual hospital reimbursement would vary depending on a number of factors, but this is important for purposes of illustration).

Under the proposed cAPR-DRG system, this same group of patients would have DRG assignments resulting in a weighted average relative weight of 1.9957. Even assuming the higher proposed OSA for 2007 (\$4884), this would result in an average hospital reimbursement of approximately \$9750 -- a 40% reduction in reimbursement compared to the current CMS-DRG system. The assessment of

open surgical repair also shows a reduction under the proposed system, however of a much smaller (~ 8%) magnitude.

We are very concerned about this projected reduction in hospital reimbursement for EVAR procedures. An average hospital reimbursement of under \$10,000 will not cover the hospitals' costs (let alone hospital charges) for the devices used in the procedure, which amount to nearly \$14,000 per EVAR procedure (data source: IMS Health Inc.; consistent with internal Cook sales data), let alone additional costs incurred during the hospital stay. With such a discrepancy between the hospitals' costs in performing this procedure and its projected reimbursement, we are concerned that the performance of this procedure will be discouraged by hospitals. This could reduce Medicare beneficiaries' access to a procedure that has been proven to have lower perioperative mortality, fewer perioperative complications, and shorter hospital stays than its open surgical alternative. And for those who aren't open surgical candidates at all, this could discourage any option for definitive treatment.

IV. Recommendations

1) We suggest that the cAPR-DRG system not be implemented unless and until issues like those described above can be further explored and appropriately addressed.

Should the cAPR-DRG system be implemented, we make the following recommendations:

2) Base Classification for EVAR

Under the current DRG system, both EVAR and open surgical repair of AAAs are typically assigned to the same Major Cardiovascular Procedure DRGs – DRGs 110 and 111. Under the proposed system, EVAR is assigned to the base classification “Other Vascular Procedures” (cAPR-DRGs 234-236), while open surgical repair of AAAs is assigned to base classification “Major Thoracic and Abdominal Vascular Procedures” (cAPR-DRGs 225-227). It is our opinion and recommendation that EVAR, along with open surgical repair of aortic aneurysm, be considered “Major Thoracic and Abdominal Vascular Procedures,” with the relative weights that are proposed for those cAPR-DRGs. We suggest that TEVAR (procedural code 39.73) also be considered a “Major Thoracic and Abdominal Vascular Procedures.”

2) Severity of Illness

We appreciate CMS's effort to align hospital reimbursement more closely with patient's severity of illness (SOI), under the assumption that more hospital resources are utilized when caring for sicker patients. However, that logic falls apart to a significant extent when applied to patients admitted to the hospital for EVAR (or TEVAR) procedures. With endovascular repair of aortic aneurysms, device costs represent a significant proportion of resources utilized, and device costs are for the most part independent of the patient's SOI. This will present a significant problem for hospitals if EVAR patients fall into cAPR-DRG 234 or 235 ("Other Vascular Procedures", SOI 1 and 2, respectively). Even if our recommendation #1 above is accepted, assignment of EVAR patients to cAPR-DRG 225 ("Major Thoracic and Abdominal Vascular Procedure", SOI 1) would result in a significant reimbursement shortfall for hospitals. In each of these cases, the proposed reimbursement would be significantly lower than the cost of the endovascular devices themselves, let alone other hospital resources utilized during that admission. With that in mind, we suggest that in conjunction with our recommendation above about a change in base classification, the algorithm for SOI calculation for EVAR procedures be modified so that EVAR patients receive an SOI classification at least one level above their SOI assignment under the proposed 3M cAPR-DRG grouper algorithm.

Summary

Endovascular repair of abdominal and thoracic aortic aneurysms offers a well-established treatment option to Medicare beneficiaries that, when compared to traditional open surgical repair, results in fewer peri-operative deaths, fewer significant peri-operative complications, shorter hospital stays, and a shorter recovery time. Cook is very concerned that the proposed change in DRG classification systems may have an unintended but deleterious effect on hospital reimbursement for these procedures, which in turn may have an intended but deleterious effect on Medicare beneficiaries' access to these procedures.

If, after further consideration, CMS chooses to implement the cAPR-DRG system, we encourage CMS to review the base classification of these endovascular procedures and Severity of Illness assignments. Changes are necessary to assure that patients undergoing these procedures are assigned to more clinically relevant DRGs and also assigned to DRGs with relative weights more accurately reflecting hospitals' costs in performing these procedures.

Mark McClellan, M.D., Ph.D.
June 9, 2006
Page 7

Cook appreciates the opportunity to comment on the proposed rule, and looks forward to working with CMS in the adoption of payment policies which ensure continued access to safe and effective health care technologies.

Respectfully Submitted,

James Gardner, M.D., M.B.A.
Medical Science Officer & Director of Reimbursement
jgardner@cook-inc.com

COOK®

June 9, 2006

The Honorable Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, Maryland 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

This comment is filed on behalf of the Cook Group, Inc. ("Cook"), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells over 15,000 different products.

Cook has reviewed with interest the proposed inpatient prospective payment system rule. We have tried as best we can to analyze the impact of this very complex proposal on the welfare of patients, and we are concerned that it may significantly reduce patient access to medical technologies. In separate letters Cook submitted specific comments related to quality-adjusted DRG payments and the proposed rules effect on two specific procedures -- endovascular repair of abdominal aortic aneurysms and endovascular repair of thoracic aortic aneurysms. In this letter, we offer some more general comments on the proposed rules.

The FY 2007 proposed rule, with its shift from a cost based system to a charge based system marks the most significant change to inpatient PPS payment rates since its inception. Revisions set forth in the proposed rule to shift from traditional DRGs to consolidated severity adjusted DRGs are also significant. Care must be taken in making

Mark McClellan, M.D., Ph.D.

June 9, 2006

Page 2

this paradigm shift so as to ensure that the proposed DRG system adequately reflects the costs of new medical technologies and to ensure that hospitals and ultimately patients can continue to obtain access to life saving medical technologies.

We fear that the proposed rule threatens to reduce rather than increase payment accuracy, and may impede access to innovative technologies that save and enhance people's lives. Cook takes this position for several reasons. First and foremost, the cost-based data on which the proposed payment system is predicated is dated. Data which are three to five years old do not reflect the rapid pace of medical innovation. It must be remembered that the average life span of a medical device is only eighteen months. Indeed, innovative technologies, such as drug-eluting stents, introduced into the marketplace within the past two to three years are not reflected in the cost-based dataset. New models of these technologies will likely be coming to the market in the very near future. If cost data is used, we know of no way to achieve accuracy without using external data.

Second, not only is the cost data dated, it is in many cases inaccurate. The current cost reporting system was designed for a cost-based reimbursement system used to pay hospitals over twenty years ago. Since the inception of a charge-based prospective payment system, hospitals have had fewer incentives to ensure that the cost reports are timely or that the internal allocations of costs are accurate. If costs are going to be used to determine payment, CMS needs to make an effort to enhance the accuracy and timeliness of the hospital-based data. Again, reliance on external data may be useful in this regard.

Third, we are concerned about potential technical errors and/or questionable technical assumptions that distort the estimated impact on payments. For example, it is our understanding that CMS excluded data from a number of large hospitals from its analysis. If these data had been included, the very large swing in payments for some DRGs would be reduced by nearly 50%.

Finally, the rule reduces payment for care provided to patients using advanced medical technologies, sometimes by as much as 20-30%. As a result, hospitals may not be able to afford critical medical technologies. New medical technologies provide patients with help and hope, and it makes no sense to discourage their development and use.

CMS seeks specific comment on the best way to address technologies which introduce increased complexity, but are not necessarily related to greater severity of illness, into the new payment system within the context of existing statutory provisions for new technology add-on payments. Based on our observations of the implementation of the program to provide new technology add-on payments, we do not believe it is adequate to

Mark McClellan, M.D., Ph.D.

June 9, 2006

Page 3

address the complexity issue raised by CMS. To date, CMS has narrowly interpreted the criteria that must be used to receive such add-on payments and very few technologies have been found to be eligible. It would appear to us that this system will not provide the flexibility CMS will need to account for changes in complexity posed by the introduction of new technologies.

Cook respectfully urges CMS to proceed with caution in implementing such significant revisions to the inpatient prospective payment system. Although sensitive to the potential for bias arising from differential mark-ups for ancillary services, Cook believes that a more pragmatic approach would be a phase-in of the proposed rule, targeting those specialty hospitals where payment differentials have been found to be greatest. At the very least, CMS should carefully consider the wisdom of implementing such complex changes in payment policy, affecting millions of patients, in less than one year.

Cook notes that we found it extremely difficult to analyze the impact of the proposed severity adjusted DRG system on our products. We expect others are experiencing similar difficulties in analyzing the proposed rule, thus making the case for a phase-in or delay in implementation even stronger.

Cook appreciates the opportunity to comment on the proposed rule, and looks forward to working with CMS in the adoption of payment policies which ensure continued access to safe and effective health care technologies.

Respectfully submitted,

James Gardner, M.D., M.B.A.

Medical Science Officer & Director of Reimbursement

jgardner@cook-inc.com

Submitter : Dr. Richard Spindler MD
Organization : Dr. Richard Spindler MD
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter :

Date: 06/09/2006

Organization :

Category : Hospital

Issue Areas/Comments

DRG Weights

DRG Weights

see attachment

CMS-1488-P-816-Attach-1.DOC



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June 9, 2006

Mark McClellan M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan,

Aurora Medical Center wishes to comment on the April 25th Federal Register entitled, Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

In particular, Aurora Medical Center would like to comment on the changing of the DRG weight calculation from a charge based to a cost based system removal of offsite non-patient care time for Indirect Medical Education reimbursement, the movement to severity adjusted DRG's, the expansion of number of quality measures to report on, and non payment for infections not present at the time of admission.

DRG Reclassification

Aurora Medical Center takes issue in the re-weighting of the Medicare inpatient DRG's based upon costs rather than billed charges. Our main issues are as follows:

- Not all hospitals have the same cost to charge ratios. In fact, in order to remain competitive, many urban facilities do not mark up expensive surgical supplies such as drug eluting stents and pacemakers very much at all to keep managed care companies from not authorizing a potentially life saving surgery. These supplies in the CMS calculation are marked up based upon overall department markup, which may not reflect actual supply mark-up.
- Two hundred sixty very large hospitals representing twenty five percent of the total charges were excluded from the cost center cost to charge ratio calculation. However, these hospitals were not exempt from the effects of the DRG weight change, even though the data from their hospital(s) were not included in the calculation of the DRG weights.

- Large hospitals offer cutting-edge technology services such as Cardiology, and Neurosurgery. Excluding these hospitals from the cost to charge ratio calculation does not give an accurate national cost to charge ratio for modeling purposes.
- Hospitals do not consistently group costs in the same manner on the Medicare cost report. This will lead to cost to charge ratio inaccuracies for the calculation of the DRG payments.
- The cost to charge ratio data used in the calculation is based upon cost report information from 2003. Current technology such as drug-eluting stents, and bi-ventricular pacemakers were in its infancy in 2003, and does not accurately reflect the utilization of these services as it exists today. This leads to inaccuracies in the way these DRG's are proposed to be reimbursed by CMS compared to the actual costs the Hospital incurs for the inpatient stay.
- Cardiology related services will be hit unusually hard in this proposal. As a result of these changes the proposed DRG's for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers reduced 12 to 14%. Drug eluting stents cost \$3,000 a piece. The average number of stents per patient is 1.65. Cost for drug eluting stents per patient is \$4,950. With the average reimbursement for DRG 558 being \$7,200, this leaves \$2,250 to cover the surgery, all of the other supplies, drugs, and the patient stay of two days. This will not even cover the direct costs much less the overhead it takes to run a hospital. The payment shortfall will have a devastating impact for Cardiology programs across the country, and will potentially cause access problems due to programs not being able to recover the cost of the leading edge technology. This is clearly not the intent of what CMS wanted to do.

With DRG's being a payment system of gains on some DRG's and losses on others, recalculation of the DRG weights based upon costs, will cause a lot more losers than gainers. This could cause hospitals not to invest in expensive life saving treatments due to lack of adequate payment, and therefore inhibit potentially life saving patient care.

Due to the drastic financial effect this has on hospitals, at a minimum this change should be delayed for one year, or be phased in over a four year period of time to allow hospitals to adjust to the new payment.

DRG's: Severity of Illness

Aurora Medical Center supports CMS's concept of paying claims more accurately by having severity payment levels within each DRG. However, there needs to be a lot more work done before severity DRG's can be implemented.

- More time is needed before implementation for coding staff training.
- The severity of illness DRG grouper needs to be released to the public so other information system vendors can perform the necessary programming for medical records and business office software systems. Having 3M maintain control of the grouper software limits access by other software vendors to begin reprogramming of the many computer systems that need to have the

severity adjusted grouper software and are not compatible with the 3M grouper. This needs to happen well before implementation so hospitals can test their systems, and study the impact on their facilities.

- The new version of the UB-92 needs to be released, so the additional ICD-9 codes beyond nine can be accepted by claims processing system. Without this change hospital providers may not get paid accurately under the severity adjusted system.
- ICD-10 codes need to be implemented in order to obtain an accurate patient diagnosis.
- The effect the severity adjusted payment system has on outliers needs to be studied more closely to make the sure payment is accurate for the resources consumed by the patient.

CMS also needs to take the additional time to implement this so their systems operate smoothly and not create accounts receivable problems for the hospitals.

Hospital Quality Data

Aurora Medical Center supports CMS's effort to expand the number of quality measures hospitals report on in order to receive the full market basket payment increase. However, more time is needed in order for hospitals to implement the expansion. With the final notice not coming out until the beginning of August, and the quarterly data that CMS wants providers to report the expanded data is due on August 15th. That is not enough time for providers to implement the change. Many hospitals use external vendors to compile and submit the data to CMS. Vendors need adequate time to deal with the programming changes necessary to implement the revised quality measures after the regulation is final. Software testing at the hospital needs to be completed to make sure the data is complete and accurate. Aurora Medical Center proposes delaying this provision for at least six months to allow for a smooth implementation.

Value Based Purchasing

Aurora Medical Center is opposed to CMS's recommendation to not pay additional payments for infections acquired while the patient is in the hospital. Hospitals, most of the time, have no control over what patient complications arise when they are in the hospital. Many visitors who may come to the hospital have drug resistant staph infections, and not even realize it. This can be passed along to the patient quite easily.

Hospital's infection control departments have measures in place to prevent infections as much as they can. However, they cannot possibly control all of the infections all of the time. Hospital's still need to be paid adequately for taking care of the patient, especially the complex hard to treat patient with acquired infections.

FTE Resident Count and Documentation

Aurora Medical Center remains opposed to CMS's interpretation of Public Law 105-33 requiring only patient care time spent be allowed in the FTE count calculation when the Intern or Resident is training outside of the Hospital.

Interns and Residents, in order to obtain proper training must spend significant non-patient care time out of the hospital. Time spent at external seminars, reviewing clinic patient charts, researching patient symptoms for related diseases, virtual learning (practice suturing etc.) and documentation coordination with the physician in their clinic, are just a few of very important functions the Intern or Resident spends doing activities outside of the hospital. These are very essential roles for the education of future

Physicians. Residents are bound to train for a maximum of 80 hours per week, so wherever the resident may have down time, they spend their time on these non-direct patient care functions. Without these functions, the training programs cannot exist.

CMS has made a commitment to fund Graduate Medical Education programs. Without adequate funding by CMS for these programs, many programs will not be able to survive and forced to shut down.

Aurora Medical Center would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call Steve Kowske at 414-647-3429.

Sincerely,



Robin Pedersen
Vice President Finance
Aurora Health Care

Submitter : Dr. David Kramer
Organization : CT Neck and back Specialists, LLC
Category : Health Care Provider/Association

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter RE: X STOP IPD

CMS-1488-P-817-Attach-1.DOC

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David L. Kramer, M.D.
David A. Bomback, M.D.
Jennifer Madonia-Barr, PA-C

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June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP Interspinous Decompression System
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I believe that the X STOP Interspinous Decompression System (X STOP IPD) should be available to Medicare patients that have no surgical alternatives. In the past year, I have implanted the X STOP in four elderly comorbid patients (aged 67 to 82 years), and three-quarters have experienced significant improvement in physical function and reduce symptoms. Post-operative x-rays show significant improvement in motion, lateral bending, and axial rotation.

About 80 percent of my lumbar stenosis patients are Medicare beneficiaries. All too often, these patients have comorbidities that prevent me from recommending a laminectomy. Also, the patients with scoliosis, which represents a significant portion of my caseload, have no surgical options. I would estimate that about half of my non-surgical candidates might be candidates for X STOP IPD.

Clinically, I have seen some startlingly good results. Patients who could walk only 100 feet pre-operatively can now walk two miles. Patients who were in wheelchairs pre-operatively are now ambulatory. Two patients have doubled or tripled the distance they can walk. Pain scores have dropped from an average of 9 (with 10 being the most intense) to about 2-3. I have been amazed that patients are mobile the day after surgery, most of my laminectomy patients often require short term rehabilitation for gait assistance.

I urge Medicare to pay for the X STOP IPD procedure, as I think it should be offered as first line treatment for LLS patients who cannot benefit from a laminectomy.

Sincerely,

David L. Kramer, M.D.

David L Kramer, M.D.
Connecticut Neck and Back Specialists, LLC

Submitter : curtis gingrich
Organization : curtis gingrich
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician involved in training family medicine residents, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Curtis L. Gingrich

Submitter : Dr. Chris Murphy
Organization : St Clares Family Practice Residency
Category : Health Care Provider/Association

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

I would comment in a negative way on this proposed change. The parceling out of "didactic" versus "patient care" time is artificial and non-realistic. Residents spend time in didactic sessions centering on patient care issues! As a family practice physician it seems odd to try to parse this out. As residents we were all over the hospital constantly seeing patients, discussing issues, grab lunch with a lecture and back to the wards. We learned by seeing, doing and reflecting on the experience in discussion that went from the specific to the general or the reverse. Education IS patient care. The preparation is continuous and contiguous. I support the Agency's 1999 position as much more realistic. Thank you.

Submitter : Mr. Edward Coyle
Organization : Mercy Health System
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-820-Attach-1.DOC



June 6, 2006

The Honorable Mark B. McClellan, MD
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1470-P; P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS-1488-P – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule (71 Federal Register 23996), and CMS-1488-P2 – Occupational Mix Adjustment to the Wage Index

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for changes to the hospital inpatient prospective payment system, published April 25, 2006 in the Federal Register. I am the Director of Revenue and Reimbursement for Mercy Health System.

Section II.C.2. HSRV Weights:

We join with the American Hospital Association (AHA) in stating that the hospital field supports meaningful improvement to Medicare's inpatient PPS system. However, the proposed changes to the DRG weights represent a significant change that we feel requires more time for analysis and feedback from the provider community. AHA has stated on conference calls to members that they have identified several CMS data errors in calculating the Hospital Specific Relative Value cost center (HSRVcc) weights. Some of these errors originate in the way that CMS attempted to short-cut the MedPAC calculation method that was the basis for HSRV. Examples of these data errors include: the national cost-to-charge ratio (CCR) used a hospital average vs. a charge average, giving the smaller hospitals the same weight as the larger volume hospitals; CMS trimmed about 200 hospitals from the data population based on large Routine CCRs, which hospitals accounted for 25% of the national charges for Routine. What other issues remain unidentified or unresolved? We join with the AHA in asking CMS for a one-year postponement of implementation of HSRVcc DRG weights, to be implemented jointly with the proposed Consolidated Severity-Adjusted DRG system, as described and commented below. In the proposed rule, CMS understands that there are still further changes to make before the Consolidated Severity-Adjusted DRG system is ready to be adopted, and we suggest that CMS recognize the same is true of HSRVcc DRG weights.

Another comment related to the HSRVcc weights is related to the large percentage change to the cardiac DRGs, several ranging from (25%) to (35%) decreases in the weight. CMS is communicating a large disincentive to providers of life-saving cardiac services with these significant changes in the cardiac DRG weights. The high cost of related supplies such as drug-



cluding stents and defibrillators combined with the decrease in payment may lead some hospitals to eliminate their cardiac programs, impacting their community's access to these vital services.

Section II.C.3. DRGs - Severity of Illness:

AHA and other internal impact analysis show large swings in Medicare payment with the implementation of HSRVcc in 2007 and then an opposite impact with the implementation of Consolidated Severity-Adjusted DRGs (CSA DRGs) in 2008. As hospital margins are already subject to numerous internal and external pressures, they cannot afford the highly volatile impacts of the two-phase implementation of HSRVcc and CSA DRGs. CMS laid out in the proposed rule several alternatives for the implementation of these programs (section II.C.6.), where they discussed pros and cons of each alternative. CMS made the point that to implement the CSA DRGs in 2007 would not be fair to hospitals, as it "...would represent a major change to how hospitals are paid for Medicare inpatient services... it would be appropriate to provide hospitals with additional time to plan for these changes...[whether] the additional 60-day delay between the publication of the final rule and implementation on October 1, 2006, to fully understand and plan for the changes." CMS has not yet released a grouper for CSA DRGs to the public, short of allowing for individual claim calculations through 3M's website during this comment period. These are reasons for CMS to postpone HSRVcc and to continue developing CSA DRGs, with the goal of dual implementation in 2008 or 2009, with more interaction with AHA and the provider community in the development process. I ask that CMS recognize these reasons for delay and resist current pressures from MedPAC and Capital Hill to implement both methodologies in FY 2007.

Section IV.A.2. Hospital Quality Data:

According to the proposed rule, the hospitals will be required to submit data on the expanded quality measures to the QIO clinical warehouse for discharges in the first quarter 2006 by the August 15, 2006 deadline. This final rule is not scheduled to be published until on or about August 1, 2006. It is not reasonable to require hospitals to report on an expanded population of quality measures on a retroactive basis, especially within two-weeks of the publication of the final rule that requires such reporting. Any changes in the quality reporting should be done on a prospective basis. Since the level of the IPPS standardized amount increase for a given hospital is based on the consistent, timely reporting of quality data, to require retroactive reporting of data in a short time frame is not reasonable.

CMS-1488-P2 Section I.D. Implementation of Proposed FY 2007 Occupational Mix

Adjustment:

CMS indicates that due to the short time-line for implementing the Occupational Mix by October 1, 2006, per court order, that they will be unable to include the wage index tables and related impacts in the final rule, as well as weights and factors used to calculate the IPPS payment rates. CMS states that these figures will be available on their website at some point prior to October 1, 2006. This conflicts with the requirements of both the Administrative Procedures Act §553 and the Social Security Act §1886(d)(6). The SSA §1886(d)(6) requires publication in the Federal Register, not the CMS website, "...on or before August 1 before each fiscal year...a description of the methodology and data used in computing the adjusted DRG prospective payment rates...."



The wage index and weights constitute “data used in computing the adjusted DRG prospective payment rates,” and therefore must be included in the final rule, even though CMS stated in the proposed rule that they “believe these procedures would comply with §1886(d)(6) of the Act.” The APA §553(d) states “the required publication or service of a substantive rule shall be made not less than 30 days before its effective date...”, the required publication of which should be in the Federal Register per APA §553(b). This would require CMS to publish the tables that do not appear in the August 1st final rule in the Federal Register no later than September 1, 2006, not just on the CMS website “...in advance of October 1, 2006.”

Thank you for your review and consideration of these comments. If you have any questions, please feel free to call me at (610) 567-5563.

Very Truly Yours,

Edward J. Coyle
Director, Revenue & Reimbursement

Submitter : Dr. MINH LE
 Organization : Family Health Center of Worcester
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

As a family medicine residency faculty member, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In addition, I cannot conceive of how a residency program would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. The documentation requirements that this would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Submitter : Dr. Andreas Cahrssen

Date: 06/09/2006

Organization : AFMRD

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Andreas Cahrssen, MD
Program Director Family Medicine
Beth Israel Medical Center

Submitter : Mr. Alan Holmes
Organization : Frio Regional Hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

**Cost-Based Weights: Outlier
Threshold**

Cost-Based Weights: Outlier Threshold

I have been in hospital administration since Medicare started in 1964 and I have seen a lot of program changes that were implimented before Medicare was actually prepare on their end (such things as software, people training, handling claims and unintended consequences). It appears to me that the proposed change in DRGs (including weights and severity) is a massive undertaking and an October 2006 (four months)startup is shaping up to be the same sort of fiasco for both CMS and hospitals. I urge you to accept the AHA recommendations to delay implimentation until you have the infrastrucure in place to avoid the customary confusion (like part D and now MA and fee for service plans)and give hospitals a chance to absorb the change.

Submitter : Mr. Bill Ryan
Organization : Albert Einstein Healthcare Network
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

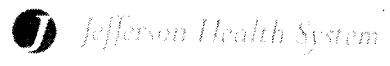
GENERAL

GENERAL

See Attachment

CMS-1488-P-824-Attach-1.DOC

Albert Einstein Healthcare Network



June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

**Re: Medicare Program; Proposed Changes to the Hospital Inpatient
Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule**

Dear Dr. McClellan:

On behalf of the Albert Einstein Healthcare Network (AEHN), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*.

Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our health system, we are writing to urge a one-year delay in implementing these policy proposals. CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

AEHN supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG

system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow AEHN and other hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

Lastly, AEHN supports the expansion of reporting quality data, recommends that CMS begin with third quarter 2006 discharges. AEHN also recommends that CMS not include measures in the validation mix for annual payment until after one full year of reporting. We believe a one-year delay will provide hospitals with the opportunity to learn from the review of records and feedback about data abstraction.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Sincerely,

Bill Ryan
Director, Government Grants & Contracts
Albert Einstein Healthcare Network

Albert Einstein
Healthcare Network

Acute Care
Medical Center

Institute of Behavioral
Health

Department of
Community Health
Services

Medical Group

Wilmington

Wilmington, DE

Submitter : Dr. Shirley Kring
Organization : Dr. Shirley Kring
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Shirley R. Kring, M.D., FAACP

Submitter :

Date: 06/09/2006

Organization : ASITN

Category : Health Care Professional or Association

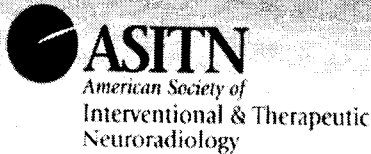
Issue Areas/Comments

GENERAL

GENERAL

Comment on the creation of new ICD-9-CM procedure code, 39.74 Endovascular removal of obstructions from head and neck vessel(s), and it being assigning to DRGs 001, 002,003, 543, 442, 443, 486. Please see the attached word document for our comment letter supporting these assignments.

CMS-1488-P-826-Attach-1.PDF



June 9, 2006

Mark McClellan, MD, PhD
 Administrator
 Centers for Medicare and Medicaid Services
 Room 445-G
 Hubert H. Humphrey Building
 200 Independence Avenue, SW
 Washington, DC 20201

Attn: CMS-1488-P

Dear Dr. McClellan:

On behalf of the American Society of Interventional & Therapeutic Neuroradiology (ASITN), I would like to commend the Centers for Medicare and Medicaid Services (CMS) for the creation of new ICD-9-CM procedure code, 39.74 Endovascular removal of obstructions from head and neck vessel(s), and for assigning this new code to the following DRGs:

- DRG 001 – Craniotomy, Age Greater than 17 with CC
- DRG 002 – Craniotomy, Age Greater than 17 without CC
- DRG 003 – Craniotomy, Age 0-17
- DRG 543 – Craniotomy with Implantation of Chemotherapeutic agent or Acute complex Central Nervous System Principle Diagnosis
- DRG 442 – Other O.R. Procedures for Injuries with CC
- DRG 443 – Other O.R. Procedures for Injuries without CC
- DRG 486 – Other O.R. Procedures for Multiple Significant Trauma

CMS' action in creating this new procedure code and assigning it to clinical coherent DRGs will help to ensure access to clinically appropriate surgical interventions for the 700,000 individuals in the United States who suffer a stroke each year, of which 88 percent are ischemic in nature.

The ASITN recommends that CMS move forward with these DRG assignments for ICD-9-CM procedure code 39.74 in the Inpatient Prospective Payment System Final Rule for FY 2007.

Background

Ischemic stroke patients who are treated with endovascular thrombectomy are typically more ill than the average stroke patient, judging by their higher baseline NIH Stroke Scale (NIHSS) scores. Specifically, patients treated with endovascular thrombectomy typically have NIHSS scores of 8 or greater, with a median score in the MERCI trial of 19, representing a moderate-to-severe stroke. Patients treated with IV tPA typically have a "measurable deficit." The median NIHSS score in the NINDS trial was 14, which represents a significantly less severe stroke population than treated in the MERCI trial. Also, for patients treated with endovascular

thrombectomy the usual time from stroke onset is already past 3 hours or there are other compromising clinical factors such as recent surgery, long-term current use of anticoagulants, or the patient has already failed intravenous tPA therapy.

Patients treated with endovascular thrombectomy experience additional CT, MR, and MRA imaging studies, approximately 2 hours of operating room time, an additional CT angiogram, and an average length of stay that is two days longer than an ischemic stroke patient treated with IV tPA. This level of service intensity is clinically similar to other endovascular procedure codes assigned to DRGs 543 and 001.

An analysis of the 2004 MedPAR data that we presented at a meeting with CMS staff of February 22, 2006 also demonstrated that the standardized charges and average length of stay for ischemic stroke patients treated with endovascular thrombectomy was similar to the overall standardized charges and average length of stay for DRGs 543 and 001.

2004 MedPAR Analysis – Endovascular Thrombectomy Patients

	Standardized Charges (Mean)	Length of Stay (Mean)	Total Payment (Mean)
Endovascular Thrombectomy Cases	\$54,960	9.4	\$21,405
DRG 001	\$54,545	10.3	\$23,213
DRG 543 (using 2004 amounts)	\$66,543	12.0	\$23,296

In closing, the ASITN has enjoyed the opportunity to work with CMS in creating ICD-9-CM procedure code, 39.74 Endovascular removal of obstructions from head and neck vessel(s), and in providing data and information regarding assigning this new code to the appropriate DRGs. Please feel free to contact Marie Williams, ASITN Executive Director, at 703-691-2272, if you have any questions or if there are areas where the ASITN can be of assistance.

Sincerely,

John D Barr, MD

John D. Barr, MD
President

Submitter :

Date: 06/09/2006

Organization :

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

I believe that only using 3 quarters of data for the validation study is not statistically significant. That involves 15 charts with approx. 220 data points. We have consistently had validation scores in the 90's except for one quarter that we scored a 49%. It involved 2 charts, one not recieved on time (late by 2 hours) and one pneumonia patient that we answered the first question incorrectly as pneumonia dx present on admission. With CMS proposing to only use three quarters, our combination score is 78.2%. If you were to use 4 quarters of data, that would be a fairer picture of an organization's overall validation of the Core measures. Please consider this as you make your final recommendations. Thank you for your consideration.

Submitter : Dr. Malcolm Gourlie
Organization : E Haddam Medical Associates, P.C.
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

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unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Malcolm Gourlie, MD

Submitter : Mr. James Cooper
Organization : Medcenter One
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1488-P-829-Attach-1.DOC



Medcenter One
medcenterone.com

June 12, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule (CMS-1488-P and P2)

Dear Dr. McClellan:

Medcenter One appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS).

The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the 508 hospital wage index, quality reporting requirements and payments for medical education, among other policies.

Specific concerns related to change from DRGs

The most serious concerns about the proposed changes are in relation to the DRG weights and classifications. Medcenter One supports meaningful improvements to Medicare's inpatient PPS. We believe Medcenter One and CMS share a common goal in 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. Analysis by the American Hospital Association shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. The validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is also uncertain. Medcenter One is concerned about moving forward with HSRVcc without addressing stability and validity concerns.

Specifically, Medcenter One supports the following related to changes related to DRGs and DRG weights:

- **One-year delay and implementation to a new classification system only if the need can be demonstrated:** A one-year delay would allow the American Hospital Association (AHA) and others to work with CMS over the next year to address the serious concerns that have been raised about changing from the DRG system to that proposed by CMS.
- **Valid cost-based weights:** Medcenter One supports moving to a DRG-weighting methodology based on hospital costs rather than charges. We are however, extremely concerned about movement to CMS' proposed HSRVcc method. Since the release of the proposed rule, the method has come under incredible scrutiny by the American Hospital Association who "believes CMS' proposed method (HSRVcc) is flawed." It may be true that some hospitals have a lower cost-based weight for some of the cardiac procedures where the most significant decrease in reimbursement is directed, but in reviewing the Medcenter One cost report and hospital records for individual patients; this is not the case in our institution.
- **Simultaneous adoption of any changes to weights and classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
- **Three-year transition:** Given the magnitude of payment redistribution across DRGs and hospitals, it would be appropriate to transition to the new system over a three year time span. It will be necessary for hospitals that will experience major cuts to implement changes in the provision of care to adjust to these financial hits. In the case of Medcenter One, we are estimating that the change will have a negative impact of \$1.4 M or approximately 5.2%. Since our in patient hospital payor mix is 55 percent Medicare, this hit is felt more deeply.
- **Collaborative approach to moving forward:** Medcenter One is committed to working with CMS directly or through the member organizations to develop and evaluate alternatives for new weights and classifications.

Comments concerning other issues within the proposed rule

APPROPRIATE PATIENT CLASSIFICATION SYSTEMS

CMS also proposes moving to an entirely new patient classification system beginning in FY 2008 *or earlier*. Currently, Medicare uses 526 DRGs to classify all Medicare patients. CMS considered use of 3M's all-patient refined DRGs (APR-DRGs) as an alternative to its current DRGs, which would increase the number of categories to 1,258. However, CMS ultimately proposed refining the APR-DRG system by consolidating APR-DRGs into fewer categories. This would result in a new DRG system with 861 consolidated severity-adjusted DRGs, or CS-DRGs.

Medcenter One believes that the need for and best approach to moving to APR-DRGs has not been concretely and objectively demonstrated. Changing to the proposed APR-DRG system is anticipated to be costly and limit full disclosure and transparency of the system's case mix grouping and severity adjustment rules. More careful analysis is needed to justify the need to move to APR-DRGs as a new patient classification system.

We believe that CMS should continue with plans to implement ICD-10 which will more appropriately reflect a patient's condition and the services provided to treat that condition. Additionally, CMS' ability to implement add-on payments for new services and technologies in the near future will continue to be limited with the use of the ICD-9-CM classification system.

HOSPITAL QUALITY DATA

The proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. **CMS should make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant patient data for all 21 measures along with information on two new measures related to surgical infection prevention beginning on or after July 1.**

We strongly urge CMS to select measures only from those used by the HQA for public reporting. CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year. This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

HOSPITAL REDESIGNATIONS AND CLASSIFICATIONS

Section 508 of the *Medicare Modernization Act* (MMA) provided \$900 million over three years for a one-time geographic reclassification opportunity, which expires March 31, 2007. Medcenter One is reclassified under Section 508 of MMA. Because the 508 reclassifications expire mid-year and hospitals may not receive Section 508 funding at the same time as any other form of reclassification, CMS has proposed special provisions for accepting or denying partial-year reclassifications for FY 2007.

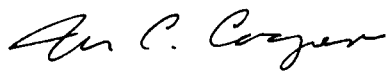
Section 508 hospitals, and those involved in a group reclassification with a Section 508 hospital, would normally have been required to accept or reject reclassification within 45 days of the publication of the proposed rule; however, the complications with the occupational mix adjustment will prevent this. **We appreciate and support CMS' flexibility around the expiration of Section 508 and the reclassification deadlines given the unusual circumstances this year.**

GRADUATE MEDICAL EDUCATION (GME) PAYMENTS

Medcenter One urges CMS to withdraw this change in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Medcenter One appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me or Janelle Johnson, director of public policy, at (701) 323-8745 or jkjohnson@mohs.org.

Sincerely,



James Cooper
President/CEO
Medcenter One
300 North Seventh Street
Bismarck, N.D. 58501
Phone (701) 323-6104
Fax (701) 323-5221

Cc: U.S. Senator Kent Conrad
U.S. Senator Byron Dorgan
U.S. Congressman Earl Pomeroy
Arnold Thomas, North Dakota Healthcare Association
Susan Bosak, Health Policy Consortium

Submitter : Mrs. Katherine Dendy, RN BSN
Organization : Ward Memorial Hospital
Category : Critical Access Hospital

Date: 06/09/2006

Issue Areas/Comments

CAHs

CAHs

We are anxiously awaiting changes that will effect us in the CAH hospital. No one has been able to give us any idea of things that will be required of the CAH hospital not already in place. Please realize that it takes us time to implement new requirements. We are all understaffed for the most part and we at this hospital have many responsibilities to deal with. Making any requirements retro until Jan 2006 will be a major hardship for CAH hospitals.

Hospital Quality Data

Hospital Quality Data

I am the QNET administrator at my small CAH facility. I am very concerned that you would implement a rule requiring the 21 measures retro to Jan 1 2006 affective Aug 1, giving us less than 2 weeks to get the data entered before the deadline for submission on Aug 15. In many cases, the new measures need to be reviewed and taught before the data is easily found on the charts. It will set my percentages back for two quarters. A better plan would be to implement the 21 measures in January 2007. Please consider those of us who have many different responsibilities in a small hospital and need teaching before major changes come into play.

Submitter : Stacey Malakoff
Organization : Hospital for Special Surgery
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

HSRV Weights

HSRV Weights

In concept, we support both Cost Based Weights and the stated goals of the HSRV weights:

" Using costs addresses bias caused by current differential charge mark-ups across cost centers, hospitals, and states.

" HSRVs intend to implicitly adjust for hospital level differences in wage levels, commitment to teaching, and provision of services to underserved populations

In practice, however, the proposal needs significant change to correct new bias introduced by how the proposed methodologies aggregate across hospitals and DRGs:

" Compression of the weights is caused by the HSRV methodology. Although the goal is to address the differences above, the reality is that it only works if there is NO correlation between costs and the factors involved. Since higher cost, difficult patients are appropriately and systematically referred to teaching hospitals located in urban areas that are designed as regional centers to treat these patients, the calculations will systematically under-price those DRGs where these difficult patients group, introducing new bias and perverse incentives.

" All nursing costs per day are assumed to be the same for every patient, regardless of the nursing needs of each patient. This will also provide a perverse incentive to admit only simple patients.

" A single set of RCC values are used across all hospitals. This introduces new bias, unless case mix is randomly distributed across hospitals. Charges should be converted to cost at each hospital prior to any aggregation.

" A single set of cost center weights (% of cost) is used across all hospitals and all DRGs. Table H in the proposal itself shows that this is an invalid assumption. Patient level charges should be converted to cost in each DRG at each hospital prior to any aggregation.

" There are some technical concerns regarding charge mapping between cost reports and MEDPAR designation available at the DRG level.

Due to the major inaccuracies in the proposals, and the significant perverse incentives implementation would introduce, we recommend:

" Delay of implementation until these concerns can be corrected.

" Full evaluation and validation of any methodologies that redistribute multiple millions of dollars of Medicare funds. This analysis should include a specific assessment of whether new bias is introduced while attempting to correct old bias.

Please see attached letter for more details.

CMS-1488-P-831-Attach-1.PDF

HOSPITAL
FOR
**SPECIAL
SURGERY**



June 7, 2006

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

<http://www.cms.hhs.gov/eRulemaking>

Re: File code CMS-1488-P.

**Specialists
in Mobility**

Comments: "HSRV Weights"

- In concept, we support the intended goals of both Cost Based weights and Hospital Specific Relative Values (HSRVs):
 - Cost Based Weights theoretically address the issue of bias caused by generally higher charge mark-ups over cost for ancillary services than for routine services. This practice thereby overvalues ancillary services and undervalues routine services, which in turn overvalues surgical care relative to medical care in DRG weights, since surgical patients use more ancillaries.
 - HSRVs intend to implicitly adjust for hospital level differences in location, wage and fringe levels, commitment to teaching, charges, and provision of disproportionate services to underserved populations when determining relative weights between patients. This reduces the reliance on the accuracy of the explicit adjustments for these factors under the current methodology.

- In practice, the proposal needs significant changes to correct compression of weights and three NEW distortions introduced in attempting to correct current bias. This is due to implicit assumptions in cost conversion using simple versus weighted averages and single sets of national averages across hospitals for RCC factors and across DRGs for cost center mix:
 - **Proposal Assumption 1:** CMS applied the same amount for nursing services to all patients. This implies that the costs of routine nursing services that patients need and receive are the same per day across all patients and all DRGs.
 - For example, nursing cost for a surgical patient just returning from the Operating Room after bi-lateral hip replacement or coronary bypass surgery, or a patient with a tracheostomy or on ventilator support is treated the same as the nursing cost for a patient with simple medical back or chest pain or a patient with laparoscopic cholecystectomy or urinary stones.
 - This assumption introduces a new distortion that understates inherently higher nursing needs for surgical patients and overstates medical care patient nursing costs.

- **Proposal Assumption 2:** CMS applied the same RCC value across all hospitals for a given cost center. This implies that all hospitals have the same mark-up on their charges for a given cost center.
 - A brief review of cost reports for several hospitals will show this assumption to be untrue. In fact, variability in charge mark-ups are a major reason to shift from charge based weights to cost based.
- **Proposal Assumption 3:** CMS applied the same % mix of services by cost center to all DRGs. This implies that the % mix of services by cost center is the same across all DRGs.
 - The proposal itself shows this assumption to be untrue – Table H on page 24020 of the April 25, 2006 Federal Register shows that the % mix of services by cost center is significantly different for Medical and Surgical patients. Medical patients have much higher proportions of routine daily costs and the costs of Lab, X-ray, and Therapy, while surgical patients have much higher proportions of Supplies and Equipment and O.R. The %mix of services by DRG is even more variable.

- **Recommended Solutions**

- **Delay Implementation Until Data and Methodology Concerns Addressed**
 - We understand that there are major charge “mapping” inconsistencies between MEDPAR designations and cost reports for many hospitals - that need to be corrected before moving to cost based DRG weights.
 - Methodologies need to be fully evaluated and validated for accuracy prior to use to re-distribute millions of dollars of Medicare funds. This should include identifying reasons/causes for observed “weight compression” and the following specific methodology recommendations.
- **Adjust for relative daily nursing needs by DRG**
 - CMS has approved Medicaid DRG rates for payment incorporating Nursing Intensity Weights in New York’s State Plan for almost 20 years. These weights could easily be implemented for Medicare to adjust DRG daily costs for relative nursing intensity (i.e. use nursing intensity weighted days to allocate routine costs to DRGs.)
 - Other CMS payment systems currently recognize that patient nursing needs vary widely per day between patients. A significant portion of Skilled Nursing Facility rates are based upon on relative daily nursing needs (which combined with relative rehabilitation needs form the basis for the Resource Utilization Group (RUGS) weights.)
- **The calculation order needs to be reversed (Now=HSRV first then convert to Cost; change to: convert to Cost first, then compute HSRV)**
 - The current proposal does the hospital specific relative value calculation using unadjusted charges first, then converts it to cost using national average assumptions for sets of RCC values and for % relative cost center mix. Reversing the calculation order to convert charges to cost first for each hospital and DRG, and then computing hospital specific relative values accommodates cost center mix and charge mark-up differences across hospitals and across DRGs – without introducing new bias.

Thank you for the opportunity to respond to these proposed Medicare payment policy changes. If you need any clarifications of these comments, please contact Mr. Brian Fullerton of our staff, (212) 774-2926.

Sincerely,

Stacey L. Malakoff
Executive Vice President and Chief Financial Officer

Submitter : Dr. Jennifer Weyler
Organization : Great Brook Valley Health Center
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Jennifer Weyler

Submitter : Dr. Sterling Ransone
Organization : Dr. Sterling Ransone
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Sterling N. Ransone, Jr, MD

Submitter : Dr. William Warning
Organization : Crozer Family Medicine Residency Program
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

William J. Warning II, MD

Submitter : Leslie Champlin
Organization : American Academy of Family Physicians
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a person who has received care from family physician residents, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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Sincerely,
 Leslie Champlin

Submitter : Dr. John McCabe
Organization : University of Minnesota Mankato Family Medicine Re
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,
John McCabe, M.D.

Submitter : Dr. Nitin Budhwar
Organization : Scotland Neck Family Medical Center
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Nitin Budhwar, MD

Submitter : Stacey Malakoff
 Organization : Hospital for Special Surgery
 Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

We support including more precise adjustments for Severity of Illness, which as defined in the proposed regulations represents Co-morbidity Severity. We also support the consolidation of some of these severity categories (usually level 4) to reduce the number of DRGs and increase numbers of patients in each. This is appropriate since the interaction and treatment of multiple co-morbidities is the major resource driver for these cases.

We strongly oppose, however, largely eliminating two other major resource drivers in the proposal that currently are recognized for payment:

- " Treatment complexity that is the major focus of payment for the current DRGs
- " Patient Complications are a major reason why difficult patients are referred to us

The proposed system is therefore less accurate than the current system in aligning payment to patient resource needs one step forward, but two steps back. It creates major new opportunities for crhme skimming AND will impair care quality for at risk Medicare beneficiaries.

The problems noted above, however, have solutions that are described in more detail in the attached letter and case study Evaluating the Proposed Consolidated Severity Adjusted DRGs for FY2008 Examples from Hip and Knee Joint Replacement. In this case study, we illustrate that materiality (based on resources/cost) is the appropriate dimension to assess adjustments for all three major resource drivers.

The solutions more closely align treatment costs and payment. We are not aware of ANY commercially available off the shelf system, including the one proposed, that currently and effectively addresses all three major resource drivers co-morbidity severity, treatment complexity, and patient complications. Current DRGs, the APR/Consolidated DRGs, or others (e.g. AP-DRGs, APS-DRGs) could all be modified to incorporate all three dimensions, however likely with different effort and time frames.

" Co-morbidity Severity of Illness is well addressed by the proposed APR/Consolidated DRGs. However, the process is difficult to understand due to both its multi-step complexity and its proprietary nature.

" Treatment Complexity can be addressed by assuring that base DRGs or other adjustments address all major and typical patient treatment categories. At minimum, the current base DRGs are a starting point for any analysis. Any collapsing of these base DRGs without appropriate adjustment introduces new bias and perverse incentives. If the current base DRG difference is \$ 6,000 per case, a \$1,500 adjustment is NOT sufficient.

" Patient Complications were removed from payment without any consideration of whether they were existing on admission (which most are), were avoidable (which most are not), and if avoidable was it at this facility or another (many difficult complications are transferred to regional centers.) We recommend for now to pay for these complications and perform retrospective review to assess Avoidability as part of Pay for Performance/ Value-Based-Purchasing perhaps at a regional level. We strongly oppose non-payment for the vast majority of these cases because a handful might be avoidable.

See attached letter and case study for more details.

CMS-1488-P-838-Attach-1.PDF

HOSPITAL
FOR
**SPECIAL
SURGERY**



June 7, 2006

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

<http://www.cms.hhs.gov/eRulemaking>

**Specialists
in Mobility**

Re: File code CMS-1488-P.

Comments: "DRGs: Severity of Illness"

- We support including more precise adjustments for "Severity of Illness" (*"the extent of physiologic decompensation or organ system loss of function...usually characterized by multiple serious diseases or illnesses"* – i.e. ***Co-morbidity Severity***) into the DRG payment system. The underlying condition of the patient is one major determinant of relative resources needed to treat the patient that is under-recognized in the current DRGs. The APR-DRGs appear to be a more precise refinement than the current DRGs in recognition of co-morbidity severity.
- We also support the consolidation of some of these (usually Level 4) severity categories as suggested by CMS. It maintains the impact of this resource determinate, while reducing the number of DRGs. By combining cases across base DRGs, where the severity of co-morbid conditions is the more important resource driver, it yields a resulting DRG category with more cases. A similar process has been in use in New York State's All-Payor DRGs for the last 15 years (Major CC DRGs by MDC and type.).

We oppose, however, eliminating two other major determinants of relative resources needed to treat the patient in order to refine Co-morbidity Severity (i.e. complexity and complications.) We are disturbed that the "refinements" to the DRGs, as currently proposed, appear to be "one step forward, and two steps back." **The proposed system is thus less accurate than the current one in aligning payment to the resources needed to treat our patient population.**

We have attached a brief case study illustrating this for hip and knee joint replacement patients: *"Evaluating the Proposed Consolidated Severity Adjusted DRGs for FFY2008 - Examples from Hip and Knee Joint Replacement."* We recommend the additional refinements below which recognize all three major resource drivers (severity, treatment complexity, and complications.)

Implementing these refinements will improve the matching of Medicare payments to meeting the clinical needs of the patient.

- **Complexity** (“*the relative volume and types of diagnostic, therapeutic, and bed services required for treatment of a particular illness*”) is the major focus of payment in the current DRG system.
 - Paying largely the same amount for one patient that needs both knee joints replaced (current DRG 471) and another that only needs one replaced (current DRG 544) because “both have arthritis without major comorbid diagnoses, and are therefore the same severity of illness” makes no sense, and is contrary to the Medicare statute.

- **Complications** (996xx- “*peculiar to certain specified procedures,*” 997xx- “*affecting body systems not elsewhere classified,*” 998xx- “*of procedures not elsewhere classified,*” and 999xx- “*of medical care not elsewhere classified*”)
 - “Complications” add to resources needed to treat the patient. They are currently recognized in the DRGs (91% of diagnoses in this range “count” as complicating conditions (CCs).) Under the proposal, only 14% would “count” for payment recognition. Even for the fraction of patients that would receive some added payment for a higher “severity” level, the amount of the added payment is significantly less than the cost of treating the complication in common DRGs in our facility.

 - The only stated justification for discontinuing Medicare payments for the cost of treating complications is that otherwise, it “*could create the appearance of incentives for less than optimal quality.*” We are unaware of any clinician that would intentionally harm a patient to get higher payment. We are very aware that patients with complications are already more likely to be referred to a regional center such as ourselves for treatment. This new policy of **not paying at all for complications regardless of the facts of the case**, we fear we will now see all or most of these patients referred to us and our regional peers around the country. This policy is contrary to current evidence that shows that complications:
 - 1) *Are usually present on admission (the majority overall, and 2/3 of complications typically seen in our orthopedic population),*
 - 2) *Arose from surgery several years ago (hip and knee joints last for years before they fail – most frequently “wearing out”),*
 - 3) *Relate to surgery done at a different hospital (half of our hip/knee revision patients had their primary surgery done elsewhere), to post-acute follow-up care in a different care setting, or to other care:*
 - *We frequently admit patients with complications acquired in nursing home or rehabilitation settings or while at home.*
 - *Approximately 6-10% of deep orthopedic infections are opportunistic infections due to absent or ineffective antibiotic prophylaxis during prior dental surgery.*
 - 4) *Were unavoidable given the standards of medical practice and technology available at the time (including adjustment for the greater risk of the patient population we treat as a regional referral center for severe and complex patients.)”*

- Eliminating significant recognition of complexity and complications from payment determinations results in several **perverse incentives and creates:**
 - New opportunities to significantly increase seeking or “cherry picking” desired patients and at the same time referring or “dumping” undesired patients to regional referral centers like us – the **exact opposite of the intended refinement.** This occurs since:
 - 1) Most treatment complexity needs are known prior to admission (surgical patients are admitted for a specific procedure.)
 - 2) Most complications are also known upon admission, and in many cases determine the surgical procedure – e.g. revision hip arthroplasty performed for periprosthetic osteolysis.
 - 3) Historical payment differentials to cover added costs for this treatment complexity are also known and significant. The most common “uncomplicated initial” joint replacement cases typically cost \$ 1,000 less per case than the average payment proposed, so are desirable. “Difficult” cases like bi-lateral and infected joints typically cost \$ 5,000 – 10,000 more than proposed payment per case – and place the facility treating them at greater risk for unfavorable Quality Indicators and Pay for Performance adjustments, making them even more highly undesirable.
 - Non-payment for the costs of complexity and complications is a de facto denial of effective coverage for the Medicare Beneficiaries who need these treatments.

- **Recommended Solutions**

The most basic solution requires that any case mix measure refinement should more closely (not less) align with all three major resource/cost drivers (co-morbidity severity, treatment complexity, patient complications.) This will pay fairly for appropriate referral of difficult patients to hospitals with programs designed to care for their needs, and remove or reduce incentives for inappropriate admission selection by others. Explicit analysis of current admission selection and referral patterns should be a significant component of the evaluation of each alternative and refinement. We are not aware of any current “off the shelf” classification system meeting these criteria, therefore we recommend further study of three alternatives:

- **Option 1 - Refine Current Medicare DRGs**
 - Review and update current CC diagnoses and exclusions to more closely reflect differences in co-morbidity severity and complexity, including diagnoses that may differ in cost impact in different major diagnostic categories or when combined with specific procedures. This could involve expansion to 3 or 4 levels (or more) from the current two.
 - Examine base DRG splits, particularly surgical (in conjunction with CC categories above) to expand or collapse where appropriate to match relative resources for these treatments. We have made several suggestions to CMS for such refinements that remain outstanding.

- **Option 2 - Refine APR-DRGs and CSA DRGs**
 - Restore base DRGs removed for major underpaid procedures. This should include specific analysis of current and proposed payment for each, including margin calculations to assess selection incentives.
 - Restore complication diagnoses to the severity assignments based on their impact on relative resources, rather than eliminating them entirely as a matter of policy.
 - To address concerns over *“creating the appearance of incentives for less than optimal quality,”* we recommend studying the feasibility and fairness of reducing payments for avoidable complications (actually avoidable, after refined risk adjustment, and attributable to the provider receiving the reduction), but maintain appropriate payment for all others. This might best be done in the context of a retrospective Pay for Performance adjustment. Additional data (present on admission indicator, some basic clinical data needed for proper risk adjustment like height/weight and smoking status, etc.) may be needed for this. In addition, regional analysis of these issues may be appropriate, since hospital specific analysis is confounded by admission selection and referral issues.
- **Option 3 - Explore Other Classification Systems (AP-DRGs, APS-DRGs, etc.)**
 - Examine extent to which all three major resource drivers are addressed and accommodated in each alternative system.
 - Examine what refinement and implementation costs would be.

Thank you for the opportunity to respond to these proposed Medicare payment policy changes. If you need any clarifications of these comments, please contact Mr. Brian Fullerton of our staff, (212) 774-2926.

Sincerely,

Stacey L. Malakoff
Executive Vice President and Chief Financial Officer

Enc.

Evaluating the Proposed Consolidated Severity Adjusted DRGs for FFY2008 Examples from Hip and Knee Joint Replacement

The Centers for Medicare and Medicaid Services (CMS) has committed to Congress and MEDPAC to modify the hospital payment system to better align costs and payments. This would reduce current incentives for “crème skimming” (seeking out profitable patients) and at the same time, reduce underpayment to hospitals for treating difficult and complex patients (both referred and complicated readmissions). The proposed changes from current Diagnosis Related Group (DRG) definitions in use through FFY2007 to the proposed Consolidated Severity Adjusted DRGs (CSA-DRGs) fix some of the current cost/payment misalignments, but create new ones that must be corrected before they are implemented. Specifically the proposed CSA-DRGs:

- a. + Adjust better for patient severity
- b. - Adjust less for treatment complexity
- c. - Remove current payment differentials for patients with complications

The proposed CSA-DRGs 414-419 for Hip and Knee Joint Replacements are presented below as examples of how the proposed CSA-DRGs will either fix or make current problems worse:

A. The proposed CSA-DRGS adjust better for patient co-morbidity severity

INITIAL JOINT REPLACEMENTS WITHOUT CO-MORBIDITIES

About 40% of these hip and knee patients are straight forward clinically – initial joint replacement with no complicating or co-morbid conditions to make care more difficult. They currently have payment levels set about \$ 1,000 over their cost (national average – will differ by locality.) The proposed adjustments would modify payments for these cases so that the margin is less than \$200 per case (Table 1.) This will alleviate of the problem of overpaying hospitals that in the past have consciously sought out patients who did not have co-morbid or complicating conditions or require complex treatment.

Table 1 – Initial Joint Replacements without Co-morbidities or Complications

Joint	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
Hip	90,677	42%	\$ 9,693	\$ 10,467	\$ 774	\$ 9,815	\$ 122
Knee	106,870	42%	\$ 9,372	\$ 10,467	\$ 1,096	\$ 9,576	\$ 204

INITIAL JOINT REPLACEMENTS WITH MINOR (Level 2) CO-MORBIDITIES

Approximately another 34% of the hip and knee patients are initial joint replacements that have minor co-morbid diagnoses that increase treatment costs slightly, but no complicating conditions. Current DRGs pay both hip and knee patients the same amount; however hip patients cost about \$ 1,000 more than knee patients. Facilities with a typical 45/55 hip/knee mix will break even. Facilities that treat more hip than knee patients are disadvantaged and vice versa. The proposed adjustments split hip and knee patients into their own DRGs, and adjust the severity level for the minor co-morbidities. This improves payments for both hip and knee patients, and narrows the margin gap between them to about \$300 (Table 2.)

Table 2 – Initial Joint Replacements with Only Minor Co-morbidities

Joint	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
Hip	66,873	31%	\$ 11,004	\$ 10,467	\$ (537)	\$ 11,282	\$ 278
Knee	93,359	36%	\$ 10,035	\$ 10,467	\$ 433	\$ 10,616	\$ 582

INITIAL JOINT REPLACEMENTS WITH MAJOR OR MULTIPLE (Level 3 or 4) CO-MORBIDITIES OR COMPLICATIONS FROM PRIOR SURGERY

About 13% of the hip and knee patients are the more difficult patients (e.g. 711.xx Pyogenic arthritis) who are typically referred to a regional center due to having either major or multiple co-morbid diagnoses or complicating conditions associated with prior surgery. Under the current DRGs, referral centers that

admit these patients lose \$ 2,500 – 3,500 on each. The proposal reduces the loss for hip referrals to (\$300), and reverses the loss to about a \$ 600 gain for knee referrals (Table 3.) A hospital with a typical 60/40 mix of these patients would almost break-even.

Table 3 - Initial Joint Replacements w Major or Multiple Co-Morbid or Complicating Conditions

Joint	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
Hip	34,768	16.1%	\$ 13,947	\$ 10,467	\$ (3,480)	\$ 13,652	\$ (295)
Knee	24,230	9.5%	\$ 12,889	\$ 10,467	\$ (2,422)	\$ 13,481	\$ 592

B. The proposed CSA-DRGs adjust less for treatment complexity

REVISIONS

About 9% of the hip and knee patients are more complex because they require a revision to a prior joint replacement. A new DRG was implemented in FFY2006 for these cases. In total, payment rates equalized for hospitals with a typical 55/45 hip/knee mix. However, there is a \$1,200 difference favoring knees in FFY2007. The proposal decreases overall payments for revision patients (averaging \$ 400) by putting the revisions and the initial joint replacements into the same initial hip and knee CSA-DRGs. The severity level of patients undergoing a revision is raised up one level for patients who do not have a significant comorbidity or complicated principal diagnosis – maximum of level 3 for hips but only level 2 for knees. Hip revisions would almost break even, but knee revisions would be underpaid by about \$800 average per case (Table 4.) This reverses the direction of the FFY2007 margin difference – an almost \$ 2,000 swing.

Table 4 – Revisions to Joint Replacements

Joint	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
Hip	21,417	9.9%	\$ 13,218	\$ 12,677	\$ (541)	\$ 13,162	\$ (56)
Knee	19,419	7.6%	\$ 11,998	\$ 12,677	\$ 679	\$ 11,228	\$ (770)

BILATERAL OR MULTIPLE JOINT REPLACEMENTS

About 3% of the hip and knee cases undergo bilateral or multiple joint replacements (two hips, two knees, or one of each – during the same patient stay.) Hospital costs are about 50% higher than for a single joint replacement, largely reflecting longer operating room time and the cost of the additional joint implant. When two joints need replacement, physicians and their patients decide clinically whether to replace both joints in a single stay or “stage” them during two separate stays, usually within 6 months. There is a separate DRG through FFY2007 for bilateral cases; however the FFY2008 proposal puts them into the same CSA-DRGs as the initial and single joint replacements. There is only a partial adjustment for a handful of cases (those having BOTH a hip and knee replaced during the same stay), resulting in an average underpayment of (\$ 5,100) per case. These difficult cases are typically treated in a few regional referral centers, which will be severely underpaid by the proposal. Added splits for Complications (without or with) are also meaningful for these cases (Table 4.)

Table 4 – Bilateral or Multiple Joint Replacements with and without Complications

Bilat/Mult Jnt. Repl	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
*Hip wo	715	0.3%	\$15,632	\$ 15,934	\$ 302	\$ 11,356	\$ (4,276)
*Hip w	652	0.3%	\$ 26,284	\$ 15,934	\$ (10,350)	\$ 12,655	\$ (13,629)
Knee wo	10,105	3.9%	14,879	\$ 15,934	\$ 1,055	\$ 10,465	\$ (4,414)
Knee w	1,776	0.7%	17,750	\$ 15,934	\$ (1,816)	\$ 11,959	\$ (5,791)

**Includes patients with both hip and knee replaced during the same stay.*

C. The proposed CSA-DRGs remove current payment differentials for patients with complications

INFECTED JOINTS WITH DEBRIDEMENT

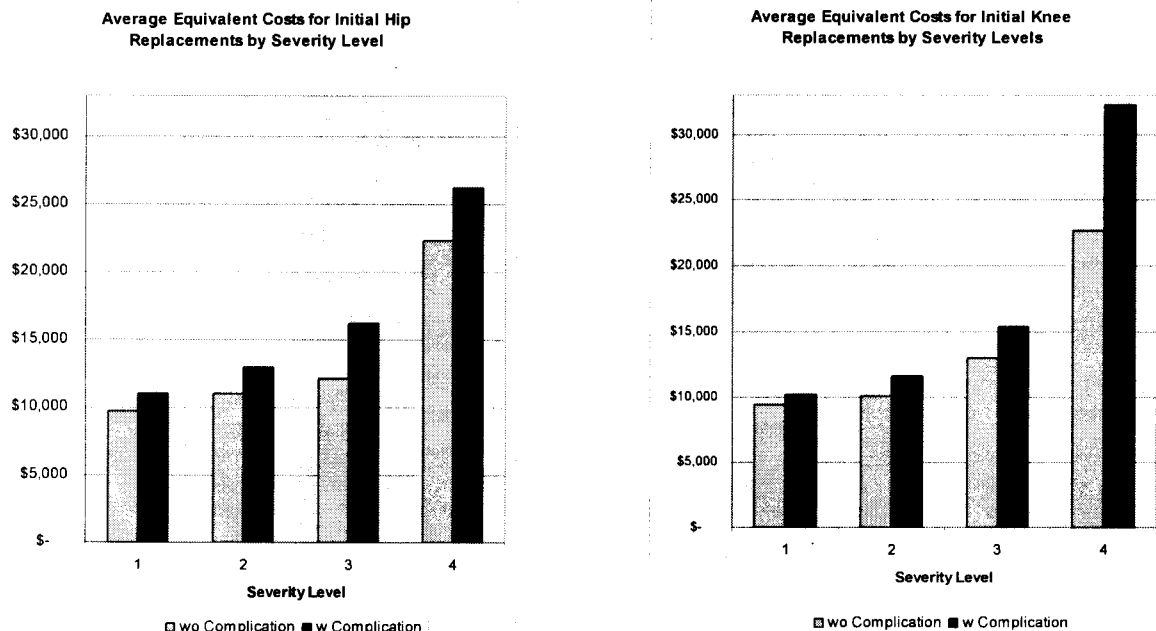
The rest of the cases currently fall into DRG 217 – Debridement. These are some of the most difficult and complex orthopedic patients to treat. Many have deep orthopedic infections not responsive to normal antibiotic treatment. Many have multiple complicating conditions, and on average stay more than twice as long as typical patients. The current DRG 217 is in effect a consolidated “complexity” DRG, consisting of patients who require wound debridement and may or may not have other orthopedic procedures and treatments during the same stay. This is similar conceptually to the level 4 “Severe” CSA-DRGs proposed for co-morbid diagnoses across a Major Diagnostic Category. The proposal eliminates this complexity DRG, and re-assigns patients to other DRGs reflecting their other (not debridement) procedures. The hip and knee patients with wound debridements are underpaid almost (\$ 11,000) each (Table 5), which has a serious disproportionate financial impact on the referral hospitals admitting these difficult cases from other hospitals around the region.

Table 5 – Joint Replacements with Wound Debridements

Joint	Est. Cases	% Cases	Est. Cost	FFY07 Est. Pay	FFY07 Est. Margin	FFY08 Est. Pay	FFY08 Est. Margin
Hip	581	0.3%	\$ 25,156	\$ 24,857	\$ (300)	\$ 14,327	\$ (10,829)
Knee	395	0.2%	\$ 24,355	\$ 24,857	\$ 502	\$ 13,527	\$ (10,828)

INITIAL JOINTS – WITH AND WITHOUT COMPLICATING CONDITIONS

As can be seen in the following charts, patients with complicating conditions have more resource needs (costs) than patients without these conditions for every co-morbidity severity level.



As a consequence, proposed payment rates set at the average at each severity level will introduce a bias to systematically overpay patients without complications and systematically underpay patients with complications. This new systematic bias will result in unnecessary patient referrals to regional centers for complications that could safely be treated locally. This places an unfair burden on these regional referral centers. They must shoulder the costs of this uncompensated care since they cannot deny access. Most of these complications are present on admission, and are therefore “unavoidable” to the admitting hospital.

These charts and (Table 6) below illustrate that facilities can avoid an extra \$ 2,000 in non-reimbursed cost per patient by avoiding admission of difficult patients with complicating conditions.

Table 6 – Cost Difference – Admitting a Patient with and without a Complication (Payment=Same)

	Level 1	Level 2	Level 3	Level 4	Weighted Average
Initial Hip – wo vs. w Complication	\$ 1,328	\$ 2,012	\$ 4,063	\$ 3,852	\$ 2,152
Initial Knee – wo vs. w Complication	\$ 791	\$ 1,571	\$ 2,383	\$ 9,589	\$ 1,809

Specific Hip/Knee Recommendations

- Implement “Base DRGs” for both Bilateral Hip Replacement and Bilateral Knee Replacement.
- Retain current DRG 217 across orthopedic cases to capture “severe complications”.
- Differentiate major complications within initial hips/knees (\$2,000/\$1,500 higher) and bilateral hips/knees (\$8,200/\$1,200 higher), either by splitting each by presence of a major complication or incorporate into determination of “resource intensity levels.”
- These high resource need patients average out with less intensive cases nationally and across a large region, but specific referral centers admit a disproportionate number of these difficult patients. Initial payment is appropriate to provide equity to the hospitals willing to admit the difficult patient and to avoid perverse “crème skimming” incentives.

Apply Concepts above to other Orthopedic DRGs and other Major Diagnostic Categories

- DRG intensity adjustments should occur along the dimension that is the most significant resource driver: procedure, medical diagnosis, complicating conditions, co-morbidities. For example:
 - Level 4 co-morbidities are 100%+ more than average for the specific procedure
 - Complex patients in DRG 217 are 100% more costly than the average joint replacement
 - Complex Bilateral joint costs are 50% higher than single initial joint replacements
 - Complex Revision joint costs are 20% higher than initial joint replacements
 - Severity levels 1-2 and 2-3 are 11-27% apart from each other in terms of average cost
 - Complication levels are 15-20% higher for initial joints, 10-50% for Bilateral, in addition to co-morbidity severity levels

Figure 1 – Hip Replacements by Severity Level

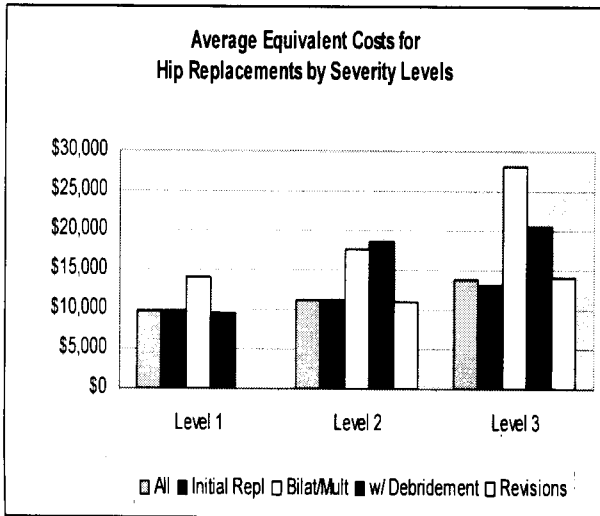
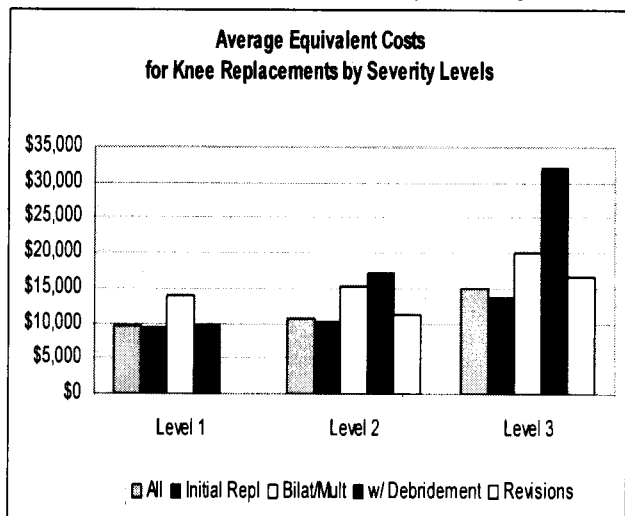


Figure 2 – Knee Replacements by Severity Level



Level 4 cases are not shown here. All level 4 cases collected into a combined CSA-DRG for Level 4 Surgical Orthopedic cases. Levels 1, 2, & 3 each have their own CSA-DRGs. The chart above shows how each joint replacement scenario compares in average cost to the total average for each severity level.

- HOW complexity is integrated into the APR/CSA-DRG structure depends on the degree that the complexity affects relative resources and risk for quality indicators and mortality
 - In the example above and as shown in Figures 1 & 2, revisions increase resources approximately the same amount as each severity level, and also increase relative risk, so incorporating them into the determination of severity level is valid.
 - The impact on relative resources for bilateral or multiple joint replacement patients is significantly higher at all severity levels, and therefore require a new “base DRGs” to accommodate them in the APR-CSA structure
- Current DRGs use **both** complications and co-morbidities to determine resource intensity for payment (cc). **Both** must also be incorporated into any new DRGs for payment equity and to avoid perverse incentives for admission/referral selection.
- Most major complications are present on admission. “Avoidability” of these complications should be reviewed retrospectively as part of Pay for Performance initiatives – both at the hospital level and across a region where many occur.
- “No measure of case mix complexity can be equally effective for all the different aspects of case mix complexity.”¹ The current structure for APR-CSA DRGs incorporates co-morbidity severity but not complications and only some complexity, and may be appropriate for severity adjusting quality indicators and mortality – their primary use over the past few years. New weights for relative resources for payment appear necessary to include complications and complexity without adversely impacting risk adjustment use. DRG hierarchy changes would only be necessary if the materiality requires it (like DRG 217 in the example above.) These could be collapsed back when using for risk adjustment for quality and mortality.
- While constructing this case study, we noted several severity adjustments that had been implemented for Hip replacements that the data indicates should also be applied to Knee replacements (TKA). These include:
 - A severity adjustment for obesity (and all diagnosis codes for BMI \geq 30), the same as done for Hip replacement (APR-DRG “Step 5”)
 - Give knee revisions an add-on severity adjustment up to level 3, the same as is done for hip revisions (APR-DRG “Step 13”).
- In review of the complicated principal diagnoses (APR-DRG “Step 10”) for Hip and Knee replacements, we noted that several other principal diagnoses are predictive of difficult cases and should be included:
 - Pyogenic Arthritis (71105, 71106, 71107)
 - Acute Osteomyelitis (73005, 73006, 73007)
 - Pathological Fractures (73314, 73315, 73316)

¹ Averill RF, et. al. “All Patient Refined Diagnosis Related Groups (APR DRGs) Methodology Overview,” 3M Health Information Systems, Wallingford, CT, March, 2006.

Submitter : Mr. Louis Bremer
Organization : Leesburg Regional Medical Center
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1488-P-839-Attach-1.DOC



Leesburg Regional Medical Center

June 9, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

I recently sent to CMS comments on behalf of Leesburg Regional Medical Center (LRMC) in Leesburg, Florida concerning the proposed changes to the hospital inpatient prospective payment systems and Fiscal Year 2007 rates (letter attached). Since that time, the American Hospital Association has written to you to express their concerns about the proposed changes and FY 2007 Rates.

My purpose in writing to you is to express strong support for the AHA's position. The proposed changes would have a very significant negative impact on the financial condition of LRMC. We have estimated that the impact of the changes is approximately \$6 million. This is due to the fact that approximately 75% of the patients are on Medicare and that many of these patients receive treatment for cardiac disease. LRMC has one of the largest cardiac programs in the State of Florida.

I would ask that you give serious consideration to the AHA's comments and to adopt their recommendations.

Please do not hesitate to contact me if I can provide you with any additional information.

Sincerely,

A handwritten signature in black ink that reads "Louis H. Bremer, Jr." The signature is written in a cursive style.

Louis H. Bremer, Jr., CHE
President & Chief Executive Officer

Attachment – June 1, 2006 letter to CMS



Leesburg Regional Medical Center

June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1488-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on the Hospital-Specific Impacts of Proposed 2007 Hospital Inpatient PPS Rule

Leesburg Regional Medical Center ("LRMC") is a 309-bed acute care not-for-profit hospital that serves a large retirement community in Central Florida. Approximately 75% of LRMC's patients are Medicare, 5% Medicaid and 5% uncompensated care, charity or self-pay. As a not-for-profit organization, we have always been committed to providing the services needed in our community. The proposed changes to the Medicare DRG Case Weights will have a significant negative impact on our ability to serve this large retiree community. We believe that our case may be unique and would invite further review of our situation.

We have evaluated the impact of the proposed changes on our organization that will go into effect on October 1, 2006. The estimated impact from the proposed changes will result in a decrease in annual payments to LRMC of approximately \$6.0 million. It is estimated that LRMC will experience a real net decrease in reimbursement of over \$2 million from our fiscal year 2006 to 2007. This decrease only accounts for nine months of operations since the hospital's fiscal year begins on July 1. The analysis shows that the decrease is primarily driven by the decrease in the cardiac DRG weights. LRMC does approximately one thousand cardiac surgeries and over 3,500 cardiac catheters each year. These large volumes are driven by the fact that LRMC is the only facility in Lake and Sumter counties that provides comprehensive cardiac services. The proposed changes will have a devastating impact and in my experience they appear to be the most devastating that I have seen since the implementation of DRG's.

We understand that the proposed changes reflect recommendations from the Medicare Payment Advisory Commission (MedPAC), and response to some Congressional concerns that the existing system may create incentives for certain hospitals to "cherry-pick" more profitable cases. The reforms will significantly affect payments to specialty hospitals – hospitals that typically are owned, in whole or in significant part, by physicians who serve as referral sources. LRMC is not a specialty hospital and is not owned by physicians and it

is our opinion that the hospital is being unfairly impacted by proposed changes and that this impact is an unintended consequence of the proposed new regulations.

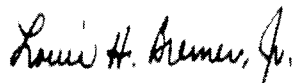
LRMC is located in Lake County which is the 21st fastest growing county in the United States and much of this growth is driven by retirees relocating to Central Florida. LRMC serves the largest retirement community in the United States in The Villages, Florida through our wholly owned The Villages Regional Hospital. LRMC is a guarantor on the recently issued \$75 million in bonds to expand the facility from 60 to 198 beds to support this fast growing retiree community. The proposed DRG weight changes dramatically impact our ability to hit the financial targets committed to six months ago when the bonds were issued to finance the expansion.

I want to reemphasize that LRMC serves and is committed to serving a large Medicare population. However, this commitment is being severely challenged by the proposed changes. It is unreasonable to expect LRMC to continue to support our retiree community's growing health care needs, with even less reimbursement than in the past year. As a result of these proposed cuts, we had to revise our FY 2007 budget and, after many painful decisions, were able to project a marginal operating profit margin of only 1.6%. This margin is simply not adequate to meet the growing needs of this elderly community. Our costs for personnel, supplies, utilities, maintenance and equipment are continually increasing yet we now find that Medicare will pay us less than was paid in the prior year. To further reduce our costs we would have to reduce services to our Medicare population, and we do not believe that this is what MedPAC, Congress or CMS intended to happen.

We respectfully request that you revise the formula to take into account those hospitals which are providing essential cardiac services to large Medicare populations. Many hospitals with smaller Medicare percentages may be able to sustain these changes but for those hospitals with a large volume of cardiac Medicare patients the changes would be a severe drain on the facilities. Should you choose not to revise then formula then we request that you phase in the reductions so that the facilities have an opportunity to adjust the services that we will be able to afford to offer to the community.

Please do not hesitate to contact me if I can provide you with any additional information.

Sincerely,



Louis H. Bremer, Jr., CHE
President & Chief Executive Officer

Submitter :

Date: 06/09/2006

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Dr. Clarice Calopiz
Organization : San Joaquin General Hospital
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Clarice Calopiz, MD

Submitter : Ms. Ellen Kugler
Organization : National Association of Urban Hospitals
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

**Cost-Based Weights: Outlier
Threshold**

Cost-Based Weights: Outlier Threshold

See attached letter

CMS-1488-P-842-Attach-1.DOC

NATIONAL ASSOCIATION OF URBAN HOSPITALS

#842

Private Safety-Net Hospitals Caring for Needy Communities

June 9, 2006

Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1488-P
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Issue Identifier: Cost-Based Weights: Outlier Threshold

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) in response to the invitation of the Centers for Medicare & Medicaid Services (CMS), in the proposed FY 2007 Medicare inpatient prospective payment system rule, to comment on MedPAC's recommendations for changes in Medicare outlier policy.

NAUH objects to MedPAC's proposal to adjust DRG relative weights to account for differences in the prevalence of high-cost outlier cases. The sole purpose of this proposed change appears to be to reduce the relative values within selected DRGs in which outliers are common for the purpose of funding the statutorily mandated pool of funds required to pay those outlier cases. This would have the unfortunate and, we believe, inappropriate effect of requiring only the hospitals that provide the kinds of care that result in outliers to pay for all of that care and absorb all of the financial losses associated with it themselves instead of spreading those costs and those losses among all hospitals.

It is important to keep in mind, in considering this issue, that outlier payments are essentially insurance, or stop-loss protection, for hospitals against the unexpected and potentially enormous costs they may sometimes incur treating just a single medical case, or only a few cases. NAUH recognizes that a more precise, severity-based DRG system should reduce the number of outliers by capturing more of those cases within the new DRGs – and also reduce the problem of hospitals seeking to take only the simplest, lower-cost, most profitable cases – but the remaining outlier cases can prove devastating to the financial health of an institution. The concept of outlier payments is to spread the impact of such cases among all providers and the public sector and not force individual hospitals to bear them alone.

Consider the following example of how MedPAC's approach could undermine this concept. A region has five hospitals, all of which provide some level of care to burn patients but one of which has special expertise in delivering such care. Within the region, the most difficult cases are treated by the hospital that specializes in burn care. Some of the cases that the other four hospitals send to the hospital with the special expertise will end up as outliers, but many will be patients who truly need that specialized care but who do not rise to the level of outliers. Within their specific DRG, these will be the most expensive patients to treat, yet because the relative weights have been reduced to pay for the outlier pool, the hospital that specializes in treating the most complex patients will see its regular reimbursement reduced to pay for outliers. Under the current system, all

five hospitals help absorb the cost of this expensive but essential care; with the proposed changes in the relative weights, the hospital that has invested the most money in this type of care, and has developed the most expertise, would pay for the outliers itself while all of the hospitals would benefit from its willingness to invest in the resources to be the burn center for the entire community. In addition to being unfair, this could discourage more hospitals from developing special expertise in response to clear community needs (even now, relatively few hospitals cultivate such special capabilities because the financial price they pay for doing so is so great) while also encouraging hospitals that have already done so to abandon it because it has become too costly. For these reasons, NAUH opposes adjusting the DRG relative weights to account for differences in the prevalence of high-cost outlier cases.

We appreciate your consideration of NAUH's views and welcome any questions you may have about them.

Sincerely,

Ellen J. Kugler, Esq.

Submitter : Mr. Andrew Wilson
Organization : St. Alexius Medical Center
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Dr. Steven Strongwater
Organization : UConn Health Center John Dempsey Hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-844-Attach-1.DOC

VIA EMAIL & CERTIFIED MAIL

June 8, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Dr. McClellan,

UConn Health Center & John Dempsey Hospital (07-0036) welcome this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Inpatient Proposed Rule for 2007 (the Rule) published on April 12, 2006.

Our letter comments on a number of proposals included within the Rule, but we focus primarily on portions specific to the Diagnosis Related Group (DRG) changes and the discontinuation of Section 508 of the Medicare Modernization Act (MMA) of 2003.

Comment 1 "HSRV Weights"

While the Hospital would support meaningful improvement to Medicare's inpatient PPS (Prospective Payment Systems), the changes proposed within the Rule are the most significant changes to the calculation of DRG relative weights since the inception of PPS. The proposed revisions would significantly redistribute current payments among both DRGs and hospitals without sufficient notice for budgetary impact and planning. Additionally, the methodologies proposed contain data errors & inconsistencies, identified by AHA, that we believe would inaccurately represent resource consumption, acuity and true costs:

- CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.
- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).
- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalars to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalars and included in the MedPAR file used to

- calculate the weights.
- **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for over 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and determine the cost shares.
 - **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:
 - This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.
 - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.
 - The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.
 - The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights.
 - Dependent on the structure of each provider, those having a Centralized Supply department will yield different cost to charge ratios than those providers with separate Cardiac Catheterization Labs and Cardiology Clinics who order, pay and keep in inventory their specific supplies. Medicare Cost Reporting processes do not take into account this operational variability.
 - Scaling the DRG weights to cost based on historical cost report data is inherently flawed because it ignores costs for new technology not present in that historical cost data. Drug Eluting Stents, for example, were not fully represented in the Cost Reporting Year of 2003. New cardiac ablation and devices for arrhythmias were also not fully represented in the Cost Reporting of prior years. Additionally, Providers with varying year ends will be impacted differently as new technology emerges.
 - It appears, after preliminary analyses, that the impact is not stable, with small changes in methods leading to large changes in hospital payment. The CSA DRGs include cardiology service lines that are categorized as both "Medical" (Congestive Heart Failure) and "Surgical" (PTCAs). Medical Centers with a higher prevalence of PTCAs would expect to see a more pronounced reduction in revenue under this methodology, while those Centers with a higher instance of non-invasive Cardiology volumes may see a net increase. Specific to John

Dempsey Hospital, the Cardiology loss would be estimated at approximately \$1,000,000.

- DRG weight changes proposed for 2007 have the opposite impact of the HSRV changes proposed for 2008. Financial impacts would swing wildly from year to year. Implementation would make significant “winners and losers” from different hospitals based upon their patient mix. Since the estimated dollars to be redistributed are expected to equate to approximately \$1.4 to \$1.6 billion, we are asking that the implementation of any system be delayed at least one year for further analysis and transitioned into payment methodologies over a three year phase in period.
- As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:
 - Compare CMS weights to MedPAC’s HSRV-cost approach;
 - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
 - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
 - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state’s Medicaid program);
 - Compare stability of weights over time; and
 - Determine whether payment policy is improved.

Comment 2 “DRG: Severity of Illness”

CMS also proposes to move to an entirely new DRG system beginning in FY 2008 *or sooner*, referencing a new patient classification system called Consolidated Severity Adjusted DRGs (CSA-DRGs). Clearly a new system, which increases the DRG choices from 526 DRGs to 861 severity-adjusted DRGs, requires software and programming changes, education, training and staffing revisions. A revision of this magnitude would need a *defined* timeline of implementation with a transitional payment period of at least three (3) years to allow providers to financially and operationally prepare for such an impact. An issue specific to CSA DRGs is the proposed adjustment for what CMS defines as “Case Mix Creep”, which is based on the idea that improvements in coding and documentation do not prove increased acuity and should not be paid for as such. The basic premise of DRGs is to reimburse for resource consumption based upon the PPS methodology established. It is the Hospital’s position that we have expended the resources, provided the patient services and documented accordingly, therefore any adjustment negating that “work” would be inappropriate. The documentation reflects the resources expended and the acuity of case mix. Proper documentation is both necessary and appropriate and does not produce “Case Mix Creep”. The rise in DRG weight would be corollary to increased costs, not a driver, and should be adequately reimbursed as such.

Also, the arbitrary limit of nine diagnoses and six procedures imposed by CMS serves to further understate the severity of illness in all Academic Medical Centers. Specific to John Dempsey Hospital (JDH), if the current limitation on these fields was relaxed, the projected increase in reimbursement would be approximately \$400,000 for the very same services. To further subdivide the severity subclasses to the cardiovascular DRG's would significantly increase the complexity of coding necessitating more resource consumption and increase the cost of caring patients with cardiovascular disorders.

CS-DRG METHOD CONCERNS

1. **Validation:** It is unclear whether there is a need for a new patient classification system. More work is needed to assess the proposed system and others that might be considered. As with the HSRVcc proposal, CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

CMS must test the degree to which the variation in costs within cases at the DRG level is reduced under both CS-DRGs and APR-DRGs. Payment classifications that still exhibit a high degree of cost variation should be identified and potentially revised. We suggest comparing the distribution of the coefficient of variation at the DRG level for various grouping approaches.

For instance, CMS chooses to collapse the tier-four cases within major diagnostic categories (MDCs). It is unclear whether all of the tier-four cases are clinically cohesive enough to be combined and whether consolidation adequately considers variations in resource requirements. CMS also aggressively collapses the DRGs with low Medicare volume such as obstetrics, psychiatric and substance use services without any discussion of the potential ramifications for other payment systems, such as other Medicare PPSs, Medicaid and the private sector that often bases payment off the Medicare inpatient DRG system. CMS believes that a new patient classification system that distinguishes more-sick from less-sick patients will reduce the "cherry picking" of healthy patients, but there may be other, easier ways to accomplish this. For example, CMS embarked on a new way to differentiate patients last year based on the absence or existence of a major cardiovascular diagnosis but did not discuss the possibility of other similar, less disruptive changes to the system as an option in this year's rule.

Even more fundamentally, today's DRG system was created to distinguish the resource use required among patients. It has been modified over time to reflect changes in clinical practice and technology. The APR-DRG system is based on severity of illness, not necessarily the resource use required. The impact of a move to CS-DRGs – an APR-DRG hybrid – is unclear. But the implications of moving from a resource-based system to a severity-based payment system must be more fully explored and understood.

Comment 3 “DRG Reclassifications “

DRGs: Dual Array Implantable Neurostimulators for Deep Brain Stimulation. We oppose CMS’ recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). CMS should recognize the higher resources associated with this technology.

DRGs: Carotid Artery Stents. We oppose the proposed delay in making any changes to carotid artery stent cases. The higher costs associated with carotid stents should be recognized within the existing DRG system.

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D). We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Atrium) to the DRG logic so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and
- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change would bring the DRGs into alignment with the change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs. We oppose the proposal to delay refining defibrillator DRGs based on MCVs. We believe it is appropriate for CMS to apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs (e.g., defibrillator DRGs) based on the presence or absence of an MCV.

DRGs: Hip and Knee Replacements. For FY 2006, new codes were created to differentiate between new and revised hip and knee replacements. In addition, more specific codes were created to identify the joint components replaced. After publication of the FY 2006 inpatient PPS final rule, a number of commenters advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) included knee and hip procedures that are not bilateral or do not involve multiple major joints. We agree with CMS’ proposal to remove the codes from DRG 471 that do not capture bilateral and multiple joint revisions or replacements.

DRGs: Severe Sepsis. We agree that hospitals have found the coding of systemic inflammatory response syndrome (SIRS), sepsis and severe sepsis confusing in the last few years. The classification of these conditions has changed several times during this

period. We also concur that data have not been consistent and that a new DRG for severe sepsis would be inappropriate. However, we recommend that a change be made so patients with severe sepsis associated with respiratory failure requiring mechanical ventilation may be properly recognized. The ICD-9-CM classification instructions require that these patients be coded with the systemic infection as the principal diagnosis. The infection codes do not group to DRG 475 (Respiratory System Diagnosis with Ventilator Support) despite the use of resource-intensive mechanical ventilation (procedure code 96.7). This results in a significant loss of reimbursement for these patients.

Since the change in coding sequencing of these patients, many advisory boards have discussed this issue several times. In addition, several proposals have been submitted to the ICD-9-CM Coordination and Maintenance Committee to allow the sequencing of respiratory failure as the principal diagnosis. To date, no changes have been made. At this point, reverting the sequencing instructions would be confusing to coders and would once again disrupt trend data.

Instead, we recommend considering mechanical ventilation as a pre-MDC DRG on the basis of the procedure code. If this is not possible, we recommend that CMS add systemic infections (038.xx,) as acceptable principal diagnoses for DRG 475 when reported in conjunction with mechanical ventilation or tracheostomy.

Comment 4 “Hospital Redesignations and Reclassifications”

Section 508 of the MMA provided \$900 million over three years for a one time geographic reclassification opportunity which expires March 31, 2007 for hospitals which met the specific criteria and wage related tests. John Dempsey Hospital is one of approximately 120 hospitals that qualified for reclassification increasing our reimbursement by approximately \$3 million annually. More specifically, the unique circumstances at JDH allowed the Hospital to be assigned their own specific wage index which enables us to recruit and retain the required clinical personnel to meet the specific health care needs of our community.

We believe that the efforts invested now by CMS to revise the existing Prospective Payment System methodology focus on short term solutions and are inconsistent with efforts to develop models that reward excellence, improved quality and safer patient care. A change of this magnitude requires more analysis and input from industry and regulatory resources. It is with this belief that we urge you to reconsider the points raised above and that you delay any further revisions of great magnitude for at least another year's time.

Sincerely,

Steven Strongwater, MD
Associate Dean, Clinical Affairs
Director of Clinical Operations
Hospital Director

Bruce Liang, MD
Chief of Cardiology and Director of
Calhoun Cardiovascular Center

Cc: Senator Christopher Dodd
Representative Nancy Johnson
Senator Joseph Lieberman

Submitter : Dr. Jeannine Rodems
Organization : Dr. Jeannine Rodems
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Jeannine Rodems, MD

Submitter : Mr. John Hicks
Organization : Platte Valley Medical Center
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-846-Attach-1.PDF

June 9, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule. DSH Adjustment

Dear Dr. McClellan:

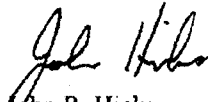
On behalf of Platte Valley Medical Center, a non-profit community disproportionate share hospital, following are comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed changes to the inpatient prospective payment system.

The rule proposes the most significant changes in the Medicare program relative to hospitals since 1983 by re-calculating the basis of payment calculations as well as adopting an entirely new regimen of DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would modify the rates, outlier thresholds, hospital wage indices, quality reporting requirements and other policies. Platte Valley Medical Center acknowledges that some attributes of the Medicare prospective payment system might benefit from some updating modification. That being said, we have serious concerns about the proposed changes. Many of our concerns are explained in the detailed comments submitted by the American Hospital Association, which we endorse without reservation. This letter is meant to serve as a supplement to those comments.

We have heard from many sources and express concern that the modifications to the DRG weights and the DRG scheme may result in significant negative changes in Medicare payment to individual hospitals, even in a budget-neutral overall implementation. More specifically, we are very concerned by the projections regarding DSH hospitals. Those projections indicate that many DSH hospitals, which are the least able to sustain any reductions in payment, are expected to experience cuts in actual reimbursement. While it is laudable that the proposed changes would increase payment substantially for those few hospitals that are over 50% DSH, this should not come at the cost of the many hospitals who make up the larger portion of the safety net. We urge you to consider revisions to the DSH formula so as to prevent material reduction in net Medicare reimbursement to all DSH hospitals.

Platte Valley Medical Center appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me at 303-637-1001 or jhicks@pvmc.org.

Sincerely,



John R. Hicks
President & CEO
Platte Valley Medical Center

*Our Community. Our Health.
Our Future!*

Submitter : Dr. Albert Meyer
Organization : New Hanover Regional Medical Center Residency in F
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Albert A. Meyer, M.D.

Submitter : Mr. Jeff Bourgeois
Organization : Hill Country Memorial Hospital
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Letter from Jeff Bourgeois, Hill Country Memorial Hospital, Fredericksburg, TX.

CMS-1488-P-848-Attach-1.DOC

CMS-1488-P-848-Attach-2.DOC

CMS-1488-P-848-Attach-3.DOC

#848

June 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, Proposed Rule

Dear Dr. McClellan:

I join with other American Hospital Association's (AHA) 4,800 member hospitals, health care systems and other health care organizations, as well as individual members, in thanking you for the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

The rule proposed the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While I, along with AHA, support many of the proposed rule's provisions, I have serious concerns about the proposed changes to the DRG weights and classifications. If the rule were to become effective as presented, the impact to Hill Country Memorial for both new weighting and patient classifications combined (HSRVcc and CS-DRGS) is estimated to be a **reduction of \$390,000 or 3.3 percent in FY 2007**. This is a severe blow to our rural hospital reimbursement.

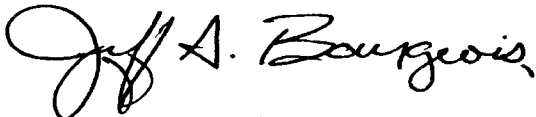
The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe the AHA and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. However, more time is needed to understand the significant proposed policy changes, which redistribute from \$1.4B to \$1.7B within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change.

I join AHA is supporting the following:

- One year delay: The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.
- Valid Cost-based Weights: We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.
- A New Classification System Only if the Need Can Be Demonstrated: The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRG or any other system should be selected or advanced.
- Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
- Three-year Transition: Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.
- Collaborative Approach to Moving Forward: The AHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

I thank you for the opportunity to submit these comments. If you have any questions about my remarks, please feel free to contact me at (830) 997-1314 or via email at jbourgeois@hcmhs.org.

Sincerely,



Jeff A. Bourgeois, FACHE
Chief Executive Officer

Submitter : Ms. Ellen Kugler
Organization : National Association of Urban Hospitals
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

HSRV Weights

HSRV Weights

See attached letter

CMS-1488-P-849-Attach-1.DOC

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

#849

June 9, 2006

Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1488-P
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Issue Identifier: HSRV Weights

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) in response to the Centers for Medicare & Medicaid Services' (CMS) publication of its proposed Medicare inpatient prospective payment system rule for FY 2007. In particular, we are writing to express our concern about the proposed changes in the Hospital-Specific Relative Value Weights (HSRV weights).

Overall, it is difficult to be very specific about our concerns because for the most part, we do not believe we have been provided the information we need to draw fully informed conclusions. Nevertheless, we feel it is appropriate to call your attention to the concerns that we do have based on the information available to us at this time. Those concerns about the HSRV weights are:

1. the lack of transparency of the proposed changes
2. the timing of their proposed implementation
3. the possible unintended consequences of the proposed changes

We address each of these concerns separately below.

Lack of Transparency of the Proposed HSRV Weights

It is very difficult for NAUH to comment authoritatively about the proposed HSRV weights because of the lack of information currently available about them. CMS is usually very generous with information about its proposed regulatory changes, openly sharing formulas, extensive data, and more. This year, however, CMS has not shared enough information for the provider community to understand completely the proposed HSRV weights. We recognize that CMS provided a good deal of information, but it was not enough – although we recognize, from our interaction with CMS officials, that they feel that they have provided sufficient information. We respectfully disagree. Today, the hospital community in the U.S. is struggling to understand this proposal and its many nuances. The typical provider or provider group, without vast resources at its disposal, cannot replicate CMS's methodology and calculations; cannot determine its potential impact on the health care system as a whole or on individual hospitals; and cannot provide useful commentary on whether this proposed change achieves a specific public policy objective. The ability to do all of these things is

absolutely essential because this is one of the biggest changes in the Medicare payment system since the introduction of DRGs more than 20 years ago.

Compounding our concern are problems that we are aware of involving the development of the proposed HSRV weights. We understand that CMS has identified flaws in its own calculations of the HSRV weights that will require recalculation of all of the relative weights. We also understand that even if CMS wished to share more data it could not do so at this time because the new HSRV weights will not be completed and published until August – well after the deadline for comments on the proposed rule and just a few weeks before the rule's implementation is scheduled to begin on October 1, 2006. We do not understand how we can be expected to comment on calculations that have not yet been completed, nor do we understand why CMS is proposing implementation of an as-yet incomplete system. In addition, explanations regarding the rationale behind and use of scaling factors have proven especially unclear.

Consequently, our attempts to analyze the proposed HSRV weights are part science, part speculation – a troubling prospect for an industry that routinely operates on razor-thin margins. Some of our speculation, moreover, suggests that the proposed HSRV weights could be highly redistributive in nature – but it is not entirely clear which institutions would benefit from such redistribution and which would be harmed. It also is very disconcerting to learn that the tentatively calculated HSRV weights included major errors and will require recalculations.

For these reasons, NAUH believes that CMS should delay implementation of the proposed HSRV weights until it is in a position to provide the hospital industry with a clearer explanation of its methodology and the data it needs to replicate that methodology, analyze the proposal's potential impact on individual institutions, and provide truly informed comment to CMS regarding its proposal.

NAUH Objects to the Timing of the Proposed Implementation

NAUH recognizes that an important part of CMS's job is to create and employ a Medicare payment system that pays providers as accurately, precisely, and rationally as possible for the services they deliver to Medicare beneficiaries. We also recognize that there may be better ways to calculate relative weights than the current method. At the same time, however, we believe that the methodology for calculating DRG weights is just one part of a two-part process that must simultaneously involve implementing severity-based DRG weights and a severity-based DRG system. The two absolutely must go hand-in-hand and be implemented concurrently because there clearly is interaction between DRG weights and a severity-based DRG system. Implementing the proposed HSRV weights without changing the classification system at the same time is therefore inappropriate. In particular, applying a case-mix when calculating HSRV weights requires simultaneous implementation of a severity-based system.

We are not alone in this view. Shortly after CMS published its proposed Medicare inpatient prospective payment system rule for FY 2007, MedPAC – which had previously recommended that CMS adopt a severity-based DRG system – wrote to CMS administrator Dr. Mark McClellan to inform him that it, too, believes that the two steps must be implemented at the same time, writing that

... we are concerned that you are proposing to delay the severity changes until FY 2008. It is important to correct for differences in patients' severity concurrently with the corrections for charging distortions.

In a May 30 letter to Dr. McClellan, House Ways and Committee Chairman Bill Thomas expressed much the same view.

MedPAC analysis revealed significant inaccuracy in the current payment system and recommended implementation of both the new severity-refined DRGs and a revised method for the weights at the same time.

Mr. Thomas also wrote that

It is not reasonable to ask that some hospitals experience financial losses from implementing the new weights this year if implementing severity would have offset some or all of those losses. To stagger implementation will cause providers to experience unnecessary payment fluctuations between FY 2007 and FY 2008...

For these reasons, we urge CMS to delay implementing HSRV weights until it can implement a severity-based DRG system at the same time.

The Possibility of Unintended Consequences

As noted, it is difficult to determine the potential impact of the proposed HSRV weights on individual providers. We can, however, draw some general conclusions, and one of those general conclusions is that the proposed changes will result in some redistribution – and in some cases, significant redistribution – of Medicare resources.

In the proposed rule, CMS acknowledges that "... adopting HSRVcc redistributes payments to the more routine intensive medical DRGs." This redistribution appears to be intended to reduce payments for cardiac-related care – and perhaps for other types of care that are sometimes provided by specialty hospitals. NAUH questions whether some of the increases and decreases in other DRGs are appropriate. In particular, we are concerned that some increases may result in a surge of hospitals seeking to provide services that they previously were uninterested in because they were not sufficiently profitable. A much greater problem, we believe, is the possibility that proposed decreases could result in some hospitals choosing not to offer selected services anymore because of reduced payments, thereby jeopardizing access to some kinds of care in some communities.

In the end, the proposed HSRV weights could result in one-time financial windfalls for some hospitals and one-time financial crises for others. These would occur almost serendipitously – that is, without any specific intent by CMS to induce such situations. Many of these one-time swings, moreover, would probably be the exact opposite of what will occur in FY 2008 upon implementation of the new consolidated severity-adjusted DRGs.

This, in turn, leads to yet another concern: the possibility that hospitals that benefit from such one-time windfalls in FY 2007 will attempt to exert great political pressure on Congress to prevent implementation of the consolidated severity-adjusted DRGs in FY 2008 because besides losing their windfall, they might end up in a worse financial position than before either major policy change was implemented. If such political efforts were successful – not a very difficult scenario to imagine – Medicare would be left with a deeply flawed payment system that rewards hospitals that do not deserve rewards, punishes hospitals that do not deserve to be punished, and is, for political reasons, virtually impossible to fix.

For these reasons, NAUH believes that CMS should eliminate the possibility of these unintended, unwanted consequences by delaying implementation of the proposed HSRV weights until it can provide the hospital industry with more specific and accessible information about its calculation methodology and all of the data supporting the calculations and until it can introduce these new HSRV weights at the same time it implements a new severity-based DRG system.

As noted previously, NAUH recognizes that part of CMS's job is to have the best Medicare payment system possible, and we agree that some change in the method of calculating weights and introducing severity-based DRGs can be major steps toward that goal. These two steps, however, must be undertaken simultaneously to have the desired effect. If not implemented at the same time, doing nothing more than introducing HSRV weights will do nothing more than introduce a new, different type of inaccurate payment system – a system that will create winners that no one really intends to reward, create losers that no one really intends to punish, and then transform many of those winners into losers and many of those losers into winners the very next year.

Making this change in separate steps might be understandable if there was a formal mandate to do so, such as a specific directive from Congress or, as is the case with the proposed occupational mix survey, at the behest of a federal court. Currently, however, CMS is under no obligation to move to HSRV weights, and while this may ultimately be a desirable thing to do – although not necessarily essential or required – it is not a desirable thing to do at any time other than when the agency also is implementing a severity-based DRG system.

For these reasons, NAUH urges CMS to delay implementing its HSRV weights for one year and to introduce a change in how it calculates relative weights at the same time that it introduces its proposed consolidated severity-adjusted DRGs. This also will give CMS the additional time it needs to finish its calculations of the HSRV weights; to recalculate those that already have been identified as having errors; to provide more, better, and more accessible information to the provider community; and to enter into FY 2008 with a substantially improved Medicare inpatient payment system that does a better, more accurate job of paying hospitals and is clearly understood by those of us whose job is to care for America's seniors.

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

Submitter : Dr. Andrea Manyon
Organization : SUNY Upstate Medical University
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Andrea Manyon, MD

Submitter : Dr. Carol Grench
Organization : Sutter West Medical Group
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Carol Grench, MD

Submitter :

Date: 06/09/2006

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attached you will find a file that includes comments from The Washington Hospital on proposed changes to the inpatient prospective payment system for your review and consideration. We thank you for this opportunity.

CMS-1488-P-852-Attach-1.DOC

June 9, 2006

Mr. Mark McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1488-P
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Mr. McClellan:

On behalf of The Washington Hospital, we appreciate the opportunity to comment on the proposed rule "**Medicare Program Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates**" as published in the April 25, 2006, *Federal Register*.

The Centers for Medicare & Medicaid Services (CMS) has proposed the most significant changes to the Medicare inpatient prospective payment system since its inception in 1983. The proposed changes redistribute approximately \$1.4 billion within the inpatient payment system.

While the proposed rule has many components, there are four key areas within the rule that will significantly impact Pennsylvania hospitals and health systems:

- ✓ Recalibration of Diagnosis Related Group (DRG) Weights
- ✓ Refinement of DRGs Based on Severity of Illness
- ✓ Wage Index and Occupation Mix Adjustment
- ✓ Hospital Quality of Care

To put our comments in context, more than 50% of Pennsylvania hospitals total reimbursement is derived from the Medicare and Medicaid programs. HAP analysis shows that Pennsylvania hospitals are currently receiving approximately \$0.96 in Medicare as compared to every dollar of cost to provide care. That coupled with Pennsylvania hospitals currently receiving \$0.82 compared to every dollar of cost incurred for Medicaid patients poses significant challenges to providing quality care and services.

In addition, The Washington Hospital has seen rapid growth in Pennsylvania of freestanding ambulatory surgical centers and imaging centers, mostly-physician owned, as well as some growth in limited-service, physician-owned hospitals.

The Washington Hospital commends the Centers for Medicare & Medicaid Services for working toward the refinement of the inpatient prospective payment system to ensure equal opportunity for return across the DRGs, as well as to afford equal incentive to treat all types of patients and conditions. However, The Washington Hospital strongly urges CMS to consider a one-year

delay in implementing refinements to the Medicare inpatient prospective system. **We are specifically recommending a one-year delay in implementing proposed changes to the DRG weights.** While The Washington Hospital supports a move to cost-based weights, we believe there are flaws in the proposed methodology, modeling, and technical data used for refining the DRG payment system. A one-year delay would allow time to enable a more thorough analysis and to address flaws before implementation.

The Washington Hospital also believes that more work must be done to assess the need and most appropriate approach for changing the patient classification system.

In addition to a one-year delay, we would encourage CMS to consider a simultaneous implementation of the DRG weight changes and new classification system (after thoughtful consideration and determination that a new classification system is necessary) over a three-year transition period.

Finally, while The Washington Hospital supports the expansion of reporting of quality data, **the Hospital recommends that CMS begin with third quarter 2006 discharges. We also suggest that CMS not include measures in the validation mix for annual payment until after one full year of reporting.** This delay will allow hospitals to learn from the review of records and feedback about data abstraction during the first year.

Given the regulatory process, The Washington Hospital does not believe that there has been adequate time for Pennsylvania hospitals to thoroughly analyze the proposed changes and assess impact to their individual facilities. Analysis that has been done has shown that even the slightest of changes in the proposed method results in potentially large changes to a hospital payment.

In essence—there is too much change, being proposed too fast. Such changes in the payment system deserve more thoughtful consideration and due diligence to ensure the end result will be the adoption of meaningful improvements to Medicare's inpatient prospective payment system. Our hope is that given the significant impact these proposed changes will have on the hospital field as a whole, that CMS will impose a one-year delay to afford CMS and the hospital field time to work collaboratively to address concerns.

Again, The Washington Hospital appreciates the opportunity to submit these comments and recommendations. If you have any questions regarding our comments, please feel free to contact me at (724) 223.3005 or mroney@washingtonhospital.org.

Sincerely,

Michael J. Roney
Vice President, Finance/CFO

MJR/dlh\CMSCComments\PPS07.doc
cc: Telford W. Thomas, President and CEO
Gary B. Weinstein, Executive Vice President
Alisa R. Rucker, Controller

Submitter : Dr. Robert Saper
Organization : Boston University Department of Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a faculty member of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

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This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Robert B. Saper, M.D., M.P.H.
Assistant Professor & Director of Integrative Medicine
Department of Family Medicine
Boston University Medical Center
One Boston Medical Center Place
Dowling 5 South
Boston, MA 02118-2393

Tel. (617) 414-6276
Fax (617) 414-3345
Email: robert.saper@bmc.org

Submitter : Mr. Carl Herde
Organization : Baptist Healthcare System, Inc.
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-854-Attach-1.DOC

#854

BAPTIST HEALTHCARE SYSTEM

4007 Kresge Way
Louisville, Kentucky 40207
502-896-5000

Electronically Submitted

June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**RE: Provider Comments
Proposed Changes to Inpatient PPS
DRG Reclassifications and Severity of Illness**

On behalf of the five member-hospitals of Baptist Healthcare System, Inc. (BHS), we appreciate the opportunity to comment on the fiscal year (FY) 2007 proposed changes to the hospital inpatient prospective payment system.

BHS supports meaningful improvements to Medicare's inpatient prospective system and shares CMS's desire to develop a payment system that provides an equal financial incentive (margin) to treat all patients, regardless of diagnosis or severity of illness. BHS further acknowledges that this payment system must be statistically robust, clinically meaningful and at the same time, administratively feasible.

BHS submits the following recommendations to the current proposals:

1. The proposed changes to the DRG weights based upon Hospital Specific Relative Value cost center (HSRVcc) and introduction of Consolidated Severity Adjusted DRGs (CS-DRGs) should be implemented simultaneously.
2. The proposed changes to the DRG weights (HSRVcc) and introduction of CS-DRGs should be implemented on or after October 1, 2008.
3. Valid cost-based weights must be developed and utilized.
4. Further refinement of the proposed CS-DRG methodology needs to be done to ensure it promotes (rather than inhibits) the accomplishment of CMS's stated goals.

Discussion and rationale for recommendations:

Recommendation 1: Simultaneous Implementation

- a. The proposed HSRVcc changes in FY2007 are projected to reduce reimbursement to BHS from the current FY2006 amount by nearly \$8.5 million.
- b. The proposed implementation of CS-DRGs in FY2008 is projected to increase reimbursement from the FY2007 amount by nearly \$8.2 million (which represents a reduction of approximately \$300,000 from the current FY2006 amount). This significant volatility in reimbursement has several implications.

First, BHS will **permanently** lose \$8.2 million in reimbursement in FY2007.

Second, BHS will **potentially** receive an increase in reimbursement in FY2008. BHS has utilized the 3M APR-DRG grouper for many years, largely as part of internal quality initiatives and the Premier Hospital Quality Incentive Demonstration. As a result, BHS had the internal APR-DRG data to convert to CS-DRGs and calculate the impact of the FY2008 proposal.

However, the underlying assumptions in the impact analysis are: (1) coding in the future is consistent with current coding practices, and (2) that Medicare will allow current coding in the future reimbursement model. Because these are assumptions and not givens, BHS has significant concerns regarding the ability to accurately forecast the proposals impact beyond FY2007, which is critical.

Third, the increase in reimbursement in FY2008 under the CS-DRG system indicates that BHS hospitals treat more severe patients on average. This finding is consistent with the mission and values of its member hospitals.

BHS is comprised of five hospitals within the state of Kentucky. It operates urban hospitals in Louisville, La Grange and Lexington, rural referral centers in Corbin and Paducah. Collectively, BHS has the largest number of inpatient admissions in Kentucky and is one of the largest providers of Medicaid services within the state.

The primary and secondary markets for BHS hospitals is comprised of 40 of the 120 counties in Kentucky and range across the central, western and southeastern parts of the state. Five of the poorest ten counties are located with the BHS service area.

Medicaid, charity and uninsured patients represent over 17% of BHS inpatient business. As part of BHS's Christ-centered mission, each BHS hospital has not only expanded its general acute care services, but also its highly specialized tertiary programs in an effort to provide a full range of surgical and medical services to all patients regardless of their ability to pay or severity of illness.

Given the mission of BHS and demographics of the communities it serves, it is clear that BHS hospitals are not specialty hospitals that target services that provide higher margins. However, given the high severity of illness for the patient population BHS hospitals serve, unless the HSRVcc and CS-DRG proposals are implemented simultaneously, unfair financial hardship will be experienced.

Fourth, CMS suggests that a budget neutrality factor may be applied to offset improvements in coding practices. This too, represents a significant unknown in the current proposal that needs to be accurately evaluated and communicated for which additional time is necessary.

Recommendation 2: Delay until October 1, 2008

- a. It is imperative that the GROUPER technology be made available to hospitals and vendors. Without direct access to the GROUPER by hospitals, it will be virtually impossible to understand its logic. Without access by multiple vendors, it will be more difficult to purchase at a competitive price and will be more difficult to integrate into existing hospital systems.
- b. In addition, many current hospital software programs will need to be modified to handle the new payment and billing system. An implementation date before October 1, 2008 will not allow adequate time to make all the necessary system changes and upgrades.
- c. CMS stated that one option to the software issue is for hospitals to submit claims without being grouped and allow CMS to assign the CS-DRG. This raises several serious concerns.

First, without the CS-DRG information, revenues and patient receivables cannot be recorded accurately. Statement of Position (SOP)-00-1(6) states, "Health care entities need to estimate amounts that ultimately will be realizable in order for revenues to be fairly stated in accordance with generally accepted accounting principles (GAAP)." Paragraph (9) states "Management is responsible for the fair presentation of its financial statements in conformity with GAAP".

Currently, the DRG assignment is critical in making an accurate estimate of the net realizable value of accounts receivable. Given the significance of and the increased uncertainty of the impact of the proposed changes for FY2007 and FY2008, it will be even more important for patient bills to be grouped prior to billing.

Second, the Medicare inpatient business represents over 41% of BHS total inpatient business. As such, changes to the Medicare payment system have a significant impact on BHS's ability to accurately estimate payments in evaluating strategic initiatives, business plans, budgets, marketing, staffing and other critical decisions. With the significance of the proposed changes, more time is required to understand and perform impact analysis.

- d. Four of five BHS hospitals are disproportionate share hospitals (DSH). Last year these hospitals received approximately \$14.7 million in DSH reimbursement. It is anticipated that the CS-DRGs will have a material impact on DSH payments and in order for hospitals to adequately plan and make appropriate adjustments in a timely manner, BHS recommends that further analysis be prepared and accurate impact estimates published prior to implementation of the proposed changes.
- e. Additional time is required to determine the impact from other third party payers (including Medicaid) that have historically modeled reimbursement rules and methodologies from the Medicare payment system. It is anticipated that these third party payers will adopt the new Medicare payment system at some time in the near future following implementation by Medicare. However, given the complexity of the proposed changes, additional time is necessary for payers and hospitals to better understand these changes and make appropriate systematic changes.

Recommendation 3: Valid Cost Weights

- a. Under the HSRV weight calculation method, the ten cost center categories were developed based on broad accounting definitions, where each cost center category represents at least five percent of the charges in the claims data. BHS acknowledges the need to remove bias introduced by individual hospital characteristics (i.e. unique cost centers reported on the cost report), but it appears that this resulted in incorrect cost center groupings in the CMS study that raises concerns regarding the accuracy of the cost-to-charge ratio (CCR) data.

For example, according to CMS-1488-P, Table-A (pp.66-67 and pp.186-187) the HSRV Cardiology cost center includes cost report lines 53 and 54. However, one BHS hospital includes its Catherization Lab revenues and expenses on cost report line 42.01, which according to the table appears to be incorrectly grouped with the HSRV Radiology cost center that includes cost report lines 41,42 and 43.

BHS is very concerned that grouping errors such as the one described here could materially impact the CCR used to calculate the DRG weights. Therefore, BHS recommends that CMS work through the Medicare intermediaries to audit the cost report line definitions for all hospitals to ensure groupings are accurate.

- b. The weighting calculation used to determine the scaling factors gives equal weight to each hospital regardless of size or volume. This methodology results not only in an inaccurate national cost-to-charge ratio, but is inconsistent with the method used when averaging the ten cost center DRG weights to which the scaling factors are applied. Therefore, BHS recommends that a consistent weighting methodology be utilized to calculate the scaling factors.

- c. HSRVcc costs were based on the 2004 cost reports. Significant changes in medical technologies, products and services have been introduced, which have significantly impacted the CCR. Therefore, BHS recommends that a more recent audited cost report be used, after audit procedures have been performed as recommended in (a.) above.

Recommendation 4: Consolidated Severity-Adjusted DRG Methodology

- a. CS-DRGs are developed by grouping APR DRGs considering average length of stay and average charges. This grouping methodology is inconsistent with the cost-based intention of the proposed changes. Average cost, using the HSRVcc methodology (applying the recommended changes), for each APR DRG by severity level should be the determinant for grouping APR DRGs into CS DRGs.
- b. CMS believes that the adoption of consolidated severity-adjusted DRGs would create a risk of increased aggregate levels of payment, similar to the 2% increase associated with the implementation of the current DRG system in 1983 and has recommended the application of a compensating budget neutrality factor. Because of the significance of even a 2% reduction in reimbursement, BHS recommends that this be further studied before implementation.

Thank you for your consideration of our recommendations. We certainly hope you can see and appreciate the legitimacy of the concerns raised. If you have any questions, please feel free to contact me at (502) 896-5011 or cherde@bhsi.com.

Very truly yours,



Carl G. Herde
Vice President and CFO
Baptist Healthcare System, Inc.

CGH247:ps

Submitter :

Date: 06/09/2006

Organization : Cedars-Sinai Health System

Category : Hospital

Issue Areas/Comments

GME Payments

GME Payments

Cedars-Sinai Health System welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to rescind the purported clarification in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not related to patient care. The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

Furthermore, what is discussed in the didactic session is essential to improving quality patient care and following identified best care practices. Didactics help insure patient care that has been identified by national core measures is carried out to the highest degree.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures...and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral and vital component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs, as well as clinical benefits to their patients.

CMS-1488-P-855-Attach-1.RTF

CMS-1488-P-855-Attach-2.PDF

ATTACHMENT 2 TO # 855



CEDARS-SINAI HEALTH SYSTEM

June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Attention: CMS-1488—P "Resident Time in Patient Activities"

Dear Administrator McClellan:

Cedars-Sinai Health System welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.*" 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care". The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

Furthermore, what is discussed in the didactic session is essential to improving quality patient care and following identified best care practices. Didactics help insure patient care that has been identified by national core measures is carried out to the highest degree.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures...and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral and vital component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs, as well as clinical benefits to their patients.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Priselac', written over a horizontal line.

Thomas M. Priselac
President and CEO

Submitter : Dr. Larry Butcher
Organization : University of Texas HSC-Houston Medical School
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Ms. Joyce Polovich
Organization : Ohio Valley General Hospital
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

The proposed regulations requiring hospitals to provide quality measures on Surgical Infection Prevention (SIP) starting with January 1, 2006 discharges would pose an undue hardship for most institutions not currently collecting this information. Based on current deadlines by CMS, vendors require information to be submitted one quarter before, thus we have already submitted the first quarter data for 2006 and are over 2/3 complete with the second quarter data capture. It would be burdensome to have to go back and reabstract the charts to capture this additional information. This requirement should have a future start date, versus going back to Jan 1, 2006 discharges.

Submitter : Mr. Rick Roberts

Date: 06/09/2006

Organization : Regions Hospital

Category : Hospital

Issue Areas/Comments

**FTE Resident Count and
Documentation**

FTE Resident Count and Documentation

See attached Word document letter

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.

Submitter : Thomas Pulling
Organization : Broadway Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Thomas Pulling

Submitter : Ms. Linda Paxton
Organization : Riverside Medical Center
Category : Nurse

Date: 06/09/2006

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

see attachment

GENERAL

GENERAL

See attachment.

CMS-1488-P-860-Attach-1.DOC

ATTACHMENT TO # 860

June 6, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

**Re: Proposed Changes to the Hospital Inpatient Prospective
Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS -1488-P**

Dear Dr. McClellan:

I appreciate the opportunity to submit comments related to the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective Payment System (IPPS), released on April 12, 2006 and published in the *Federal Register* on April 25, 2006. I appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services. I further recognize the significant complexities associated with gathering reasonably accurate cost data – data that should serve as the foundation of payment systems such as the proposed IPPS.

I am the Director of the Heart Center at Riverside Medical Center in Kankakee, Illinois. I am responsible for the operations of all invasive and non-invasive cardiology testing and would be directly affected by the proposed legislature for the IPPS. Our hospital serves a very rural area in central Illinois and we are constantly striving to move our services to areas where the availability of cardiac services is low. My comments further elaborate how a drastic change in cardiac reimbursement would occur with the proposed changes mentioned above.

The Medical Center owns and operates a general acute care hospital in Kankakee, Illinois, which is licensed for 341 beds, of which 238 beds are currently staffed. In addition to the main hospital facility, the Medical Center operates the Resolve Center in Manteno, Illinois (the "Resolve Center") which houses an 18-bed licensed inpatient substance abuse program and associated outpatient services. The Medical Center also operates Riverside Ambulance Service which provides ambulance service to the Medical Center's primary

service area from four (4) remote locations in Momence, Kankakee, St. Anne and Ashkum. Riverside Ambulance is also responsible for 16 communities through its Emergency Medical Service System.

The Medical Center operates nine community, primary and specialty health centers ("Community Health Centers") located in Kankakee, Bourbonnais, Manteno, Monee, Momence, Hopkins Park (Pembroke Township), Wilmington, Peotone and Manhattan. The clinic sites are Medical Center-owned and aggregate to a total of approximately 75,000 square feet.

Origins of the Proposal

CMS is proposing to make the most significant changes to the hospital inpatient payment system since the late 1980s. The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPAC report when considering policy changes. However, the proposed changes to the inpatient payment system are the equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPAC report should begin and end with the specialty hospital subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Issues with the proposed IPPS

Setting aside the issues associated with specialty hospitals, I observe two major areas of concern with the proposed IPPS.

First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007.

Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

Estimated, Not Actual, Costs

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's

proposed methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs – namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost when attempting to apply derived averages. The following table demonstrates this principle and points out that high-cost technology such as defibrillators and drug-eluting stents would be unfairly accounted for in the proposed reimbursement methodology, causing hospitals to lose substantially with these technologies. This example also highlights why cost reports were never intended to be utilized for the sake of developing accurate procedure specific payment rates.

Impact of Assuming Uniform Mark-up in Costs

	Acquisition Cost	Actual Hospital Mark-Up	Charges After Mark-Up	CMS Derived Average Mark-Up	CMS Estimated Costs Based on Avg Mark-Up	Delta Between CMS to Actual
Dual Chamber ICD	\$ 20,000	200%	\$ 40,000	267%	\$ 14,998	\$ 5,002
Bi-Ventricular ICD	\$ 28,000	200%	\$ 56,000	267%	20,997	\$ 7,003
Drug-Eluting Stent	\$ 2,500	200%	\$ 5,000	267%	\$ 1,875	\$ 625
Other supplies	\$ 8	400%	\$ 32	267%	\$ 12	\$ (4)

Gross Impact on Cardiac Care

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services. These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement.

However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Sincerely,

Linda L Paxton, BSN, MBA
Director, Rush Riverside Heart Center
Riverside Medical Center

Submitter : Dr. GREGORY BALES
Organization : Dr. GREGORY BALES
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

GREGORY S BALES, DO, RPh

Submitter : Dr. Christopher Ewin

Date: 06/09/2006

Organization : One To One MD

Category : Physician

Issue Areas/Comments

GME Payments

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. William Gifford
 Organization : Sparrow Health System
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. This exclusion is not constructive and will be very destructive to the training that residents receive. Training in these settings is required to achieve a rounded education and the ability to be a good physician.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Again I would like to reiterate that this move will be destructive to the educational process of primary care physicians and in turn damaging to the health of the nation over time.

Sincerely,

William P. Gifford MD

Submitter : Mr. William Grigg
Organization : Southcoast Hospitals Group, Inc.
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

Geographic Reclassifications

Geographic Reclassifications

June 9, 2006

Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1488-P
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Issue Identifier: Multi-campus Hospitals

To whom it may concern:

I am writing on behalf of Southcoast Hospitals Group to express our opposition to a change proposed by the Centers for Medicare & Medicaid Services (CMS) governing how multi-campus hospitals report their wages when seeking Medicare wage index reclassification.

Southcoast Hospitals Group is a multi-campus hospital in the unusual position of having campuses in different wage index areas. Current CMS regulations provide that for hospitals in such a situation, all wages for all campuses should be combined when applying for wage index reclassification. Now CMS proposes repealing this rule, and requiring multi-campus hospitals to separate the wages at their individual campuses for reporting purposes. We oppose this proposed change.

Southcoast is truly one hospital. It is the product of a full asset merger of three separate hospitals into one. The merger reduced duplicative administrative and overhead expenses in excess of \$25 million, thereby reducing unnecessary health care costs for Medicare, Medicaid and all other payors. This is as opposed to the process of creating a hospital system that many other organizations pursue, but does nothing to reduced duplicative costs as they each retain their individual entities. Southcoast is one hospital with one Medicare provider number, not three separate, autonomous hospitals. The demands that would be made by the proposed change would truly be burdensome, necessitating additional time and expense to attribute wages and benefits to each individual campuses. In addition, the wage and benefit programs for the three campuses are the same, which therefore negates any potential benefit from identifying the expenses by site.

For these reasons, we request that CMS not change the current rule. Alternatively, we request that the current rule be extended for five more years. This is important because Southcoast will need to apply for Medicare wage index reclassification in two years. Applying for reclassification requires three years worth of data, but if the rule is changed now, the most we could have is two years worth of data, which means we would not even be able to apply for wage index reclassification. Our desire to be reclassified could never even be weighed on its merits because the lack of available data would make it impossible even to apply for reclassification. We believe this is fundamentally unfair and request that CMS not adopt the proposed rule change.

We appreciate the opportunity to submit these comments and welcome any questions you may have about our position on this issue. I can be reached at 508-961-5016.

Sincerely,
William Grigg
Sr VP and CFO
Southcoast Hospitals Group

Submitter : John Tieben
Organization : MAFP
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a Medical student, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 JOh Tieben

Submitter : Mr. Koty Mize
Organization : St. Francis Health Center
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

We are concerned that the 60 days between the final rule and the implementation date of October 1st is not enough time to make the necessary changes to our software systems that are required by the proposed changes.

HSRV Weights

HSRV Weights

We are concerned that the amount of time between the final rule publication and the implementation date of October 1st is not enough time to make the necessary changes to our software systems that are required by these proposed changes.

Submitter :

Date: 06/09/2006

Organization :

Category : Physician

Issue Areas/Comments**GME Payments**

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Mike

Submitter : Dr. Nadine Skinner
Organization : Eastern NC Medical Group
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Nadine Skinner, MD

Submitter : Dr. Janice Daugherty
Organization : Brody School of Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

As a family physician who has taught in a residency program since 1981, I have grave concern about the language in the proposed rule that excludes teaching time which directly relates to patient care, versus and time spent in "patient care activities." Medical resident time spent in didactic activities is central to assuring quality of care for patients durinf "patient care activities." In the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments, both of these are necessary to be counted.

If activities such as journal clubs, classroom lectures and seminars must be excluded when determining the full-time equivalent resident counts, then these activities will largely stop. Due to decreasing reimbursement for care from almost all sources, family physicians especially are under trememdous pressure to increase our time in direct patient care. Teaching of residents and medical students is already suffering, and looks to get worse. Family Physicians in particular are interested in teaching care of the whole patient in the context of his or her family, whatever that may be. One cannot teach comprehensive care effectively and in a structured manner at the bedside or in the examining room exclusively. It takes planned curriculum time to deliver the information and interactions that will allow learners to become excellent.

As you are undoubtedly aware, this position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency_s 1999 position, for the reasons noted above.

Family physicians generally do not engage in "bench research." Our research activities are based in and around the care of patients, so for our trainees there is no residency experience that is not related to patient care activities.

Please rescind the clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs. The health of the populations both now and in the future depend on the ability to pay those of us who love to teach patient care to teach patient care. If we are always seeing patients there will be no time to pass along our knowledge and skills except in anecdotes-- and the people of our country deserve better than that.

Sincerely,

Janice E. Daugherty, MD
 Associate Professor of Family Medicine
 Director of Medical Student Education
 Department of Family Medicine
 The Brody School of Medicine at
 East Carolina University
 Greenville, NC 28934
 252-744-2601

Submitter : Dr. John Gross
Organization : Dr. John Gross
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled b,SMedicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in b,Spatient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physicians office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient careb, .

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Thank you for your consideration,

John Gross, MD

Submitter : Mr. J. Larry Read
Organization : University Health Care System
Category : Health Care Professional or Association

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-871-Attach-1.DOC

ATTACHMENT TO # 871



June 9, 2006

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

Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

University Health Care Systems appreciates the opportunity to comment on the proposed rule regarding Medicare's inpatient hospital payment system. University is a 551 bed, urban, acute care facility located in Augusta, Georgia. University prides itself in being the community's largest provider of care for Medicare beneficiaries in the area (46%), as well, as the largest provider of indigent and charity care for the MSA. University's patient population is comprised of more than 50% Medicare beneficiaries; seeing approximately 10,084 Medicare Inpatient in fiscal year 2005.

We appreciate and support the efforts of the Centers for Medicare and Medicaid Services (CMS) to improve the inpatient hospital prospective payment system (IPPS) so that it will more accurately allocate payment for inpatient operating costs. At the same time, we have a few concerns that we ask CMS to consider as it works toward improvements of IPPS. Specifically, we want to ensure that any changes of this magnitude are done in a measured way so that hospitals such as us have ample opportunity to adapt to the changes at all levels. Moreover, we need to have full and timely access to all aspects of the revised methodology, as we do now, so that we can continue to make knowledgeable decisions about how to operate economically within IPPS. These issues are addressed in more detail below.

DISCUSSION

A. Cost-Base & Severity Adjusted Consolidated DRG changes

For Federal Fiscal Year (FFY) 2007, CMS proposes moving away from the "Charge-based" system to a "Cost-based" system. While University agrees with the philosophy, we believe the weight changes are too dramatic and are not warranted. University has modeled (6 months of FFY 2006) the impact for the 2007 "Cost-Based" change on our operations and the modeling shows our overall Hospital CMI drops by 4% which translates to a 3% reduction in Medicare reimbursement. However, this drop in CMI and reimbursement is caused by our main service line ---Cardiac decline. The Cardiac Service Line's CMI dropped by 13.5% resulting in a 22% decline in reimbursement. While you may note that this was due to the "CMS Correction" of the DRG's weights from "Charge-based" to "Cost-based". University believes the shift is too dramatic for one (1) year and is supported when FFY 2008 Severity Adjusted Consolidated DRG's are modeled using the same data. Using the Proposed FFY 2008 data, University's overall CMI will increase from the FFY 2006 level by 4.6% and the Cardiac Service Line's CMI will only decrease by .6%. Medicare reimbursement has driven to some degree the development of technology and interventions related to treatment and diagnostics in the Cardiac service line. Economics has driven the complicated, high cost, invasive heart surgery to be replaced with less costly, less interventional procedures. We fear that a reduction in the Cardiac service line will have a cooling effect on any future development in the cardiac area. With Cardiac disease being the number one mortality for adults, this dramatic decrease in Medicare's support seems short-sighted.

Based on the above analysis, University agrees with the Medipac recommendations that both factors (1) Cost-based and (2) Severity Adjusted Consolidated DRG changes need to be implemented at the same time. In addition, University recommends a 3 year phase in of the above major revisions to the IPPS.

B. Timeframe for Change

In the proposed rule, CMS says that it is considering revising the IPPS methodology to use All Patient Refined Diagnosis Related Groups (APR-DRGs) as early as the upcoming fiscal year. We do not believe it is realistic to expect hospitals to be prepared for a change of this magnitude effective in less than 5 months. Neither University nor its Information Systems vendors can overhaul our systems and be ready to process clean claims in 5 months.

Also, when University makes capital and operational investment decisions, we do financial feasibility analysis to include payment assumption of major payors. For University, Medicare is a major payor with Medicare beneficiaries comprising more than 50% of our patient population. University's expansion and development of medical services needed for the Augusta and surrounding areas is based on a financial feasibility analysis which projects major payors' reimbursement expectations and the need for the

services. University has broken ground on a \$94 million capital project of which \$50 million represents Cardiac expansion. The decision to expand the Cardiac center to this magnitude was based on faulty Medicare reimbursement data and erodes the funding source for a successful service expansion. While CMS may note that the intent of the regulations were to diminish the "profit" centers and redistribute the reimbursement equally to all DRGs; the Health Care Systems need to have an opportunity to adjust and adapt expansion projects. Had University known about the reimbursement decline, then we may have chosen to spend less than \$50 million on Cardiac. Therefore, University Hospital request that (1) the implementation be delayed for 1 year to review the total impact these changes will have on hospitals and (2) the changes be implemented over at least a three year phase in period.

In addition, we understand that the government has been considering moving to the International Classification of Diseases, 10th Revision (ICD-10) for billing purposes. This also would present a major shift affecting IPPS and hospitals for some of the same reasons mentioned above. In addition, there are a number of quality initiatives required by the Deficit Reduction Act that will also impact on how a hospital manages and bills. We ask CMS to carefully consider the timing of these major changes and their impact on hospitals. In any event, we urge CMS not to revise the IPPS methodology effective in Federal fiscal year 2007 so that, among other things, hospitals such as ours would have sufficient time to evaluate the full impact of this change and plan for such a change unless CMS implements revisions that are in keeping with the current DRG system and structure. It is imperative that we have time so that there is no disruption of any kind in the services we provide to Medicare beneficiaries and all hospital patients.

C. Full Access to the Methodology

As you know, under the current IPPS, we have full access to the methodology underlying IPPS, as CMS makes the necessary software available through the National Technical Information Service. This has proven to be very helpful to us because our IT vendors are able to completely understand the rules for Medicare reimbursement and can implement software to help us operate effectively. Our advocacy groups such as our hospital association can truly understand the impact of new regulations and help us plan for change. An open system also spawns a fertile industry of consultants and other experts on whom the industry relies to operate effectively. However, as CMS modifies the IPPS, hospitals must retain an equivalent level of access to the underlying methodology, and we have particular concerns about this with respect to APR-DRGs. The APR-DRG system is a proprietary system and we see no assurance in the proposed rule that the same level of detail that is currently available would be available if the agency were to move to APR-DRGs. While access to some information about the APR-DRGs is made available through a website, the level of detail is limited, so much so that it is difficult to fully respond to the proposed rule. Accordingly, we request that, regardless of the classification system adopted by CMS, the agency provide, in advance, sufficient detail about the system so that hospitals and others can address whether it should be adopted and assess what they will need to do to operate under the new scheme.

We are also concerned that access to the system be available to all vendors and not just those developing the system to be adopted. It is essential that CMS not grant any vendor a monopoly in this area as this can only further drive up the costs of healthcare in this country.

In addition, it is important that hospitals, our vendors, and suppliers of technology all have access to CMS, as currently is the case, to petition for changes in the selected DRG methodology. Historically, there has been an open dialogue between the industry and CMS for updating the DRG methodology. This dialogue needs to continue.

D. Minimizing the Complexity of a Revised Classification System

As CMS considers different options for a revised classification system, we strongly recommend that the agency consider minimizing the complexity of the new system. Hospitals have been working with a consistent coding framework for over 20 years and our coders work efficiently within this framework. When evaluating revised classification schemes, CMS should consider using a scheme that utilizes the existing coding framework. Schemes such as the one proposed by CMS will require retraining of all of our coders. The proposed system will require learning a completely new classification system from the ground up. It took years for the industry to assimilate the DRG system and will take similar time to truly understand the processes and procedures to code under a totally new system. Similarly, greater complexity will decrease coder productivity and extend revenue cycles.

CONCLUSION

University Health Care Systems fully supports efforts to improve the functioning of the IPPS by more accurately allocating payments for inpatient hospital services. However, we are concerned about CMS' proposed rule because it seems to move too fast to a major system change without adequately considering other possible classification schemes, without providing the public with full access to information necessary to comment on the proposal, and without minimizing the burdens of the proposal on hospitals. Thank you for your attention.

Sincerely,



J. Larry Read
President and CEO

Submitter : Dr. Rebecca Gladu
Organization : Dr. Rebecca Gladu
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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Submitter : Ms. Ann-Marie Lynch
Organization : AdvaMed
Category : Device Association

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment 1 - This letter addresses hospital quality data, value-based purchasing, transparency of health care information.

See Attachment 2 -- This letter addresses proposed DRG weights, New Technology, DRGs: Carotid Artery Stents; DRGs: Neurostimulators; DRGs: Severity of Illness; HSRV Weights; DRG Reclassifications

CMS-1488-P-873-Attach-1.PDF

CMS-1488-P-873-Attach-2.PDF

ATTACHMENT 1 TO #873

1200 G Street NW, Suite 200
Washington, DC 20005-3814
Tel: 202 783 8750
Fax: 202 783 8750
www.AdvaMed.org



June 9, 2006

Via Electronic and U.S. Mail

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

File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this **comment letter on quality-related issues** in the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). **AdvaMed is providing a second comment letter on proposed changes in reimbursement.** AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

This letter summarizes our positions on three key quality provisions contained in the Proposed Rule: hospital quality data; value-based purchasing; and transparency of health care information.

Honorable Mark B. McClellan, M.D., Ph.D.

June 9, 2006

Page 2

HOSPITAL QUALITY DATA

AdvaMed supports CMS efforts to improve the quality of care delivered to Medicare beneficiaries. The Deficit Reduction Act requires that CMS expand the "starter set" of 10 quality measures that it has used since 2003, by adopting the baseline set of performance measures as set forth in the 2005 report issued by the Institute of Medicine (IOM) of the National Academy of Sciences, effective for payments beginning with FY 2007. These IOM measures include the Hospital Quality Alliance measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS[®]) patient perspective survey, and three structural measures. In addition, CMS was given broad discretion to add other quality measures that reflect consensus among affected parties, and to replace measures when they are no longer appropriate.

Furthermore, CMS is required to establish procedures for making quality data available to the public, after ensuring that a hospital has the opportunity to review its data in advance. CMS is also required to report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in inpatient settings on the CMS Web site.

AdvaMed believes that quality measures should conform to clinically appropriate care established by peer-reviewed literature or professional consensus. Furthermore, we believe that financial incentives to encourage providers to meet standards based on quality measures of this kind are appropriate. Financial incentives must allow sufficient flexibility to meet the unique needs of individual patients, and not encourage providers to avoid the most difficult cases.

The 21 quality measures selected for implementation appear to meet AdvaMed's requirements that they conform to clinically appropriate care established by professional consensus, as they were recommended by the IOM and endorsed by the National Quality Forum (NQF). As CMS expands quality measures in the future, it should recognize the special challenges that could occur with measures related to new technology.

AdvaMed believes that process measures of quality should not specify a particular brand or model of device. Quality measures should be flexible enough to allow access to new, improved technology or devices, and should be reviewed and updated periodically to reflect new benchmarks and standards of care. If all providers satisfy a particular measure, it should be removed to reduce the burden of reporting.

If CMS were to adopt a process quality measure that assesses whether or not a provider uses a particular medical device or technology, it should consider allowing exceptions. Providers who use a different new device or technology could be excluded from measurement on this indicator, by exclusion from both the numerator and denominator for the measure. Providers who use a different new device or technology could be

Honorable Mark B. McClellan, M.D., Ph.D.

June 9, 2006

Page 3

required to report this use through a separate measure. As use of new devices or technologies often begins in a particular locality, CMS should allow for variation in measures across the country to capture this variability. If CMS does not recognize use of new devices or technologies when evaluating providers on the basis of process measures, it runs the risk of freezing medical treatment in place, even after it has become outdated. Medical innovation and successful patient outcomes would be inhibited by such limits.

As CMS continues to examine potential new quality measures, we urge you to assure that all relevant stakeholders are part of the process. Manufacturers of medical technology and patients who benefit from this technology should have a seat at the table when quality and cost measures are developed. Potential interested parties should not have to pay a membership fee or any other fee to participate fully in the deliberations and decision making about quality measures.

Since the current CMS hospital quality reporting program ties receipt of a full update to *reporting* of hospital quality data, not the *values* of the hospital quality data, adequate and appropriate risk adjustment and other technical standards, such as sample sizes, are of lesser concern. However, because CMS publicly reports the percent of a hospital's cases that meet quality standards on Hospital Compare, appropriate risk adjustment and technical standards should be applied to the publicly reported data to assure fair treatment of hospitals. Medicare patients, Medicare Advantage plans, and other public and private sector patients and payers have access to the quality information reported on Hospital Compare. As more measures are reported covering more conditions and services, hospitals and others need to be guaranteed that they will not be penalized for treating patients who are frail, have multiple chronic conditions, and fail to comply with treatment orders.

CMS is charged with reporting on hospital efficiency and costs of care. AdvaMed strongly believes that reports on cost cannot be separated from reports on quality, and that both cost and quality are components of efficiency. We define efficiency as delivering high quality care at the lowest cost. An efficient provider is not one who provides low cost care, but one who provides high quality care at low costs. We encourage CMS to develop measures that examine quality and costs of care within and across settings and over time.

We prevail upon CMS to continue its policy of affording hospitals the opportunity to view information regarding their performance before it is made public. We believe that CMS should establish a formal mechanism for provider appeals of performance ratings, if providers believe that the information being made public about their performance is inaccurate.

VALUE-BASED PURCHASING

AdvaMed's comments on value-based purchasing focus on measures, data infrastructure, incentive methodology, public reporting, considerations related to certain conditions and

Honorable Mark B. McClellan, M.D., Ph.D.

June 9, 2006

Page 4

health information technology. CMS defines the best value as quality services at the best possible price. We support a value-based purchasing program for hospitals that encourages the delivery of high quality care with appropriate payment. In addition, the association supports rewarding providers for delivering high quality care.

Measures

A value-based purchasing program is based on measures of efficiency, which consider both quality and cost of care over an appropriate time period, such as an episode of care. AdvaMed agrees with the IOM criteria that measures of quality of care should focus on effectiveness, safety, patient-centeredness and timeliness. We believe that the two other IOM criteria – efficiency and equity – can only be determined for a high level of quality. We also believe that efficiency measures must be based on robust measures of the patient's outcome of care.

We are especially concerned that the measures and the incentive structure be designed to address the potential conflict between appropriate treatment and less cost. We do not support a value-based purchasing program based on efficiency measures that degenerates into incentives to provide the lowest cost care. For this reason, AdvaMed opposes using process measures to assess quality in the context of efficiency and supports using patient outcome measures instead. Reliance on process measures of quality when assessing efficiency could inhibit access to new technologies. Incentives should be aligned such that physicians and other providers are encouraged to deliver high quality care with patient access to advanced medical technologies. In addition, physicians who participate in clinical trials should not have the data from those trials included in their ratings. This would allow for the development of new procedures and other innovations.

AdvaMed believes that costs of care measures must conform to clinically appropriate care as established by peer-reviewed literature or professional consensus. Examples of costs of care measures that meet these standards are those that accurately calculate the savings from reducing medical errors, reducing rates of surgical complications, reducing preventable hospitalizations, reducing inappropriate use of emergency rooms, eliminating services that have been shown as unnecessary and possibly harmful, and eliminating duplicative procedures through better coordination among providers. AdvaMed strongly believes that costs of care measures should not be used to compare the "efficiency" of providers who do not deliver the same quality of care.

We note the work that CMS has undertaken with relevant stakeholders and consensus building organizations to develop quality measures to date. While consensus building organizations have recommended 21 measures of quality of care for use in Medicare, they have made no recommendations regarding the costs or equity of care. As development of additional measures and revision of existing measures occurs, we urge CMS to consider appropriate episodes of care for assessment of quality, cost and equity. For example, some Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge some of the older implant designs.

Honorable Mark B. McClellan, M.D., Ph.D.

June 9, 2006

Page 5

Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry. Newer implants are more durable but more expensive. When comparing the value of treatment with a new device versus an older device, CMS must consider the long-term benefits and costs. A one-year period would be an insufficient to assess the benefits to patients of many new technologies.

AdvaMed supports the open process that CMS has used to develop quality measures, and urges that an open process be used to develop cost of care measures. This process includes the goals that performance measures be based on appropriate evidence, effectively related to desired outcomes, derived through a transparent process involving all relevant stakeholders, and routinely updated. We encourage CMS to collaborate with consensus-building organizations that allow input from all stakeholders and guarantee transparency when developing, selecting and updating performance measures. AdvaMed's experience with the AQA (formerly the Ambulatory Care Quality Alliance) indicates that some consensus-building organizations are not completely transparent in their operations.

Data Infrastructure

CMS must plan for the reporting, collection and validation of performance measures, including both quality and cost of care measures. AdvaMed urges CMS to develop a strategy for allowing comparisons of quality and costs of care over extended periods of time. This is particularly important with respect to medical devices and technologies that often provide benefits that are realized over an extended timeframe. A one year timeframe for measuring costs and quality is often too short, and may inappropriately favor procedures and services that are less expensive in the short run but provide more value over the long-term.

Incentive Methodology

CMS notes that incentives could reward hospitals for meeting a particular standard of performance, for improvement over a baseline level of performance, or for both. In its Premier demonstration, CMS provides incentives for high achievers and penalties for those who fail to meet established minimum levels of performance. MedPAC recommended rewarding providers, including hospitals, for both improving care and exceeding benchmarks in order to improve care for as many beneficiaries as possible, and to ensure that all providers would be encouraged to improve care and have an opportunity for rewards.

Consider the dilemma which could occur if CMS uses both attainment and improvement in the same market and provides the same rewards for both. Suppose the market contains two hospitals, both of which receive the same payment under the CMS inpatient prospective payment system. Hospital A meets the CMS standards for performance, while Hospital B does not. However, Hospital B does meet the CMS standards for improvement. If CMS rewards both Hospital A and Hospital B with the same incentives,

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it would pay the same amount for the delivery of high quality care as it would for the delivery of lower quality, albeit improved, care. This example argues for differential rewards for attainment versus improvement, with a larger reward for Hospital A than for Hospital B.

The situation becomes more complicated if the market includes a third hospital, Hospital C, which delivers care that exceeds the quality provided by Hospital B, but meets neither the standard for performance nor the threshold for improvement over baseline. In this case, Hospital C would not receive any increase in payment, but Hospital B, which delivered lesser quality care would receive a bonus payment. As long as all hospitals in a given market start out at the same payment rate, which they do under the current payment system, there is no way to guarantee that this result can be avoided.

Although little research has been conducted on the size of incentives necessary to stimulate hospitals to improve performance, CMS has experience with hospitals' almost complete willingness to report data on 10 measures when a 0.4 percent reduction in payments was on the table, and will have additional experience through expansion of the reporting requirement to 21 measures with a possible 2 percent reduction for non-reporting. AdvaMed urges CMS to continue to monitor its programs and the types and sizes of incentives offered by other payers for performance improvement.

AdvaMed urges CMS to carefully monitor performance to ensure that quality is not diminished and that patients continue to have access to new treatments and technologies. We agree with CMS that value-based purchasing methods are still under development, and that CMS will need to assess incentives and evaluate their effects in order to revise them quickly as it learns more about their impact on hospitals and Medicare beneficiaries.

When determining the timing of incentive payments in relation to performance, CMS should consider that the quality and costs of some procedures involving medical devices and technology are realized over an extended timeframe. When medical care includes use of a device or technology, many years may elapse before the quality and cost of that care can be accurately assessed. Incentive payments should be distributed only after the full effect of the care is known – which in some cases may be 5 or 10 years after care was delivered.

Public Reporting

Public disclosure of information on hospital performance has the potential to increase the delivery of quality health care using appropriate types and quantities of services. Public disclosure of this information also has the potential to limit access for beneficiaries who are difficult to treat because they are frail, have multiple chronic conditions, or often ignore physicians' orders. Such disclosure could also lead to reliance on older, less effective, less costly services, procedures, equipment, or devices in order for a hospital to appear less costly, or more efficient.

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In order to reap the advantages of public reporting without the disadvantages, CMS should develop standards for public reporting with input from the many stakeholders who will use these reports for a variety of reasons. Patients and physicians may use public reports on hospital performance to select where to receive or deliver care. Payers may use these reports to identify hospitals that they wish to include in their networks, to negotiate payments, or to vary patient cost-sharing to provide incentives for patients to use particular hospitals. Hospitals may use the reports to gauge their performance relative to other hospitals, and to identify areas for improvement.

We believe that the most important aspect of public reporting is that performance measures on costs not be reported without performance measures on quality for the same services. Informed decision making about performance cannot occur if costs are reported divorced from quality.

We also believe that it is critically important for providers whose performance is being reported have the opportunity to review the reports before they are made public, and to work with CMS if questions of accuracy are raised. We applaud CMS's decision to inform hospitals before their quality ratings are posted on Hospital Compare, and urge CMS to develop a formal procedure for review of appeals from providers who disagree with their performance ratings.

Considerations Related to Certain Conditions

AdvaMed supports the collection of all secondary diagnoses for all hospital admissions. The association believes that this data will provide useful information about hospital quality related to hospital-acquired infections. It will also provide information that could be used to adjust for patient risk and patient complexity.

Health Information Technology

AdvaMed supports widespread, rapid adoption of health information technology (HIT) throughout the health care system, including universal adoption of electronic health records. We believe that any value-based purchasing system should include incentives for adoption and use of HIT. In addition, we support removal of barriers to the dissemination of resources (financial, equipment or otherwise) from hospitals to physicians to allow for the use and adoption of HIT.

AdvaMed supports incentives to reward new modes of providing services that result in quality improvement or cost reduction for patient care, such as remote patient monitoring, computer-assisted surgery, imaging, telemedicine, and virtual physician visits.

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TRANSPARENCY OF HEALTH CARE INFORMATION

AdvaMed supports dissemination of accurate information on the value of health care services. We urge CMS to use caution when releasing such information to ensure that the care being measured is appropriate, that all costs and benefits are included, and that the episode of care examined spans the full period over which benefits and costs accrue.

CMS states that part of the reason that health care costs are rising is patients' lack of information about the actual costs and quality of their care. Furthermore, many patients are shielded from the full costs of services because insurance pays much of these costs. CMS argues that these factors produce few incentives or means for patients to shop for providers offering the best value, or for providers to offer the best value to patients. CMS defines the best value as quality services at the best possible price.

CMS argues that consumers must have accessible and useful information on price and quality of health care items and services to choose providers that offer the best value. On June 1, 2006, CMS posted Medicare payment information on its web site for 30 common elective procedures, by Diagnostic Related Group (DRG). These procedures include heart operations and implanting cardiac defibrillators, hip and knee replacement, kidney and urinary tract operation, and other surgical and non-surgical admissions. This information shows the number of procedures performed by each hospital in FY 2005, and gives a range of Medicare payment information for the procedure at the county level. This payment information does not reflect variation in the technology used within the DRG. Hospitals that provide patients with medically advanced technologies that improve patient outcomes are not identified. Most importantly, no information is presented about the quality of care provided by the hospital.

CMS proposes to identify several regions in the US where health care costs are high and where there is significant interest in reducing costs while improving quality. When identifying these regions, CMS should ensure homogeneity within the area and heterogeneity outside. For example, all hospitals in an MSA may not exhibit the same levels of cost or quality. Even within hospitals, some departments may deliver high quality care at reasonable cost, while others may not.

CMS presumes that quality information available through Hospital Compare is sufficient to cover quality of care issues. AdvaMed believes that any pricing information that is made public should be accompanied by evidence-based quality information in order for consumers of that information to assess the value of services. This is not the case for the recently posted Medicare pricing for 30 common elective procedures.

CMS cites three possibilities for publishing pricing information: lists of hospital charges and/or Medicare payment rates; lists of hospitals' prices for the uninsured or policies for discounts or other assistance for the uninsured; and posting Medicare payments for an episode of care. To better serve the uninsured, hospitals should be required to inform potential patients about their possible out-of-pocket costs and hospital policies to help

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defray those costs for the needy. Posting estimated payments for an episode of care, such as hip replacement surgery or cardiac bypass surgery, assumes that certain conditions should be treated in certain ways. In fact, individual patients may have very different needs and therefore, general pricing information should not attempt to identify the appropriate treatment for a particular condition.

AdvaMed urges CMS to consider posting pricing and quality information on appropriate evidence-based protocols. A provider may perform a certain procedure, or deliver care at the lowest possible cost, yet the procedure may not represent appropriate care. For example, a hospital may provide high quality, low cost hysterectomies, but if those hysterectomies are not appropriate treatment, the quality and cost are irrelevant. Delivering the best value medicine requires delivering appropriate evidence-based protocols, not unnecessary high quality, low cost procedures.

AdvaMed also urges CMS to consider the time-frame over which quality and costs are assessed. If an episode of care encompasses a too-short time frame, costs and quality may be inaccurately determined. For example, use of an implant for total joint replacement may have to be assessed over the lifetime of the patient, or implant, which may extend over a period considerably longer than one year.

AdvaMed applauds CMS's efforts to increase the quality of care provided to Medicare's seniors and persons with disabilities. We believe that hospital reporting on the expanded set of quality measures is appropriate. Furthermore, we concur that CMS should develop a comprehensive plan for a hospital value-based purchasing program with input from the public and for increasing transparency of health care information. Our overarching concern is that information on costs of care not be reported, or used as a basis for payment, without consideration of the quality of care provided. Low cost, low quality care is not our goal. We strive to provide patients access to advanced medical technology to improve their health. Please contact us directly if you have any questions on this letter. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,



Ann-Marie Lynch

Executive Vice President

Payment & Health Care Delivery

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Advanced Medical Technology Association

Via Electronic and U.S. Mail

June 9, 2006

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File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this **comment letter on payment issues** in the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). **AdvaMed is providing a second letter on proposed quality issues.** AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goal of assuring beneficiary access to services, and believes that improving the accuracy of payments will help achieve this goal. AdvaMed supports

movement toward improved accuracy in reimbursement under the inpatient prospective payment system (IPPS), and appreciates that CMS has worked very hard to produce a set of proposed changes that would affect all of IPPS. However, we do not believe that the wholesale changes to the IPPS contained in the Proposed Rule are either the appropriate solution or ready for implementation in FY 2007. AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007. Regardless of the IPPS changes that CMS ultimately implements or the timeframe in which those changes are implemented, we believe that the following issues are of paramount importance and need to be addressed:

- **The hospital-specific relative value methodology ignores any hospital-level variation that is not explained by the PPS case-mix index, which may include meaningful and valid cost variations. If certain services are provided predominately in hospitals with higher average costs, this method will produce lower DRG weights for these services. If legitimate costs are not recognized, Medicare beneficiaries' access to care may be diminished.**
- **Using 10 cost center groupings within the Hospital Specific Relative Values (HSRVs) to calculate DRG relative weights ignores detailed data in the cost reports that could be used to derive a more accurate set of weights. This will exacerbate many of the more problematic aspects inherent in the use of weights based on estimated costs, including data lags, data omission, and charge compression.**
- **CMS proposes to implement a new severity-adjusted patient classification system in 2008 or earlier. However, the Proposed Rule models the impact of these changes using FY 2004 inpatient claims, instead of the FY 2005 inpatient claims used to model the estimated cost-based DRG weight changes. This discrepancy, and the fact that CMS did not make the new patient classification system software (the "grouper") available when the regulation was released, made it impossible to accurately assess the impact of both changes from tables provided in the Proposed Rule.**
- **When calculating payment weights, CMS did not use standard methods to weight hospital payment data and trim Medicare claims data. CMS omitted data from 238 hospitals, representing 25 percent of routine hospital charges. This omission and failure to apply appropriate weights significantly decreased the payments for technology intensive cases. These methodological flaws need to be evaluated and addressed by CMS prior to the imposition of any cost-based methodology scenario.**

Due to the magnitude of the changes, the lack of complete information to fully assess the proposed changes, and the importance of improving the accuracy of the payment rates,

AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007.

- **AdvaMed would support implementation of an estimated cost-based weight system in FY 2008, with an appropriate phase-in, analogous to the methodology that is currently used in the outpatient PPS system, as CMS makes changes that would result in improved timeliness and accuracy of the cost report information used to calculate estimated costs and makes a full adjustment for charge compression. To determine methods of improving hospital cost reports, CMS should assemble an expert panel or work group comprising hospital finance experts, prospective payment authorities, hospital charge master personnel and other experts. This group could make timely recommendations on how to refine the cost reports to yield more accurate and timely data that may be used in setting PPS weights. In this letter, AdvaMed is proposing a methodology to address the issue of charge compression when cost-based weights are implemented.**
- **AdvaMed also would support simultaneous implementation of a revised estimated cost methodology and a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.**
- **AdvaMed would oppose a two-step implementation, whereby CMS would implement the movement from charge-based weights to estimated cost-based weights in one year followed by wholesale refinement of DRGs based on patient classification reforms in a following year. Making these changes simultaneously would minimize swings in payment rates for many diagnosis-related groups.**

The Proposed Rule seeks to both create and implement the most significant and complex changes in Medicare reimbursement since the IPPS was implemented more than 20 years ago. And, it does so in just one regulatory cycle, providing stakeholders only one 60 day comment period to review the regulation, analyze the methodological changes, and provide input. The details of these complex proposals were neither discussed nor scrutinized in any public forum prior to the release of the Proposed Rule. Nor were the methods used to arrive at these proposals validated by anyone other than CMS.

Upon the release of the Proposed Rule on April 12, 2006, stakeholders, including AdvaMed, began to work diligently to perform the detailed analyses that were necessary to replicate the methodology of the CMS proposals. We acknowledge the enormity of the task that CMS faced in making the recommendations contained in the Proposed Rule.

We applaud CMS for its ability to complete the new methodologies in time for release in the Proposed Rule, and for releasing the MedPAR data in advance of the Proposed Rule. However, many other necessary pieces of information were not available to enable stakeholders to perform a thorough evaluation of the proposed changes when the Proposed Rule was released.

AdvaMed has exerted intensive efforts to model and assess the impact of these proposals prior to the expiration of the comment period. Nevertheless, we believe that 60 days is insufficient time given the complexity of the changes proposed by CMS. Additionally, we believe that the time between the close of the comment period (June 12) and the August 1, 2006 expected publication of the Final Rule, is insufficient to fully consider, test and implement the significant, substantive changes of the magnitude contained in the Proposed Rule.

The decision to delay implementation of any changes until FY 2008 would allow CMS, hospitals, patients, physicians, device manufacturers and other stakeholders the opportunity to fully assess any proposed changes before these are applied to every Medicare participating hospital and the services provided to Medicare beneficiaries. Assessment of these changes in the current cycle is simply not possible due to the complexity of the changes proposed, the potential overlay with a completely different DRG system, and the lack of available data and sufficient time to do the assessment that is necessary.

I. HSRV Weights, Cost-Based Weights and Cost Reports (“*HSRV Weights*”)

AdvaMed supports the goal of improving accuracy within the IPPS. Before CMS implements an estimated cost-based payment system, it should address a number of significant concerns raised by the use of cost-based weights. Estimated cost-based weights would be derived, in part, from Medicare cost reports, which were not designed for use in a prospective payment system. The cost reports are a vestige of the “reasonable cost” based reimbursement system that was implemented when Medicare began in 1966. When the hospital inpatient prospective payment system was implemented in 1983, hospitals began to be paid a fixed amount based on the patient’s diagnosis, rather than incurred costs. Under IPPS, reimbursement became independent of the actual costs incurred, and the cost report no longer played a key role in the reimbursement received by hospitals, with some limited exceptions for items such as bad debt, graduate medical education, pass-through, or outlier payments.

There are several serious problems in using cost reports to derive estimated costs which are then used to calculate DRG relative weights that should be carefully considered and addressed. These include: 1) the accuracy of the cost-report data and limited auditing; 2) the overall timeliness of the cost report data; 3) the omission of data on new

technologies; 4) comparability of costs reports due to variability in how hospitals allocate costs; and 5) the compression of the weights both across and within cost centers.^{1 2 3}

Accuracy of Reporting and Limited Auditing--Under prospective payment systems, providers' payments are not based on their actual incurred costs. Hospitals have little incentive to report accurately and completely for the items and services provided during the patient encounter or length of stay. The cost reports were not designed to establish payment rates for individual services and, as such, do not contain the detailed costs that are necessary to accurately determine estimated costs at the DRG level. Instead, cost reports provide payment, costs, and some reimbursement totals by department or cost center. An analyst must make several assumptions and perform complex calculations before she can translate cost reports into the estimated costs of individual items and services used to determine DRG payments.

CMS and fiscal intermediaries perform limited auditing of cost reports. If DRG weights are based on costs, they will be based on largely un-audited cost reports and, perhaps, extrapolation of average audit findings to un-audited cost reports. According to CMS, approximately 15% of hospital cost reports are audited each year. These audits are limited scope audits that focus primarily on factors that affect Medicare payment, such as bad debt or medical education. Full scope audits are done only rarely. Instead, audits for IPPS providers mostly involve payments for one or more items including DSH, GME, IME, bad debts, and organ acquisition. The fiscal intermediary determines what issue(s) will be audited based on the desk review and experience with the particular provider. Validation audits are not conducted by fiscal intermediaries. If cost reports are to be used to calculate DRGs, additional auditing might be advised. MedPAC estimated that a full scale audit could require 1,000 to 2,000 hours from a fiscal intermediary, as well as additional time and resources from the hospital.⁴

Overall Timeliness of Cost Report Data--The cost report data are old, significantly older than the charge based data currently used to determine payment weights under the IPPS. In the current system, the DRG weights are calculated using claims that are 2 years older than the payment year. Under an estimated cost-based IPPS system, the DRG weights are calculated using cost report data that is 3 to 4 years older than the payment year. The quality of the information is reduced because it is outdated. The use of

¹ J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01, March 1993; MedPAC, "Sources of Financial Data on Medicare Providers," Report to Congress, June 2004.

² Cost-based weights would further exacerbate the problem of "charge compression," which has been observed in the early years of IPPS (when cost-based weights were used) as well as in a number of studies and in the current OPSS. AdvaMed has conducted a study that documents the effects of charge compression using current MedPAR data.

³ A 1998 study by MedPAC's predecessor, ProPAC noted concerns with cost report data such that "cost report data may, in some cases, produce imprecise DRG weights." ProPAC further noted that the "Secretary [of HHS] should verify the accuracy of cost report data and implement changes as necessary."

⁴ MedPAC, *op cit.*, p. 17

estimated cost-based weights requires matching billed charges from over 13 million hospital claims to cost reports for each individual hospital. Under the estimated cost-based system in the Proposed Rule, CMS used hospital claims data from FY 2005, and hospital cost reports from FY 2003. AdvaMed supports an approach that uses the most recent claims data available.

Omission of Data on New Technologies--Inherent lags between the time period covered by the cost reports and the payment year mean that recent important medical technology advances are omitted from the costs, which in turn determine the cost-to-charge ratios that are used to calculate cost-based DRG weights. Data that are three to four years old would exclude many of these technological advances in the calculation of cost-to-charge ratios. The older the data, the greater the omission of new technologies. This will translate into reduced accuracy in DRG weights.

For example, cost-based DRG weights as proposed by CMS could systematically underpay for new technologies because the proposed methodology assumes that hospital ancillary cost-to-charge ratios (CCRs) will not change with the introduction of new technology. The illustrations below demonstrate how a new technology that reduces routine charges by allowing patients to be discharged sooner results in a lower DRG payment under cost-based DRG weights, even under a scenario where total charges are unchanged (due to higher ancillary costs from the new technology). While total charges remain the same after introducing the new technology (resulting in no payment change under the current charge-based method), applying a CCR from an earlier period results in a reduced estimate of costs. Over several years, the ancillary CCR would eventually reflect the new technology; however, the methodology proposed by CMS would reward a hospital that maintains the older treatment with the longer length of stay, due to a higher 'cost-based' payment rate.

**Patient Treated with High Concentration of Routine Services
and Longer Length of Stay**

	<u>Charges</u>
Routine Services (85% CCR)	\$15,000
Ancillary Services (34% CCR)	\$5,000
Total Charges	\$20,000
Estimated Costs Based on Proposed CCR	\$14,500

**Patient Treated with High Concentration of Ancillary Services
(Supplies and Equipment) with Shorter Length of Stay**

	<u>Charges</u>
Routine Services (85% CCR)	\$5,000
Ancillary Services (34% CCR)	\$15,000
Total Charges	\$20,000
Estimated Costs Based on Proposed CCR	\$9,350

By comparison, the current charge-based system, if continued through FY 2007, would use 2005 hospital claims data to set the IPPS DRG weights. Switching to cost-based weights would entail the use of cost report data from FY 2003 and new technologies that were approved for use subsequent to 2003 would not be reflected in the cost report data. The use of estimated cost-based weights thus induces greater systemic bias against newer technologies by omitting them from the cost report data and the rate calculations.

Comparability of Cost Reports due to Variability in How Hospitals Allocate Costs --

The high degree of variability of hospital cost reports is attributable to several causes, including the allocation of joint costs, such as hospital administration costs, to various revenue generating sectors. This presents a problem for the accurate measurement of other costs such as inpatient, outpatient and skilled nursing costs. Hospitals have a range of options to allocate their overhead costs. Some of the methods of allocation, such as square footage, can result in an over-allocation of costs to secondary services compared to other, core function services. These allocation decisions have a significant impact on the comparability of the cost report data across hospitals.

Compression of Charges Within Cost Centers-- CMS uses hospital cost-to-charge ratios (CCRs) to convert charge data into estimated costs of individual items and services. CMS uses a single CCR for the many items and services in a single department. This process assumes that hospitals apply the same uniform percentage mark-up when setting the charges of each item in the department. Many observers have noted that hospitals do not act this way, but instead use a lower percentage mark-up for high cost items than they use for lower cost items. Hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."⁵ If hospitals do not use a constant percentage mark-up for items in the department, methodologies that rely on uniform CCRs underestimate the cost of

⁵ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs, and of prospective payment rates.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.⁶ The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges led to a stronger impact on the device and supply CCR. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over \$30,000) was associated with a much larger increase in the average device and supply CCR than was a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over \$20,000), which in turn had a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). These results are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.⁷

II. HSRVcc Methodology Exacerbates Problems Inherent in Estimated Cost Based Weights (“HSRV Weights”)

AdvaMed does not support the use of the HSRVcc methodology in the Proposed Rule because it exacerbates many of the problems that are otherwise present with the use of estimated cost-based weights. Under HSRVccs, CMS calculates charge-based weights for each hospital at the cost center level. It is important to note that the HSRVcc methodology proposed by CMS differs both from what MedPAC proposed and from how CMS calculates *cost-based* weights for the outpatient prospective payment system. AdvaMed believes that the CMS methodology produces inaccurate and distorted DRG weights due to at least four major deficiencies.

⁶ C. Hogan, Direct Research LLC., March 2005. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data.

⁷ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, “Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: <http://www.gao.gov/highlights/d04772high.pdf>. The Effect of “Charge Compression” on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of “Charge Compression” on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

- First, the cost (revenue) centers are collapsed from the full set of at least 37 cost centers into only 10 centers.⁸ Although each of the 37 cost centers has a unique cost-to-charge ratio, the CMS grouping methodology employs only 10 cost-to-charge ratios. This approach essentially throws out detail that is available on the cost report and that CMS uses in calculating the outpatient prospective payment system rates. AdvaMed is concerned that CMS disregards information that would increase accuracy and does so as part of an initiative intended to improve accuracy.
- Second, the national cost-to-charge ratio approach eliminates the specificity of cost-to-charge ratios for supplies and equipment in individual hospitals that perform more procedures involving implantable devices. These hospitals in general have higher cost-to-charge ratios for supplies than other hospitals, and using the hospital-specific CCR for supplies and equipment instead of the national CCR better reflects the mix of patients in the hospital and the accompanying costs. [These hospitals still experience charge compression for implantable devices and an adjustment to address this issue (described below) is important in any move to cost-based weights.]
- Third, the HSRVcc methodology proposed by CMS contains two serious mathematical flaws that affect the DRG weights very materially. These problems arise due to the manner in which CMS proposes to implement the HSRVcc methodology. They can be corrected, and the corrected results are illustrated in the table below, or the problems would be removed altogether if CMS abandons the HSRVcc methodology and adopts the methodology used for the outpatient prospective payment system, as AdvaMed recommends. **Fixing these flaws will have a significant impact on hospital-level payments and hospitals that may have assumed that their payments would increase may see reductions.**

⁸ CMS's HSRVcc methodology uses two cost centers for routine services (routine days and intensive care services) and eight for ancillary services (drugs, supplies and equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services and charges).

The following examples show the dramatic effect that correcting the flaws would have on the weights for selected DRGs.

IMPACT ON SELECTED DRGs OF HSRVcc		CMS	Corrected
558	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W/O Maj Cv Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W Major Cv Dx	-26%	-15%
125	Circulatory Disorders Except Ami, W Card Cath W/O Complex Diag	-28%	-20%
124	Circulatory Disorders Except Ami, W Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant W Cardiac Cath W Ami/Hf/Shock	-26%	-16%
536	Cardiac Defib Implant W Cardiac Cath W/O Ami/Hf/Shock	-25%	-13%

The HSRVcc is a complex calculation that begins with calculating charge-based weights for each cost center for each DRG for every hospital. At this stage, CMS has 10 hospital-specific, charge-based weights for each DRG – one such weight for each of the 10 collapsed cost centers. Next, CMS combines these hospital-specific charge-based weights for each cost center for each DRG to get a set of 10 national charge-based weights for each cost center for each DRG. In computing the national weights for each cost center for each DRG, CMS properly weighted each individual hospital number by the hospital's count of cases in the DRG.

Both of the major flaws occur in the final phase of determining the DRG weights. In this stage, CMS is combining the 10 cost center weights to get a single weight for each DRG and simultaneously converting from charge-based to cost-based weights. Both flaws arise as CMS calculates national cost-to-charge ratios to use in converting charges to costs.

Flaw #1: In calculating the national cost-to-charge ratios (CCRs), CMS severely over-trimmed the data and threw out hospital data with CCRs for routine days with a value less than 0.26. These CCRs appear to be real and valid, however. They apply mostly to about 238 very large hospitals that contribute roughly one-quarter of all routine day charges. In dropping these data, CMS is not only throwing out a large amount of valid data, but it is distorting the results by omission of such a significant segment of hospitals with a unique pattern of CCRs. This problem is compounded because CMS retained these hospitals for other steps in calculating the national DRG weights. The table below shows the impact of CMS's trimming.

Trimming of Routine Accommodation Charge Per Day				
CMS CCR trim action	Hospitals	Charges (\$ in billions)	Days (in millions)	Charge per Day
Not Trimmed	3133	\$ 34.11	39.1	\$ 873
Trimmed	238	\$ 12.37	3.3	\$ 3,723
Total	3371	\$ 46.48	42.4	\$ 1,097

Source: Direct Research. Ltd. estimate based on 2003 cost reports matched to edited 2005 MedPAR file.

Flaw #2: In calculating the national CCRs for each of the 10 cost centers, CMS uses the geometric mean of the individual hospital CCRs, after they are erroneously trimmed as discussed above. CMS's calculation of the national CCRs does not account for the volume of charges and costs across hospitals. It is important to note that similar calculations in other CMS prospective payment systems and fee schedules use an appropriate weighting methodology rather than counting each hospital equally. Only with appropriate weighting will the calculated number actually equal the overall national average. In this case, weighting should be based on the aggregate amount of charges in each hospital. Specifically, national CCRs should be calculated using the charge-weighted arithmetic mean. As shown in the table below, the flaw causes a substantial overestimate of the aggregate national level of costs incurred by prospective payment system hospitals. Routine costs are so overstated by the proposed CMS methodology that total costs compared to total actual payments on the MedPAR file show that hospitals would have lost \$23 billion dollars in 2005, or about 29 percent, on care provided to Medicare beneficiaries. We know from MedPAC and CMS reports that this is not true, and that hospitals experienced a small positive margin on inpatient care provided to Medicare beneficiaries. Consistent with this fact, the correct weighting methodology provides an estimated patient care margin of 2.2 percent, as shown below:

	With CMS CCRs ⁹	With Charge-Weighted CCRs
▪ Total charges on MedPAR file	\$ 315	\$ 315
▪ Estimated 2005 costs <u>before</u> charge inflation adjustment	\$ 134	\$ 107
▪ Estimated 2005 costs <u>after</u> charge inflation adjustment (.92 X previous line)	\$ 123	\$ 98
▪ Actual 2005 payment on MedPAR	\$ 100	\$ 100
▪ Estimated 2005 payment-to-cost ratio	0.812	1.022

⁹ All numbers listed in billions.

The combined impact of the two flaws significantly decreases the payments for technology intensive cases as noted above. AdvaMed strongly urges CMS to fix these problems if it continues to use the HSRVcc methodology, though, as noted above, we recommend an entirely different approach for cost-based weights.

- Fourth, the hospital relative value methodology (HSRV) is unnecessary, compresses the DRG weights, and particularly and unjustifiably cuts payment rates for cardiac care. Under the current standardization methodology, DRG weights are set by determining the average per-case standardized charges or costs in a DRG across all hospitals and dividing that figure by the average per-case standardized charges or costs for all cases in the DRG system. The key is that the weights are based on pooled charges or costs from across all hospitals nationally. This helps to assure appropriate valuation of all services, including services which tend to be highly concentrated in limited centers, such as cardiology services.

Under hospital specific relative values, rather than pooling charges or costs across hospitals, CMS first creates relative weights from the charges or costs within each hospital for each DRG to get a hospital-specific weight and then averages those hospital-specific weights across all hospitals (using a case-weighted average) to arrive at a single weight for each DRG. In this manner, average charges or costs in a particular DRG are compared with average charges or costs in each hospital rather than with average charges or costs across all hospitals. The hospital-specific relative value (HSRV) methodology reduces the weights for DRGs that are performed predominantly in hospitals with higher average charges or costs. This is true even if the costs are valid and if these hospitals are the only hospitals where the particular services are performed.

Under the hospital-specific relative value approach, each hospital's data is scaled up or down so that its costs or charges match the level predicted by the hospital's case mix index. All other variation in costs or charges is simply ignored. The hospital-specific approach removes from the data all the hospital-level variation that is not accounted for by case mix. No other hospital-level variation in costs or charges is allowed to affect the calculation of the DRG weights. HSRV contrasts with the current standardization approach which removes from the charge or cost data *only* the hospital-level variation that Medicare will pay for in another part of the payment formula: wage index, indirect teaching and disproportionate share. Under current IPPS, all other hospital-level variation (anything the IPPS does not pay for) is allowed to affect the calculation of the DRG weights.

The main difference between these two approaches is how you treat charge or cost variation that is not otherwise explained with IPPS payment factors. In the standardization approach, any variation in hospital costs or charges that is not explained with CMS payment factors is allowed to affect the calibration of the DRG weights. The hospital-specific approach, by contrast, ignores any hospital-

level variation that is not explained by the IPPS case-mix index. The current standardization methodology recognizes that hospital-level variations should not be ignored just because they cannot be explained. In throwing out otherwise unexplained variation in hospital-level costs or charges, the HSRV methodology risks ignoring meaningful and valid cost variations. To the extent that certain services are provided predominantly in hospitals with higher average costs, the HSRV methodology predictably will result in lower DRG weights for these services. If these hospitals' legitimate costs are not recognized, Medicare beneficiaries' access to care for these services could be jeopardized.

AdvaMed strongly believes that HSRV is unnecessary and inappropriate under cost-based weights. If under cost-based weights the cost of care in each DRG has been estimated as accurately as possible, then it is not sound policy to ignore part of what was estimated, as occurs under HSRV. AdvaMed recommends that HSRV be dropped and that costs or charges be standardized using the current methodology. If CMS wishes to remove other sources of cost variation from calculation of the DRG, the standardization process could be expanded to include other factors beyond wage index, indirect teaching and disproportionate share. Such a factor-specific approach would lead to more precise and valid adjustments than the "black box" approach of HSRV.

There are several excellent research studies on the impact of the hospital-specific relative value methodology and, though many of these date from the early 1990's, their findings are remarkably consistent with the impact of HSRV in the Proposed Rule. In general, the HSRV approach tends to lower relative weights for the higher weighted DRGs and reduce the range of DRG weights between the lowest and highest weighted DRGs. Since the inception of the Medicare inpatient prospective payment system, such compression of the DRG weights has been a closely watched issue due to concern that patients might experience reduced access to the higher cost DRGs if compression became a problem and the DRG weights were too low for high cost cases. Finally, considering type of service, research has consistently shown that cardiology services would be hit especially hard by a change to HSRV. In fact, for hospitals that lose under HSRV, they lose more on cardiology services than they lose overall (they make up some of their cardiology losses on other services). Earlier research found that about 83 percent of hospitals losing under HSRV engaged in cardiac surgery compared to 5 percent for other hospitals.

Cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. Hospitals performing cardiology services tend to mark up their charges for those services less than they mark up their charges for other services. Hospitals performing cardiac surgery charge more than average for typical cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, surgical cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV

methodology. These collective effects cause particular disadvantage to cardiac surgery and interventional cardiology services.

Clearly, adopting HSRV is a policy choice with significant implications for hospitals. We seek opportunities to work with CMS to assure that services are paid appropriately and that patient access to these life-saving services and technologies is not diminished. We strongly believe that changes in the Proposed Rule are necessary both to preserve access to care and to continue to encourage the technological innovation and adoption of new technologies that has brought substantial reductions in mortality and morbidity for patients.

III. Charge Compression (“*HSRV Weights*”)

To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by “backing out” the average mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of \$1,000 would be reduced to a cost of \$500.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is significantly less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid “sticker shock.”¹⁰ This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates.

Charge compression occurs when items with different markups are combined in the same cost center. The HSRVcc methodology would combine estimated costs into only 10 cost centers nationally, increasing the variation of items placed in a particular cost center. Modeling of the HSRVcc methodology confirms that the degree of charge compression inherent in the use of cost-based weights is exacerbated under the HSRVcc methodology.

To examine further the empirical evidence of charge compression, AdvaMed recently commissioned research to investigate whether Medicare claims data provided statistical evidence of charge compression. The results indicated a strong statistical relationship

¹⁰ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

between a hospital's case-mix and the device cost-to-charge ratio (CCR). Specifically, the study found that there is a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the device case-mix increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the research also showed that basing the case-mix index on the percentage of cases with higher device and supply charges led to a stronger impact. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over \$30,000) is associated with a much larger increase in the average device and supply CCR than is a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over \$20,000), which in turn has a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). The results of this research are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.¹¹ It is significant that this study was conducted exclusively on Medicare claims data with no use of external data.¹²

IV. An Alternative Cost-Based Method Should be Used to Calculate Cost-Based Weights and the Detailed Impacts Should be Provided for Public Comment (“HSRV Weights”)

AdvaMed supports efforts to improve the accuracy of inpatient hospital payments. The HSRVcc methodology is too complex, omits important data, and results in a systematic bias against the hospitals that provide patients access to many medically advanced technologies. Rather than improving the accuracy of the payments, it further distorts payments by using a distorted estimate of costs. If CMS chooses to move to a cost-based payment system, we recommend a cost-based payment methodology similar to the one used to calculate the hospital outpatient prospective payment rates, with adjustments for both charge compression and biases in the Medicare cost report that lead to over-estimation of routine costs and under-estimation of ancillary costs.

To calculate hospital outpatient prospective payments, CMS matches outpatient hospital claims to Medicare costs reports using hospital-specific cost-to-charge ratios to determine

¹¹ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, “Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: <http://www.gao.gov/highlights/d04772high.pdf>. The Effect of “Charge Compression” on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of “Charge Compression” on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

¹² C. Hogan, Direct Research LLC., March 2005

estimated costs for each hospital encounter. These are then combined to determine the payment rates after adjusting for certain factors. While there are several problems associated with the hospital outpatient PPS, the general methodology of adjusting the most recent claims data using hospital specific and department specific cost-to-charge ratios could be used for inpatient hospital payments.

We support using a modified version of the OPSS methodology in determining cost-based relative payment weights for the inpatient setting. Such a methodology would provide an improvement over the proposed HSRVcc methodology in that it would produce estimated costs that would better reflect the variation in costs across hospitals and procedures. At least two modifications are needed in the outpatient methodology. First, as discussed below, CMS must adjust for charge compression. Second, the weight calculation methodology needs to account and adjust appropriately for known biases in the Medicare cost report that lead to over-estimation of hospitals' routine costs and under-estimation of ancillary costs. Further research may be needed on the magnitude of this bias and options to correct for it. The recommended one-year delay allows time for this additional work.

Although evidence of the effect of charge compression is not new, research that could support an adjustment to offset charge compression was not previously available. Research just completed now presents a solution. It takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital. By pooling the information from all hospitals, research using regression analysis was able to develop one set of CCR adjustments reflecting national average CCRs for each of the five supplies sub-categories. Next, the research applied this national-average set of adjustments to each hospital (combining the adjustments with each hospital's actual supplies CCR), and inserted a "decompressed" estimate of cost on each MedPAR record.

The research found a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs. CMS could use the coefficients from a regression model such as this to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. The research found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.33 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker

category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.46 (or just slightly more than a 100% average markup). The category of general supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Estimated Cost-to-Charge Ratios for Supplies Sub-Categories	
Supplies Subcategory	Net Average CCR After Budget-Neutrality Adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29

Source: Direct Research, Ltd. analysis of 2004 5% standard analytic file and hospital cost report data. May 2006.

The research showed that this variation in CCRs across sub-categories has a significant impact on some DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers.

AdvaMed strongly believes that any change toward cost-based weights, whether accompanied by the hospital relative value methodology or not, must address the distortion caused by charge compression. The recently completed research demonstrates that such an adjustment is possible and provides a solid analytical basis for a specific adjustment.

V. Severity-based DRGs (“DRGs: Severity of Illness”)

CMS solicited comments on a consolidated, severity-based DRG system (CS-DRGs) in the Proposed Rule. The CS-DRGs are similar, though not identical, to the All Patient Refined DRGs (APR-DRGs). CMS stated in the Proposed Rule that it was seeking comments on the CS-DRGs as well as alternatives that could be used to capture DRG severity and complexity. CMS also requested comments on a time frame for implementation (FY 2007 or FY 2008) of a severity-based DRG system.

AdvaMed’s ability to conduct modeling on the impact of the proposed CS-DRGs was hampered by the fact that there was only limited information available from CMS at the time the Proposed Rule was released. As noted above, CMS did not provide the necessary “grouper” software to analyze the CS-DRG impacts.

In its specialty hospital recommendations last year, MedPAC recommended the use of severity-based DRGs in conjunction with hospital specific weights and cost-based weights. MedPAC examined APR-DRGs and recommended that CMS implement a severity-based DRG system, similar to APR-DRGs, but did not recommend that APR-DRGs be used.

In the Proposed Rule, CMS noted that implementation of APR-DRGs without modification caused several concerns, including the volatility of rates for low-volume procedures and the potential incentives for more thorough coding of severity due to financial incentives provided by severity-based DRGs.

AdvaMed believes that CMS should not implement CS-DRGs or any severity-based DRG system in FY 2007. We support a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.

CMS notes in the Proposed Rule that the CS-DRGs do not capture complexity of treatment, but provides no suggested mechanism for doing so in the future. We would like to work with CMS in ensuring that any DRG system that will be used by the Agency will fully recognize complexity and patient benefit. AdvaMed believes that it is essential for any DRG refinements to fully acknowledge these factors.

AdvaMed conducted extensive modeling of one version of severity-based DRGs after MedPAC made its recommendations last year and in November 2005, shared with CMS a number of potential concerns with moving to severity-based DRGs. Included in those concerns were the failure of the severity-based DRGs to recognize newer technologies with an appropriate payment weight and associated payment level. Our analysis of the proposed CS-DRGs reveals that concerns still needs to be addressed. The following examples illustrate several problems with the proposed CS-DRG that call into question the readiness of the proposed severity-based DRG system that fails to recognize such important categorizations.

Improper Classification Under CS-DRGs--Our analysis has revealed that the movement from the current system to CS-DRGs places procedures into inappropriate categories. These mis-categorizations fail to accurately describe accurately the procedure itself, the technology being used, or the resources, complexity or patient benefit of the procedure. Examples are as follows:

- **Current DRGs 118, 551** – In 1997, CMS moved ICD lead and ICD generator/replacement to the pacemaker system with AMI, HF, Shock DRG as justified by average charges (Federal Register, Vol. 62, 45974, August 29, 1997).

Under the CS-DRGs, generator replacement procedures for pacemakers, implantable cardiac defibrillators (ICD), cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D) would be inappropriately categorized together into the same CS-DRGs 243, 244 and 245 (Cardiac pacemaker and defibrillator device replacement with a severity of illness (SOI) levels 1-3) and the ICD lead procedures would map to CS-DRGs 246-248 (Pacemaker & ICD revision). Changing the logic so that ICD generator/replacement map with pacemaker replacements and the ICD lead procedures map with pacemaker and ICD revisions would reverse CMS's 1997 decision without data to justify the change. This, in addition to the fact that there is no variation in the CS-DRGs based upon the type or complexity of the device, would result in a significant penalty to hospitals that treat patients needing implantable defibrillators, which are more complex and resource intensive than pacemakers.

- **Current DRGs 518, 555, 556, 557, & 558** – All of these DRGs would group to CS-DRGs for Percutaneous Cardiovascular Procedures both with and without acute myocardial infarction (CS-DRGs 237-242). DRGs 557 and 558 include drug-eluting stents, and would be placed inappropriately into the same category with bare metal stents.
- **Current DRGs 471, 544 & 545** -- These DRGs for either bilateral or major joint replacement procedures, group to CS-DRGs 414 – 419, which are solely for either hip joint or knee joint replacement. The CS-DRGs thus fail to differentiate between single replacement procedures and revisions, which are more resource intensive and complex. The only distinction made by the CS-DRGs is the distinction based on whether the procedure is performed on a hip or on a knee. Under CS-DRGs, the DRG weight for performing bilateral knee replacement is approximately equal to the payment for one knee replacement.
- **Current DRG 496 (combined anterior/posterior spinal fusion)** -- Based on the CS-DRG descriptions, it does not appear that there is an appropriate CS-DRG crosswalk from current DRG 496. The effect is that combined anterior/posterior spinal fusion procedures, which require two separate incisions and turning the patient over during surgery, get regrouped with all other spinal fusions. This inappropriate categorization ignores the resource intensive nature and greater length of stay associated with this procedure, and is also contrary to CMS policy dating back to the FY 1998 Final IPPS Rule.
- **Current DRGs 110 and 111** – Endovascular aneurysm repair (EVAR), a new generation of surgical services, will experience payment reduction in excess of 12% due to the proposed shift of EVAR into proposed CS-DRGs 234 – 236. EVAR for treatment of Abdominal Aortic Aneurysms (EVAR-AAA) was first approved in late 1999. EVAR for treatment of Thoracic Aortic Aneurysm

(EVAR-TAA) was approved in early 2005. The benefits that this technology offers to patients were reinforced by the implementation of a new "Welcome to Medicare" screening benefit for AAA, enacted under the Deficit Reduction Act of 2005, with implementation effective January 1, 2007, and an award of "New Technology" status for EVAR-TAA in FY 2006. EVAR reduces hospital stays, risk of complications and risk of death resulting from surgery, and is an alternative for many patients where limited or no suitable options were previously available.

Classification of EVAR into CS-DRGs 234 – 236 is inappropriate, and ignores the patient benefit and complexity of these procedures. The CS-DRGs 234 – 236 "Other Vascular Procedures" primarily contain surgeries for peripheral arterial disease – primarily PTA (w, w/o stent) and surgical bypass of the lower limb. This inappropriate classification for EVAR that does not recognize the significant clinical and resource differences (i.e. "complexity") inherent in the treatment of aortic and thoracic aneurysms versus peripheral disease. The disparity of net resource consumption for EVAR versus other procedures in the classification is large, yet would not be recognized under CS-DRG reclassification.

Difficult to Obtain a High Severity Level Absent Adverse Patient Consequences--

Our analysis has also identified concerns regarding the fact that patients may need to suffer adverse consequences in order for the case to be assigned to a higher severity level. While in certain cases this may appropriately reflect the greater use of resources, our analysis uncovered that in some cases it was impossible to obtain a higher severity level unless the patient had a life-threatening complication. We believe that the severity grouping should reflect complexity and patient benefit as well, and should allow for an increased severity/complexity level even without adverse patient consequences. Our examination of this issue led us to review a number of related procedures for arterial repair or occlusion as follows:

- **DRGs 014, 110, 533, 534, 553, 554, and 559** -- When many of the resource intensive procedures within these DRGs are mapped to the proposed CS-DRGs, there are large reductions in payment as virtually none of the procedures map to either of the two highest severity levels. In order to reach the highest severity levels, the patient must have a number of comorbidities that are unrelated to the basic nature of the procedure, such as a severe infection or renal failure.

CS-DRGs Fail to Adequately Recognize Patient Benefit--Our analysis revealed that CS-DRGs appear to be markedly inadequate to recognize patient benefit. One example that demonstrates this deficiency occurs in the context of the use of a more expensive, but longer lasting medical device, such as a hip with hard-bearing or other novel surfaces, that may be dictated by a beneficiary's greater health, activity level and greater potential utility over the individual's lifespan. A subset of today's Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge

some of the older implant designs. Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry.

Additionally, implant fixation and range of motion requirements are much more demanding for these patients. Some providers are working to identify patients that are most appropriate to receive these implants based upon such things as family history, overall health and activity level. Unfortunately, the tendency toward better health and higher activity level of these patients would work against them receiving an implant that would be better tailored to their needs, because under the CS-DRGs, such patients would be categorized into the lower level severity. We believe the severity adjustment is flawed because it does not capture resource utilization or the utility of technologies that would be more appropriate for beneficiaries who are more active, healthier, and require a greater range of motion.

Reversal of Recent DRG Refinements--AdvaMed's analysis has revealed that the CS-DRGs, if implemented in FY 2007, would arbitrarily eliminate several important changes to DRGs deemed necessary to encourage promising new technologies. This is illustrated by the following examples:

- **Current DRGs 544 and 545** – In last year's Final Rule, CMS eliminated DRG 209 for primary and revision total hip and knee replacement procedures and replaced it with DRGs 544 (primary total hip and knee replacement) and 545 (revisions hip and knee replacement). CMS also created new and updated existing ICD-9 procedure codes to map to DRG 545 for a more accurate description of the various permutations of potential hip and knee revisions. Under CS-DRGs, revision procedures would map to CS 415 (hips) and 418 (knees) with weights reduced approximately 19 to 20%. Relative weights for bilateral total joint replacement, could likewise decline by as much as 40 to 45%. In the FY 2006 rule, CMS noted that

“we examined data in the FY 2004 MedPAR file on the current hip replacement.... as well as the replacements and revisions of knee replacement. . . . We found that revisions were significantly more resource intensive than the original hip and knee replacements.”

It is difficult to understand how CMS can suggest complete reversal of a categorization in FY 2007 that was not only just implemented in FY 2006, but also supported by CMS with the award of additional ICD-9 procedure codes.

- **Current DRGs 110 and 111** – As stated previously, CMS agreed that endovascular aneurysm repair (EVAR) for treatment of Thoracic Aortic Aneurysm (EVAR-TAA) merited the award of a new technology add-on payment in FY 2006. This technology was also made part of the “Welcome to Medicare” screening benefit under the Deficit Reduction Act of 2005, implemented effective

January 1, 2007. Implementation of the CS-DRGs would move these procedures inappropriately to CS-DRGs 234-236 (for more general vascular surgeries), serving to nullify or minimize these recent policy decisions recognizing this technology.

- **Current DRGs 557, 558** – CMS agreed, effective after April 1, 2003, to increased payments for drug-eluting stents. These changes, deemed necessary and appropriate by CMS after careful examination and analysis, would simply be eliminated under movement to CS-DRGs. In 2005, CMS noted that the resource differences between bare metal and drug-eluting stents, stating

“We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate...” Federal Reg. Vol. 70, 47294, August 12, 2005.

- **Current DRGs 551-552.** In FY 2006, CMS introduced new severity classifications for a number of cardiovascular DRGs based on the presence major cardiovascular conditions (MCV). CMS stated: “Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly increased resource use for nine surgical cardiovascular DRGs.”

Under the proposed CS-DRGs, pacemaker implants would be grouped to CSA-DRGs 228-233 (Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock), reverting back to classification based on presence or absence of heart failure, AMI, or shock, rather than major cardiovascular condition.

- **Current DRG 103** – In last year’s Final Rule, CMS made a significant coding change to account for the use of an external heart assist devices to recover native heart function. Heart assist devices designed for recovery are increasingly used to treat acute heart failure, thus, avoiding the need for heart transplantation. However, patients with recoverable heart conditions may be as ill and utilize as many hospital resources as a heart transplant patient. CMS recognized the need to accurately reimburse for the use of recovery heart assist devices in the FY 2006 Final Rule, and noted that

“...our data do support that patients having an external heart assist device implanted and removed during the same admission are comparable to in costs and average length of stay to heart transplant and implantable heart assist system patients in DRG 103. ... we believe that consideration of the comments is best served by recognizing this unique subset of patients,

and making a DRG change that acknowledges the increased resources required for improvement in their care. ”

The implementation of CS-DRGs would de-couple external heart assist devices from heart transplantation and regroup them with considerably less costly devices.

As a result, reimbursement for external heart assist devices would be reduced significantly and the coverage decision made less than one year ago would be nullified. There has been no clinical data or considered policy justification for this change and it is difficult to understand the rationale for CMS to propose undoing their carefully crafted analysis in less than one year.

AdvaMed is against the elimination of carefully considered DRG reclassifications, performed with stakeholder input and/or pursuant to notice and comment rulemaking -- some as recently as last year -- that would occur if CS-DRGs were to be implemented. We believe that the CS-DRGs are therefore not ready for implementation in FY 2007, and should not be implemented until the problems noted above are addressed fully. Rather than revisiting past policy decisions, AdvaMed believes that CMS should develop and propose a system that establishes severity adjustments for the current DRGs (after eliminating the current CC/no-CC splits), including all of those DRGs that reflect complexity of treatment for some patients. We note that CMS indicated in the Proposed Rule that “a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system.” A good first step would be to continue to recognize those technologies that have already been deemed to be worthy of additional consideration under the DRG system.

AdvaMed believes CMS should devote significant additional study to the implementation of any refined or revised DRG system, and seeks opportunities to work with CMS in making revisions to the current DRG system to ensure appropriate recognition for severity, complexity and patient benefit.

VI. DRG Reclassifications

“DRGs: Carotid Artery Stents”

In the Proposed Rule, CMS rejects requests to create a new DRG(s) for carotid stenting or to assign all carotid stenting cases paid under DRGs 533 (Extracranial Vascular Procedures with C/C) and 534 (Extracranial Vascular Procedures w/o C/C) to DRG 533 on an interim basis for FY 2007. Instead, CMS proposes continuing to pay for carotid stenting procedures under DRGs 533 and 534, which would result in payment decreases of 2-3% under the proposed HSRVcc weights.

AdvaMed strongly disagrees with CMS’s proposal to keep the current DRG assignments for CAS, as this step would not adequately reflect the resources consumed in the procedure.

Stroke is a leading cause of death and disability for Medicare beneficiaries. Carotid stenting provides an alternative, less invasive treatment option for beneficiaries at risk of stroke but who are not good candidates for surgery. FDA has approved two carotid stent systems for use in the population at high risk for surgery and it is expected that FDA will approve additional manufacturers' carotid stent systems in 2006. CMS has recognized the value of carotid artery stenting by expanding coverage to a subset of the Medicare population that is at high risk for surgery. Adequate payment for carotid stenting is essential to assure that Medicare beneficiaries have access to the therapy.

In the Proposed Rule, CMS includes an analysis of the 2005 MedPAR data which compares the charges and length of stay ("LOS") associated with carotid stenting procedures to the average charges and LOS for all procedures in DRGs 533 and 534. The analysis finds that while the average length of stay was slightly shorter for the carotid stenting cases than for all other cases in DRGs 533 and 534, the average charges for the carotid stent cases were higher by \$6,968 in DRG 533 and \$7,804 in DRG 534. The average charge for a carotid stent case in DRG 534 is \$25,000, much closer to the average charges for DRG 533 (\$26,376) than the average charges for DRG 534 (\$17,196).

The charge data presented by CMS suggests that carotid stenting cases are underpaid in both DRG 533 and 534. However, CMS suggests that the higher charges associated with carotid stenting may result from higher device mark-ups rather than higher procedure costs. Specifically, CMS observes most of the cases assigned to these DRGs, unlike carotid stent placements, do not involve a device cost. For this reason, CMS concludes that "the higher average charges and lower length of stay for the cases involving carotid artery stents are likely accounted for by the cost of the device." Yet despite acknowledging that the device "likely" accounts for the higher costs, the Agency goes on to speculate that the "hospital's charge markup may also explain the higher charges but lower average length of stay," citing a national average CCR for medical equipment and supplies of approximately 34 percent.

However, CMS does not provide any actual evidence that markup -- and not the cost of the device -- accounts for the charges associated with carotid stenting. Likewise, estimating device markups based on the national average CCR for the category of medical equipment and supplies is inappropriate. This broad category encompasses products with very different markup levels, ranging from higher cost, low-markup devices like stents to lower-cost, high markup medical supplies. As described above in our discussion of the need for an adjustment to address the issue of charge compression, implantable devices typically have lower mark-ups than other supplies and equipment rather than higher mark-ups as suggested by CMS, so the overall charges for carotid stenting are probably deflated relative to other procedures in the DRG. Given our findings above on charge mark-ups for implantable devices, we recommend that CMS rely on its standard current methodology of using MedPAR charge data to determine appropriate DRG assignment for carotid stenting.

In addition to questioning whether carotid stenting cases actually are underpaid, CMS is proposing postponing resolution of this issue until the consolidated severity-adjusted DRG system is implemented. We disagree with this proposal. CMS already has acknowledged that the severity-adjusted DRGs as currently constituted do not adequately capture the costs associated with many medically complex procedures that use advanced medical technology, and that refinements will need to be adopted. CMS has given no indication of how those refinements might work, however, or the time frame for implementation of such refinements. Thus, relying on future severity adjustments is not a viable alternative for addressing the current inadequacy of payment for carotid stenting procedures – especially since CMS already has the authority to modify payment in FY 2007 under the current DRG framework.

AdvaMed urges CMS to create a new DRG or pair of DRGs for carotid artery stenting effective FY 2007.

Alternatively, as an interim solution, we urge CMS to assign all carotid artery stenting cases to DRG 533 for FY 2007, pending further analysis of MedPAR data and the possible future implementation of severity-adjusted DRGs.

This would enhance the DRG groupings in several important ways:

- **Mean standardized charges for DRGs 533 and 534 would be more tightly aligned:** The difference in mean standardized charges for the proposed DRG 533 (all discharges) and the proposed DRG 533 (CAS cases only) is 12% (versus 26% as currently configured);
- **Little or no impact to overall standardized charges for both DRG 533 and DRG 534:** (0% impact to standardized charges for DRG 533 and -3% impact to standardized charges for DRG 534 if proposed changes are implemented);
- **Greater predictability within both DRGs:** standard deviations for DRGs 533 and 534 would be slightly reduced if CAS cases were all grouped to DRG 533; and
- **Clinical criteria for procedures in each DRG are more appropriately aligned,** given that all CAS patients eligible for Medicare coverage are at high risk for surgery due to the presence of a detailed list of complications and comorbidities. By definition, these patients require a higher level of procedural complexity and resource intensity, which justifies all CAS cases being assigned to DRG 533.

“DRGs: Neurostimulators”

Kinetra is an implantable dual array neurostimulator pulse generator used in deep-brain stimulation for the treatment of Parkinson’s disease that was approved for a new technology add-on payment beginning in FY 2005. The add-on payment will end at the close of the current fiscal year, but a request was made to reassign the therapy from DRGs 001-002 to DRG 543, a more clinically and cost coherent DRG.

While on average the charges associated with Kinetra procedures are significantly more consistent with the charges in DRG 543 than DRGs 001-002, CMS rejected the proposed reassignment on the basis that it believed the charges associated with the device (and thus the overall procedure) were marked up excessively, and because it wanted to postpone resolution of the issue until the consolidated severity-adjusted DRG system was implemented.

Similar to our comments on the proposed reclassification of carotid stent procedures, we disagree with CMS’s statements that mark-ups associated with the Kinetra device are excessive and overstate the total charges of the implant procedure. As described above, we are submitting information in this letter that we believe conclusively finds that hospital charge mark-ups for implantable devices are in fact significantly lower than for other, lower cost supplies and equipment. (Based on this finding, we are submitting a proposal that would make adjustments to correct for the impact of charge compression in the setting of cost-based weights).

We therefore believe that, if anything, the total charges found in MedPAR associated with Kinetra implant procedures may be understated relative to other procedures in DRGs 543, 001, and 002, and that the reassignment of the technology to DRG 543 is fully warranted. Given that we are recommending deferral of the implementation of the consolidated severity DRGs until at least FY 2008, we believe the CS-DRGs should not be a factor in CMS’s decision to make DRG reassignments this year. **We strongly encourage CMS to reclassify the Kinetra procedure – determined by CMS to be a significant clinical improvement over previous therapy for Parkinson’s disease – to the more appropriate DRG 543.**

VII. New Technology DRGs (“New Technology”)

AdvaMed believes that the new technology add-on program is a vital payment mechanism that helps to ensure patient access to new medical services and technologies and to recognize the often higher costs of new technologies more quickly than would otherwise be possible through the underlying DRG system. AdvaMed has worked extensively with both Congress and CMS to create and improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies. AdvaMed and its member companies are committed to continuing to work with CMS to

ensure that the program works as smoothly as possible, and continues into the foreseeable future.

In the Proposed Rule, CMS indicated that it intended to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments. CMS invited public comment on this issue. AdvaMed believes that the new technology add-on payment is an absolutely essential element of hospital inpatient reimbursement, and that it should be maintained regardless of whether CMS moves toward an estimated cost reimbursement system.

Given the sweeping and complex changes, and uncertainties regarding this year's Proposed Rule, and the potential for a large degree of refinement prior to implementation, AdvaMed supports a robust new technology add-on program that fully recognizes new technologies. At a minimum, we believe that CMS should follow the MMA's report recommendation and raise the new technology add-on payment percentage from 50% to 80% of the difference between the standard DRG payment and the cost of the procedure with the new technology. Doing so would offer some stability and consistency for hospitals providing their patients access to new technologies.

CMS appeared highly non-committal to initial new technology applicants in this year's Proposed Rule. There were three technologies that were proposed for an initial application for the new technology add-on payment, and CMS declined to be definitively positive on any of them. CMS noted that one, C-Port met the threshold criteria, but also noted an FDA finding that the device was 'substantially equivalent' to predicate devices.

In its discussion of NovoSeven, CMS disclosed very little analysis regarding whether the product met the "newness" criterion. It appears that CMS will wait to see if the device gains FDA approval before it engages in definitive analysis. However, as we have pointed out in past comment letters, we believe that CMS should clearly signal its intentions while awaiting additional information. The comment period after the Proposed Rule is released is the last opportunity for many of these technologies to engage in meaningful dialogue with CMS on whether they meet the criteria, and CMS should define its position as thoroughly as possible in the Proposed Rule to allow the best opportunity for input during the comment period. CMS's reluctance to disclose its preliminary views on these new technology applicants hampers discussion during the comment period.

The third new applicant, the X-Stop Interspinous Decompression System, was found by CMS to satisfy both the newness and cost threshold criteria, although CMS expressed concerns regarding whether the device met the substantial clinical improvement criteria. CMS was again non-committal when it offered no preliminary indication on whether it believes X-STOP meets the substantial clinical improvement criterion, and noted that it will await receipt of additional comments before making a decision.

Honorable Mark B. McClellan, M.D., Ph.D.

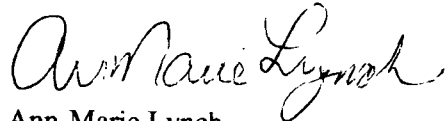
June 9, 2006

Page 28

AdvaMed appreciates that CMS took a firm preliminary position on the new technology renewal applicants, and proposed to continue all but one. However, we would like to see CMS be more willing to indicate its preliminary views regarding initial new technology applicants, as this would enhance stakeholder dialog with the Agency on these issues during the comment period.

AdvaMed supports movement toward improved accuracy under the IPPS, so that patients continue to have access to advanced medical technologies. We look forward to working with you and your staff to address the issues discussed in this letter. Please contact us directly if you have any questions or concerns. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

A handwritten signature in cursive script that reads "Ann-Marie Lynch". The signature is written in black ink and is positioned above the printed name and title.

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org



AdvaMed

Advanced Medical Technology Association

cc: Herb Kuhn
Tom Gustafson
Liz Richter
Marc Hartstein

Submitter : Dr. Jamal Islam
Organization : UTMB
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. lisa walinski
Organization : hinsdale family medicine residency
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,

Lisa Walinski, D.O.

Submitter : Dr. Marc Matthews
Organization : Mayo Clinic
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Marc Matthews, MD

Submitter : Dr. Donald Spaeth
 Organization : Dr. Donald Spaeth
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Background

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Submitter : Mr. John Carroll
Organization : Cardiac Partners, LLC
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

See Attachment (second copy of letter was inadvertently attached - we apologize)

CMS-1488-P-878-Attach-1.PDF

CMS-1488-P-878-Attach-2.DOC

ATTACHMENT 1 TO # 878

Friday, June 9, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTENTION: CMS-1488-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

We appreciate the opportunity to comment on the proposed rule change for the payment rates for the 2007 fiscal year. Cardiac Partners manages five cath labs in several states including Colorado where we work directly with the hospital in each instance.

In association with these major health care providers, we manage implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of the services we provide in our cath labs, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

At this time, the bulk of hospital costs these services are paid out to the vendors of implantable devices. Drug-eluting stents are supplied only by two vendors. I understand that two additional vendors will enter the drug-eluting stent market within 18 to 24 months. I urge CMS to not reduce drug-eluting stent prices until after the competitive market impacts and reduces the implantable supply costs to the hospital. Otherwise, the hospital is squeezed in the middle.

Similarly, the bulk of the cost of hospitalization for implantable cardiac defibrillators (ICDs) is for the cost of the device itself. The ICD technology is still relatively new and the manufacturers continue to leap-frog in technologies. The competition has been in technological innovation, rather than price reductions. Perhaps a small decrease in reimbursement would signal to the manufacturers that they should begin to compete on price, rather than technological innovations. Again, to reduce reimbursement puts the hospital in the middle and creates a financial squeeze.

First, this change adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

Medicare FY07 Inpatient Payment

June 9, 2006

Page 2

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, hospital technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on the hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than the hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure the cardiac care industry now faces the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area built up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by the hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

John S. Carroll, Principal
Cardiac Partners, LLC
1200 N. El Dorado Place, B-200
Tucson, Arizona 85715-4444
(520) 886-7889
Fax: (520) 886-1768
jcarroll@cardiacpartners.com

cc: Wayne Allard, US Senator

cc: Ken Salazar, US Senator

Wayne Allard, Colorado US Senator
521 Dirksen Senate Office Building
Washington, DC 20510
Fax DC: 202-224-6471

Ken Salazar, Colorado US Senator
Pikes Peak Region
3 South Tejon, Suite 300B
Colorado Springs, CO 80903
Fax DC: 202-228-5036

ATTACHMENT 2 TO H878

Friday, June 9, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTENTION: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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Wayne Allard, Colorado US Senator
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Fax DC: 202-224-6471

Ken Salazar, Colorado US Senator
Pikes Peak Region
3 South Tejon, Suite 300B
Colorado Springs, CO 80903
Fax DC: 202-228-5036

Submitter : Dr. Elizabeth Baxley
 Organization : Department of Family and Preventive Medicine
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Ms. Ellen Kugler
Organization : National Association of Urban Hospitals
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

See attached letter

CMS-1488-P-881-Attach-1.DOC

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

June 9, 2006

Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1488-P
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Issue Identifier: DRGs: Severity of Illness

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) to express our views on the consolidated severity-adjusted DRGs that were presented in the proposed FY 2007 Medicare inpatient prospective payment system rule.

For more than a decade, NAUH has been a strong proponent of upgrading the Medicare inpatient prospective payment system by introducing a severity-based DRG system, and we are pleased that the Centers for Medicare & Medicaid Services (CMS) is moving in this direction. We also have been very supportive of the APR-DRG system on which CMS's proposed consolidated severity-adjusted DRG system is based. Nevertheless, we are concerned about the manner in which CMS has chosen to implement a severity-based DRG system – through consolidation – and would like to convey our concerns about the manner in which this consolidation has been undertaken and about the agency's plans for its implementation. Because the planned implementation of this system is still more than a year away, we also identify areas where we believe it would be beneficial for CMS to provide additional information that will enable the hospital industry to offer more informed, constructive comments about this proposed system.

We also would like to respond to CMS's request for feedback on the subject of Medicare claims coding and outliers.

The Timing of the Proposed Implementation

NAUH recognizes that an important part of CMS's job is to create and employ a Medicare payment system that pays providers as accurately, precisely, and rationally as possible for the services they deliver to Medicare beneficiaries. We also recognize that introducing a severity-based DRG system is an important step toward a system that more closely matches payments with the resources expended to provide care. We are very pleased with CMS's desire to improve the Medicare payment system and support the general approach that the agency is taking. NAUH also is pleased that CMS is previewing this proposal this year in anticipation of implementing it in FY 2008. This will give hospitals ample opportunity to understand the proposed system – and give CMS ample time to make any needed adjustments.

NAUH does not believe, however, that CMS should implement the proposed hospital-specific relative value weights (HSRVs) a year before it introduces a new DRG system. The impact analyses that we have seen show that the HSRVs, when paired with the current DRG system, do not allocate resources to the services that the HSRVs will when paired with the proposed consolidated severity-adjusted DRGs. In fact, it appears that in many situations, they will allocate resources in opposite directions. Consequently, NAUH feels it would be inappropriate to direct some resources in a totally different direction in FY 2007 and then reverse directions in FY 2008. Under separate cover, NAUH has submitted comments to CMS on the proposed HSRVs. In that letter, we outline our concern that we believe CMS has not yet provided sufficient information about the HSRVs for us to determine either their impact on individual hospitals or their success in achieving their stated objectives. We do have enough information, however, to be able to state unequivocally that the HSRVs must be implemented only in concert with consolidated severity-adjusted DRGs and not by themselves.

We are not alone in this view. Shortly after CMS published its proposed Medicare inpatient prospective payment system rule for FY 2007, MedPAC – which had previously recommended that CMS adopt a severity-based DRG system – wrote to CMS administrator Dr. Mark McClellan to inform him that it, too, believes that the two steps should be implemented at the same time, writing that

... we are concerned that you are proposing to delay the severity changes until FY 2008. It is important to correct for differences in patients' severity concurrently with the corrections for charging distortions.

House Ways and Means Committee Chairman Bill Thomas expressed a similar view in a May 30 letter to Dr. McClellan, writing that

MedPAC analysis revealed significant inaccuracy in the current payment system and recommended implementation of both the new severity-refined DRGs and a revised method for weights at the same time.

For these reasons, we urge CMS to delay implementing HSRVs, as called for in the proposed FY 2007 Medicare inpatient prospective payment system rule, until it can implement a severity-based DRG system at the same time.

Concerns About How DRGs Have Been Consolidated

As noted, NAUH supports implementation of a severity-based DRG system for Medicare and supports the APR-DRG system on which CMS's proposed consolidated severity-adjusted DRGs are based. Nevertheless, we have a number of concerns about how the APR-DRG system has been transformed into CMS's proposed consolidated severity-adjusted DRGs.

The Methodology for Consolidating Low-Volume DRGs

As long-time supporters of the APR-DRG system, NAUH is very familiar with that system. Based on that familiarity, we have a number of concerns about the manner in which that system was consolidated into the proposed consolidated severity-adjusted DRGs.

We question, for example, how many DRGs were consolidated because of low volume. Because CMS is proposing its implementation in FY 2008, not in FY 2007, we believe it would be appropriate for CMS to identify the specific DRGs that were identified for consolidation and provide the criteria that were used to select them. As long as the consolidated DRGs are appropriately similar, NAUH has no objection to such consolidations.

Using Charges to Consolidate Other (Non-Low-Volume) DRGs

NAUH has similar concerns about the consolidation methodology used for non-low-volume DRGs. Because of the significant amount of consolidating that was undertaken to reduce the original APR-DRG system (with 1258 DRGs) to the consolidated severity-adjusted DRGs (with 861 DRGs), NAUH assumes that not all of the consolidating was done because of low volume. The proposed rule implicitly confirms this, stating that "By using a three-digit number for the consolidated severity-adjusted DRGs, we also avoid the need for reprogramming of computer systems that would be necessary to accommodate a change from the current three-digit DRG number to separate fields for the base consolidated severity-adjusted DRG number and the severity of illness subclass." If this is indeed true, NAUH urges CMS to reconsider this decision. This vital aspect of the most important change in the Medicare DRG system in more than 20 years should not be influenced to such a significant degree by routine systems and software concerns.

Because of this apparent decision to consolidate DRGs for reasons other than low volume, NAUH asks CMS to share its criteria for identifying the DRGs that it decided could be consolidated with one another because they were sufficiently similar to enable their combination in a manner that would enhance the accuracy of Medicare payments. The proposed rule suggests that many consolidations were determined based on hospital charges. We find this surprising because in the section on the proposed rule addressing HSRVs, CMS states that charges are not a good measure of the actual costs that hospitals incur when providing care. NAUH agrees: charges are not a good measure to use when consolidating if you plan to develop the weights for the DRGs using HSRVs. NAUH is especially concerned about the use of charge data instead of cost data when CMS consolidates across multiple DRGs within major diagnostic categories without accounting for the differences in the cost-to-charge ratios of different hospital cost centers. This is important because it is a major component of the HSRV system that CMS intends to use in concert with consolidated severity-adjusted DRGs. We are concerned that this, when used together with the HSRVs, will contribute to the consolidation of DRGs with very different HSRVs.

NAUH would like to see an average charge comparison for the DRGs that have been consolidated. We also ask CMS to develop and share a comparison of the HSRVs calculated with the APR-DRG system and those calculated with the consolidated severity-adjusted DRGs. Whether those relative values remain fairly constant under both systems should be a more appropriate barometer of whether the DRGs are sufficiently similar and suited for consolidation than whether their charges are similar. This will be useful because there may be instances in which DRGs with very disparate relative weights have been consolidated, and we would like to be aware of such situations, if there are any, and have an opportunity to address them before the new system is implemented.

NAUH also is concerned that DRGs that meet CMS's current criteria for consolidation could, at some point in the future, be far less suited for continued consolidation. Changes in medical technology, for example, could significantly increase or decrease the cost of providing one service within a consolidated DRG while leaving other services within that DRG more or less unaffected. The developers of APR-DRGs spent a great deal of time testing and retesting their DRGs to ensure consistency and a solid rationale for their groupings. CMS has not shared any data demonstrating a similar approach using data over many years for validation and verification. For these reasons, NAUH urges CMS to implement, as part of any consolidated severity-adjusted DRG system, a systematic plan for the periodic re-evaluation of the consolidations made to the APR-DRGs. This should be done annually, at least for the first few years, and then at least every five years, if not more often.

The Limiting of Diagnosis and Procedure Codes

One of the strengths of the APR-DRG system is its recognition of the impact that multiple diagnoses have on resource consumption. The system, we feel, offers an excellent opportunity for hospitals to convey to Medicare exactly what they have done for their patients and for Medicare to pay hospitals with unprecedented accuracy for those services. Limiting the proposed consolidated severity-adjusted DRG system to just nine diagnosis codes and six procedure codes, however, negates much of the system's overall accuracy and precision. NAUH urges CMS to update its system's capacity so it can recognize the full array of diagnosis and procedure codes built into the APR-DRG system. Because this is such a significant revision of the Medicare DRG system, we encourage CMS to do it completely, not partially.

Claims Coding

In the proposed FY 2007 rule, CMS asks hospitals for their views on the potential challenges posed by the need to ensure complete and accurate claims coding upon implementation of a new DRG system while also achieving budget-neutrality. NAUH believes it is difficult to project the effect that coding issues may have on overall Medicare inpatient expenditures.

We do feel comfortable, however, suggesting that the impact should not be nearly as great as when the Medicare DRG system was first introduced. At that time, hospitals did not capture nearly as much information as they do now, so it was a learning experience for them. Today, many hospitals are already capturing the data they will need for a consolidated severity-adjusted DRG system.

Historically, CMS has not retroactively adjusted payments to correct for the differences between the estimated and actual effects predicted for budget-neutral adjustments. Because there is no data that CMS can use to predict the financial impact of a new DRG system, an estimated adjustment could be grossly inaccurate. NAUH suggests that to avoid unjustly underpaying or overpaying some providers, any necessary budget-neutrality adjustments should be reconciled retroactively.

Outliers

While CMS has postponed its analysis of MedPAC's recommendations for outlier policy change, it has invited comment on those MedPAC proposals. NAUH objects to MedPAC's proposal to adjust the DRG relative weights to account for differences in the prevalence of high-cost outlier cases. The sole purpose of this proposed change appears to be to reduce the relative values within selected DRGs in which outliers are common for the purpose of funding the statutorily mandated pool of funds required to pay those outlier cases. This would have the unfortunate and, we believe, inappropriate effect of requiring only the hospitals that provide the kinds of care that result in outliers to pay for all of that care and absorb all of the financial losses associated with it themselves instead of spreading those costs and those losses among all hospitals.

It is important to keep in mind, in considering this issue, that outlier payments are essentially insurance, or stop-loss protection, for hospitals against the unexpected and potentially enormous costs they may sometimes incur treating just a single medical case, or only a few cases. NAUH recognizes that a more precise, severity-based DRG system should reduce the number of outliers by capturing more of those cases within the new DRGs – and also reduce the problem of hospitals seeking to take only the simplest, lower-cost, most profitable cases – but the remaining outlier cases can prove devastating to the financial health of an institution. The concept of outlier payments is to spread the impact of such cases among all providers and the public sector and not force individual hospitals to bear them alone.

Consider the following example of how MedPAC's approach could undermine this concept. A region has five hospitals, all of which provide some level of care to burn patients but one of which has special expertise in delivering such care. Within the region, the most difficult cases are treated by the hospital that specializes in burn care. Some of the cases that the other four hospitals send to the hospital with the special expertise will end up as outliers, but many will be patients who truly need that specialized care but who do not rise to the level of outliers. Within their specific DRG, these will be the most expensive patients to treat, yet because the relative weights have been reduced to pay for the outlier pool, the hospital that specializes in treating the most complex patients will see its regular reimbursement reduced to pay for outliers. Under the current system, all five hospitals help absorb the cost of this expensive but essential care; with the proposed changes in the relative weights, the hospital that has invested the most money in this type of care, and has developed the most expertise, would pay for the outliers itself while all of the hospitals would benefit from its willingness to invest in the resources to be the burn center for the entire community. In addition to being unfair, this could discourage more hospitals from developing special expertise in response to clear community needs (even now, relatively few hospitals cultivate such special capabilities because the financial price they pay for doing so is so great) while also encouraging hospitals that have already done so to abandon it because it has become too costly. For these reasons, NAUH opposes adjusting the DRG relative weights to account for differences in the prevalence of high-cost outlier cases.

* * *

NAUH is pleased that CMS is moving toward a Medicare severity-based DRG system. This is a worthy goal – a goal that NAUH has advocated for more than a decade. As is the case with any new, major policy implementation, reasonable people can disagree about how to undertake individual steps. In this letter, we have raised a number of concerns that we hope CMS will agree to consider and to address, and we are pleased that the plan to implement the proposed consolidated severity-adjusted DRG system leaves a full year for careful consideration and fine-tuning of this much-needed improvement in the Medicare payment system.

At this point, however, the hospital industry has not been given enough information to determine the impact of the proposed changes on either a system-wide or a hospital-specific basis, so we believe it is appropriate to withhold our final judgment until such information is provided. With more than a year remaining until the system's planned implementation, we hope that CMS will work with us to make this possible.

We appreciate your consideration of NAUH's views, invite any questions you may have about them, and are prepared to work with CMS officials and others in the hospital industry toward the best, most precise payment system possible.

Sincerely,

Ellen J. Kugler, Esq.

Submitter : Dr. Jade Schechter
Organization : Dr. Jade Schechter
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 Jade Schechter MD

Submitter : Dr. Alan LeBato
Organization : LSUHSC Family Medicine Residency in Lake Charles
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,

Submitter : Dr. Velinda Paranal
 Organization : Santa Monica Bay Physicians
 Category : Physician

Date: 06/09/2006

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Velinda Paranal, MD

Submitter :

Date: 06/09/2006

Organization :

Category : Physician

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Sincerely,

Dennis Dimitri MD

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Submitter : Dr. DENNIS STUART
Organization : Dr. DENNIS STUART
Category : Physician

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

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Sincerely,
(Dennis O. Stuart MD, ABFP)

If you have any questions, please feel free to contact me at (910-738-3957).

Submitter : Dr. Harry Clifton Knight
Organization : Community Health Network - Indianapolis, IN
Category : Physician

Date: 06/09/2006

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs. Thank you for your careful consideration of this important issue.

Sincerely,

Harry Clifton Knight, MD

Submitter : Dr. Suzanne Eaton Jones
Organization : Dr. Suzanne Eaton Jones
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Suzanne Eaton Jones, MD, MPH

Submitter : Dr. Andrew Wright
Organization : Marshall University
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. Austin Bailey
Organization : Fort Collins Family Medicine Residency Program
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient CareI firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Austin Bailey, MD
Program Director
Fort Collins Family Medicine Residency Program
Poudre Valley Hospital

Fort Collins, Colorado
bail@pvhs.org

Submitter : Dr. KEVIN PEARCE
Organization : UNIVERSITY OF KENTUCKY
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a vice chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

With the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

I cannot imagine how my faculty and myself would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if not just impossible. To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients would be futile. The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden at high personnel costs which we (and every training program I know of) could not pay for.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Ms. Kathy Buto
Organization : Johnson & Johnson
Category : Device Industry

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-1488-P-893-Attach-1.DOC

893



KATHLEEN A. BUTO
VICE PRESIDENT
HEALTH POLICY
GOVERNMENT AFFAIRS & POLICY

1350 EYE STREET, N.W.
WASHINGTON, D.C. 20005-3305
TEL. (202) 589-1000
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June 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Proposed Changes to Hospital Inpatient Prospective Payment Systems, FY 2007
(CMS-1488-P)

Dear Dr. McClellan:

On behalf of Johnson & Johnson, I am pleased to submit comments and recommendations in response to the Proposed Changes to Hospital Prospective Payment Systems, FY 2007, issued in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) on April 25, 2006. This letter summarizes our recommendations in response to the proposed rule, and the first attachment to this letter discusses our comments in detail.

Johnson & Johnson (J&J) is the world's most comprehensive and broadly-based manufacturer of health care products for the consumer, pharmaceutical and medical devices and diagnostics markets. For 120 years, J&J has supplied hospitals with a broad range of products and has led the way in innovation; from the first antiseptic bandages and sutures to the first drug-eluting stents. The consistent fundamental objective of J&J is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life.

In that regard, our greatest concern with this proposed rule is the threat that it poses for patients' access to the latest medical advances. Taken together, the proposed changes represent a fundamental and disturbing shift away from Medicare's current and past efforts to ensure full access to advanced medical technology for beneficiaries. The proposals particularly harm academic medical centers that lead the way in technology adoption and development. First, the proposed methodology would remove all cost variation across hospitals from the calculation of the diagnosis-related group (DRG) weights, without fully analyzing or understanding the reasons why some hospitals may have higher average costs than others (even after adjusting for patient mix). Second, the proposed methodology estimates costs using average cost-to-charge ratios that ignore the variations across hospitals in patient volume, thereby skewing the results toward smaller hospitals and negatively impacting large hospitals. Third, CMS proposes a severity-

adjusted DRG system that would roll back the clock on past policy decisions recognizing the higher costs of beneficial medical technologies that are already in widespread use

We support efforts to improve the accuracy of the DRG weights, and better reflect variations in patients' severity of illness. However, we believe the proposal is flawed from both a methodological and policy perspective, and should be delayed to allow more complete consideration before such sweeping changes are implemented. In our opinion, the proposal, if implemented, would unnecessarily disrupt current positive trends that reflect medical advances that enable less invasive patient care.

SUMMARY OF RECOMMENDATIONS

1. Withdraw the methodologically flawed proposal for 2007 and use the current standardized charge-based approach.

As detailed in our attached comments, there are several methodological flaws in CMS' proposed methodology that must be corrected in order to maintain the overall integrity of the DRG system. Correcting these flaws significantly affects the payment impacts of the change, and therefore, at a minimum, it is necessary to publish a corrected methodology for public comment prior to implementation.

2. Delay implementation of the hospital-specific relative value methodology at least until further analysis is conducted of the impacts and interactions with cost-based weights.

Hospital-specific relative values (HSRV) eliminate the effects of all cost variation between hospitals, without regard to whether the costs are legitimate or otherwise compensated through the payment system. Currently, CMS standardizes hospitals' charges to remove variation due to identifiable factors such as geographic variation in labor costs and treating a disproportionate share of low income patients, but does not remove the effects of other unidentified costs. Especially prior to implementation of a refined severity DRG system, some of the costs being removed are likely due to patient severity that is unexplained by the current DRG system.

In addition, the attachment describes past research that found the HSRV method has a significant negative impact on hospitals that perform above average numbers of cardiac surgical or interventional procedures, due to cross-subsidization through hospitals' internal charging practices. This raises questions about the interactions of the HSRV methodology and cost-based weights, which also adjusts for variations in charging practices. This issue needs to be fully explored and understood before proceeding with a combination of HSRV and cost-based weights.

3. Abandon national average cost-to-charge ratios (CCRs) and instead use hospital-specific CCRs as are currently used for the outpatient prospective payment system (OPPS).

CMS believes that using national average rather than hospital-specific CCRs enables it to use claims data from a different year than the cost report data. However, it is not readily

apparent that the same objective could not be achieved using hospital-specific CCRs. In fact, as outlined in the attachment to this comment letter, we believe this would be more accurate (because it matches CCRs with charges relative to hospitals that actually perform each DRG) and administratively simpler (because it avoids the step of calculating national averages) than either the proposed national average CCR methodology or a corrected version.

4. The cost reports are inadequate to support an accurate cost-based DRG system.

While we support the concept of cost-based DRGs, we are concerned the cost report information necessary to accurately support this system is not currently available. For example, charge compression is an ongoing concern under the OPSS. Although charge compression also biases the charge-based DRG weights downward, the downward bias on device-intensive DRGs would be much more significant under cost-based DRG weights. Similarly, past research has shown the cost reports overestimate routine area costs and underestimate ancillary costs. These combined effects have the potential to cause cost-based DRG weights to systematically underpay for technologies that have the potential to reduce patient stays through less invasive procedures.

Therefore, we are recommending that CMS commission an expert panel to explore ways to better capture the information needed to support a cost-based DRG system. Ultimately this effort should identify changes to the cost reports that reduce the net information burden on hospitals, while improving overall payment accuracy. An example may be a separate cost center for implantable devices. The panel would report its recommendations by April 2007.

We also support further development of recent analysis to identify a potential adjustment for charge compression using more specific revenue center codes than are available from the cost reports. This analysis is described in some detail in AdvaMed's comments on this proposed rule. We believe this analysis could potentially support an adjustment if cost-based DRG weights are adopted in 2008.

5. We support implementing severity-adjusted DRGs that better reflect the resources hospitals use to treat different types of patients, but CMS' proposed system is seriously flawed because it eliminates numerous existing DRGs that recognize the higher costs of some medical technologies.

We believe a starting point for any severity-adjusted DRG system that CMS would adopt is that it incorporates the current DRGs that CMS has already created to recognize additional costs of medical technology. CMS has indicated its interest in incorporating case complexity into severity-adjusted DRGs. The place to start in this effort would be to split the current base CMS DRGs into severity levels, rather than using 3M's APR-DRGs.

6. We support the position that severity-adjusted DRGs must be implemented at the same time as the other changes to avoid a whip-sawing effect on hospital payments from one year to the next.

This should be done no sooner than in FY 2008. We also believe that, like many previous major changes to the inpatient prospective payment systems, any eventual change to the DRG weighting methodology should be phased-in over a multiple year transition schedule.

7. We applaud the Administration's efforts to improve patients' access to information about the care they receive.

The proposed rule also discusses the Administration's interest in greater transparency of health care information, including charge and pricing data. We urge CMS to integrate pricing and quality information on appropriate evidence-based protocols. Patients need to know both the costs and benefits of the care they receive, in a format that is understandable and accessible. We also urge CMS to consider appropriate timeframes for measuring quality and costs, and to look across all sites of care delivery to assess efficiency.

J&J appreciates the opportunity to submit our comments and recommendations to CMS. We look forward to working with you and your staff to ensure the accuracy and fairness of Medicare's payments to hospitals.

Sincerely,

A handwritten signature in black ink that reads "Kathleen A. Buto". The signature is written in a cursive, slightly slanted style.

Kathleen A. Buto

Attachments: 2

Attachment 1: Johnson & Johnson's Comment Letter On CMS-1488-P

Hospital-Specific Relative Value (HSRV) Weights

As noted in the proposed rule, last year the Medicare Payment Advisory Commission (MedPAC) recommended changes to the DRG weight calculations out of concern that the charge-based weights have introduced bias into the calculation due to differential charge mark-ups for ancillary services among the DRGs. MedPAC's analysis concluded that, as a result of this bias, some DRGs are much more profitable than others, potentially giving rise to hospitals that specialize in those profitable DRGs.

CMS has proposed to adopt two of the approaches to calculating the DRG weights MedPAC proposed for 2007, with modifications in the methodology. First, CMS proposes to adopt the HSRV methodology. Second, CMS proposes to use cost-based weights rather than charge-based weights, although the methodology is substantially different from MedPAC's approach. Additionally, CMS has proposed to adopt patient severity-based DRGs beginning in 2008 or earlier, although it indicates it will consider an alternative implementation schedule for all of these changes. Our comments on this proposal are in a later section.

Although we support efforts to improve the payment accuracy of the DRGs to ensure hospitals are fully and fairly compensated for the services they provide, we have a number of concerns with the specifics of CMS' HSRV cost center (HSRVcc) methodology. We also have broader concerns about the HSRV methodology and cost-based DRG weights, and these concerns are described below.

HSRVcc Methodology Issues

CMS proposes an administratively simpler methodology than the one MedPAC used. According to CMS, this simpler approach facilitates annual updating of cost-based DRG weights. We support CMS' efforts to ensure the DRG weights are updated annually to reflect the most recent trends in inpatient care. It is essential that any DRG recalibration methodology use the most recently available claims data in order to adequately reflect new technology.

However, we believe there are methodological flaws as well as policy concerns associated with the HSRVcc methodology as proposed. In proposing this approach CMS stated its belief that it achieves similar results to the MedPAC methodology. We disagree with this conclusion based on the following analysis. Furthermore, even if these flaws are corrected, the resulting impacts on hospitals would be so different from those shown in CMS' proposed rule that there would not be an opportunity for the careful consideration that is warranted by such a monumental change in the DRG system.

Unweighted Means In the proposed rule, CMS uses national geometric mean CCRs for each of 10 cost centers. These means are unweighted and therefore do not account for the varying amount of Medicare charges each hospital contributes to total charges. As a

result, very small hospitals individually have just as much impact on the mean CCRs as larger hospitals. Mathematically, the only correct way to get from total hospital charges to total hospital costs is to use a charge-weighted average of the hospital CCRs.¹ Therefore, applying these unweighted ratios to charges does not produce an accurate estimate of the national average cost per case.

We are not aware of a similar calculation in Medicare's payment systems that weights providers equally regardless of their case volume. Using unweighted CCRs in the calculation to arrive at cost-based DRG weights raises questions about the consistency of the DRG weights with other aspects of the inpatient prospective payment system that have been calculated by weighting based on case volume, such as the standardized amounts, the indirect medical adjustment factor, and the adjustment for treating a disproportionate share of low-income patients.

We are also concerned that using national mean CCRs that are not weighted for charges has the potential to introduce instability into the DRG relative weights. Because small hospitals contribute to the calculation as much as large hospitals with many more charges, there is the potential that the mean CCRs could be disproportionately affected from one year to the next by the greater rate of closure or consolidation among small hospitals (or by these hospitals becoming critical access hospitals).

Trimming Routine Care CCRs CMS trimmed the cost center CCR calculation at 1.96 standard deviations from the geometric mean. That systematically excluded hospitals with high markups on routine accommodation charges from the CCR calculation. On net, the CMS trim excluded 238 large hospitals that together accounted for 25 percent of total routine accommodation charges. However, the CCRs for these hospitals appear to be predominantly correct. In addition, the charges for these hospitals are included in calculating the cost center DRG weights despite them being excluded from the calculation of the average CCR. The result is a significant mismatch between the CCRs and the pool of charges to which they are applied.

¹ Let H subscript hospitals, let Σ_H mean the sum across all hospitals, let Charges be the charges for routine days, and let Cost be the cost for routine days. Then:

- Cost at a hospital is charges times that hospital's CCR:

$$\text{Cost}_{(H)} = \text{Charges}_{(H)} * \text{CCR}_{(H)}$$
- Total US cost or total US charges is the sum of that, across all hospitals:

$$\text{Cost}_{(US)} = \Sigma_H \{ \text{Cost}_{(H)} \}$$

$$\text{Charges}_{(US)} = \Sigma_H \{ \text{Charges}_{(H)} \}$$
- Substitute Charges x CCR for cost (algebra)

$$\text{Cost}_{(US)} = \Sigma_H \{ \text{Cost}_{(H)} \}$$

$$\text{Cost}_{(US)} = \Sigma_H \{ \text{Charges}_{(H)} * \text{CCR}_{(H)} \}$$
- Multiply by 1, in the form of total US charges divided by total US charges.

$$\text{Cost}_{(US)} = [\frac{1}{\Sigma_H \{ \text{Charges}_{(H)} \}} * \Sigma_H \{ \text{Charges}_{(H)} * \text{CCR}_{(H)} \}] * \Sigma_H \{ \text{Charges}_{(H)} \}$$

$$\text{Cost}_{(US)} = [\Sigma_H \{ \text{Charges}_{(H)} \} / \Sigma_H \{ \text{Charges}_{(H)} \}] * \Sigma_H \{ \text{Charges}_{(H)} * \text{CCR}_{(H)} \}$$
- Re-arrange the terms (commutative law)

$$\text{Cost}_{(US)} = \Sigma_H \{ \text{Charges}_{(H)} \} * [\Sigma_H \{ \text{Charges}_{(H)} * \text{CCR}_{(H)} \} / \Sigma_H \{ \text{Charges}_{(H)} \}]$$

The term on the far right is the definition of the charge-weighted cost-to-charge ratio.

These CCR issues (unweighted means and excessive trimming of the data) are not minor technical errors, but rather they are significant methodological flaws with significant impacts on the analysis presented in the proposed rule. Where CMS estimates a routine accommodation CCR of 0.85, the charge-weighted, charge-trimmed, CCR is 0.55. Similarly, CMS calculated the intensive care CCR to be 0.72, while the charge-weighted, charge-trimmed CCR is 0.48. This affects the cost shares used to calculate the final DRG weights, overweighting routine and intensive care unit costs relative to ancillary costs, and grossly exaggerating the impact of a shift from standardized-charge DRG weights to cost-based DRG weights. The DRG weight changes in the CMS proposed rule are typically two to three times larger than the changes that would have occurred if correct CCRs had been used, and leaving the rest of the proposed methodology unchanged.

The following table illustrates the dramatic effects of these combined flaws. This table shows the average payment impacts of the proposed DRG changes on DRGs within major diagnostic category (MDC) 19, Mental Diseases and Disorders, and DRGs within MDC 5, Diseases and Disorders of the Circulatory System. The table shows that correcting the errors reduces the impact on MDC 19 due to the high proportion of routine area charges in these DRGs, and also reduces the negative impact on MDC 5, due to the high proportion of ancillary charges in these DRGs.

MDC	Title	Impact of Proposed Rule	Impact After Correcting Errors
5	Diseases and Disorders of the Circulatory System	-16%	-9%
19	Mental Diseases and Disorders	64%	46%

A simple way to understand the impacts of these errors is to compare total cost to total payment using the CMS CCRs. Even after adjusting for charge inflation between the 2003 cost reports and the 2005 claims, estimated costs per case using the CMS CCRs are at least 20 percent higher than Medicare's average payment per case. This suggests that either CMS' cost estimate methodology is seriously flawed or Medicare is paying hospitals well below costs. If indeed CMS were paying hospitals at only 80 percent of costs, the repercussions for Medicare patients would be massive. Therefore, it seems much more likely that CMS' proposed methodology is seriously flawed.

Moreover, the impact varies across DRGs depending on the proportion of routine or intensive care charges in the DRG, causing distortions in the relative weights and creating major disincentives for certain forms of treatment. By overestimating routine costs relative to ancillary costs, the proposal would actually create incentives favoring DRGs with longer lengths of stay relative to DRGs where higher ancillary costs are incurred but length of stay is reduced.

Impacts Misleading as Published Moreover, correcting these errors significantly affects the hospital impacts as displayed in the proposed rule, resulting in misleading conclusions about the effects of the proposed policies. For example, the proposed rule

suggests that rural hospitals would benefit by 3.0 percent from adopting the HSRVcc methodology (Table I, page 24407). If these errors were corrected, the positive impact on rural hospitals would be approximately 1.6 percent.

Consequently, we believe CMS must provide a full notice and comment period after correcting the errors noted above in order to allow hospitals and other stakeholders sufficient opportunity to evaluate this proposal. Such a change to the DRG weight calculation, the core of Medicare's payment for inpatient services, is much too significant to implement without a completely transparent and thorough evaluation by all interested parties.

National Average CCRs for 10 Cost Centers MedPAC's analysis matched claims data with the dates covered on the latest available cost reports. Because claims data are available sooner than cost report data, this approach necessitates using older claims data than are actually available. This would mean an even longer delay before data reflecting new medical technologies are used to establish DRG weights.

We acknowledge CMS' goal to minimize the administrative complexity of cost-based weights, and we fully support CMS' commitment to using the most recently available claims data in the DRG recalibration methodology. This at least ensures the most recent medical technology is reflected in the charge data. However, we have the following comments about several aspects of the proposal to use national average CCRs rather than hospital-specific CCRs.

We understand that CMS believes that using national average rather than hospital-specific CCRs enables it to use claims data from a different year than the cost report data. However, it is not readily apparent that the same objective could not be achieved using hospital-specific CCRs. In fact, we believe this would be more accurate (and administratively simpler) than either the proposed HSRVcc methodology or a corrected version with charge-weighted average CCRs.

Using hospital-specific CCRs would not require weighting and would incorporate data only for hospitals that actually perform specific DRGs. Notably, this is the approach CMS uses to establish payment rates under its outpatient prospective payment system (adjusting the most recently available claims data by prior years' hospital-specific CCRs).

In the proposed rule, CMS said the hospital-specific approach used by MedPAC required detailed cost center distinctions for each hospital that would require using the Standard Analytical File (SAF). According to CMS, using the SAF "increases processing time and adds further complexity to the process of setting the relative weights" (p. 24007). However, according to the record layout description for CMS' Medicare Provider Analysis and Review (MedPAR) file, the file CMS currently uses to set the charge-based DRG weights, MedPAR does include detailed charge information by cost center. Therefore, it is not apparent why CMS would be required to use the SAF if it were to adopt hospital-specific CCRs in a cost-based DRG methodology.

CMS also expressed concern that using hospital-specific CCRs would result in more data being excluded due to missing CCRs. However, no analysis is presented to indicate the extent to which this missing data may bias the calculation (i.e., relative to using national average CCRs that include hospitals that may not perform a particular DRG). Furthermore, to the extent this is a problem it could be resolved by using national average CCRs only for hospitals with missing CCRs.

HSRV Policy Issues

MedPAC recommended HSRV weights as a way to remove the effects of differences in hospitals' overall cost levels on the DRG weights. Currently, CMS standardizes hospitals' charges to remove variation due to factors that are otherwise recognized through the payment system, such as geographic variation in labor costs and treating a disproportionate share of low income patients. All other sources of variation across hospitals remain. However, using the HSRV methodology eliminates the effects of all cost variation between hospitals, regardless of the source or whether it is related to patient care (but not accounted for due to limitations in the patient classification system).

CMS notes "it is evident to us that some hospital types (for example, teaching hospitals) are systematically more expensive overall than the average hospital and certain case types are more commonly treated at these more expensive facilities. This fact results in an upward bias in the weights for these types of cases (page 24007)." We believe it is incumbent on CMS to better understand the sources for this variation prior to taking the position that none of it should be reflected in the DRG weights. Teaching hospitals in particular treat patients that are referred by other hospitals that are unable to provide the necessary specialized care. Eliminating all cost variation between teaching and nonteaching hospitals may, in fact, eliminate legitimate cost differences that are appropriately included in the current DRG weights. This would be especially problematic if CMS were to implement HSRV weights without adopting severity-adjusted DRGs, as proposed.

Furthermore, it is questionable whether it is necessary or appropriate to combine the HSRV methodology with cost-based weights. Analysis by RAND researcher Grace Carter found that "hospitals that lose under HSRV charge more than expected for their typical cases but not for their expensive cardiac surgery cases is consistent with these hospitals subsidizing very expensive services with excess revenue from less expensive services."² In other words, to the extent hospitals differ in how they mark-up charges across cost centers, the HSRV and cost-based weights both adjust for this effect.

Neither MedPAC nor CMS addressed this interaction of the HSRV methodology and cost-based weights. Specifically, both methodologies remove the effects of differential charge mark-ups. Therefore, it is unclear whether the two methodologies work independently to remove effects not adjusted by the other, or whether there is

² Carter, G., "How Recalibration Method, Pricing, and Coding Affect DRG Weights – Diagnosis-Related Groups," Health Care Financing Review, Winter 1992 (accessed May 2006 at: http://www.findarticles.com/p/articles/mi_m0795/is_n2_v14/ai_13275193/print).

inappropriate overlap between the two resulting in double-removal of the same differential mark-ups by both methodologies. To ensure the transparency and accuracy of the changes, this issue needs to be fully explored and understood before the two methodologies are adopted together.

Cost-Based Weights Policy Issues

Concern that different charge mark-ups across cost centers within hospitals (e.g., higher mark-ups in ancillary areas compared to routine areas) cause distortion in the DRG weights led MedPAC to recommend cost-based weights. At a conceptual level, cost-based weights should better reflect the actual resources hospitals employ to provide inpatient care. As noted previously, charge compression for costly medical devices is a current source of inaccuracy in the payment system.

However, because the claims submitted by hospitals currently reflect charges and not costs, the accuracy of cost-based weights is dependent on the data available to adjust charges to costs, specifically the CCRs. Research has shown that CCRs are inaccurate estimators of costs at the individual cost center level. Unfortunately, the problem of charge compression is compounded when using the current cost center CCRs to estimate costs.

One problem when trying to estimate costs by applying CCRs to charges on a claim is that this approach has been shown to overestimate routine area charges. One study found that routine and special care cost estimates for Medicare patients using this approach were overstated by more than 12 percent.³ This finding was attributed to the use of a single routine area CCR for all patients despite the fact that pediatric patients “are significantly more expensive to treat on average than the average aged patients who comprise the vast majority of the Medicare population.”

This same study found that using ancillary cost center CCRs resulted in underestimating ancillary costs for Medicare patients by nearly 5 percent. The study concludes that, while the cost reports are reasonably reliable for determining Medicare’s share of total costs, “(t)he cost report’s reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately. And cost report data, supplemented by charge data from the MedPAR system, are clearly not reliable or accurate for analyzing micro-level costs.”

Unfortunately, no more recent analysis has been done to either confirm or refute that conclusion. This draws into question not only the significant shift in payments from surgical DRGs to medical DRGs resulting from CMS’ proposal, but it also raises questions about MedPAC’s conclusion that many cardiac DRGs are overpaid relative to their costs. Because MedPAC estimated costs using the same methodology that was applied in the study, it is likely the analysis underestimated the ancillary costs for cardiac DRGs, causing them to appear to have lower costs than they actually do.

³ Ashby, J, “The Accuracy of Cost Measures Derived From Medicare Cost Report Data”, Prospective Payment Assessment Commission, Intramural Report I-93-01, March 1993.

In fact, using hospital-wide CCRs (those currently used by Medicare to determine whether hospitals qualify for outlier payments) indicates much smaller adjustments are appropriate to the DRG weights in MDC 5 than indicated by MedPAC's analysis. Interestingly, the study referenced above found that hospital-wide CCRs appeared to produce better estimates of actual costs (comparing with their internal "state-of-the-art" accounting systems) than using cost center CCRs.

The policy issues associated with this overestimation of routine costs and underestimation of ancillary costs are significant, especially when it comes to the incentives to use medical technology to find new ways to discharge patients sooner with less trauma. Overpaying DRGs with a greater proportion of routine costs relative to DRGs with relatively few routine costs (and more ancillary costs), as CMS' proposal would do, will cause hospitals to under invest in new medical technologies because they would be systematically underfunded by Medicare.

In addition to this overestimation of routine costs and underestimation of ancillary costs, there are other problems with the cost report that would need to be addressed under a cost-based DRG weighting approach. One is the inconsistency in how hospitals report medical devices and other items on their cost reports. For example, one hospital may assign drug-eluting stents to the cardiology cost center, while another hospital may assign them to medical supplies and equipment. This is one reason why, as discussed above, hospital-specific cost center CCRs would be more accurate than national average CCRs.

Another well-documented issue with using cost center CCRs is the below-average markup of charges for expensive medical devices (charge compression). Changing to cost-based weights using cost center CCRs would underestimate the costs of these devices because the average CCR for the cost center would be less than the CCRs for these individual devices. The impact of charge compression would be made even worse under the proposal, because the national average CCRs for all hospitals are often lower than the average CCRs among hospitals actually performing a procedure.

Charge compression is already a significant source of underpayment under Medicare's outpatient prospective payment system. It also depresses the DRG weights currently for those DRGs where the charges would otherwise be higher. Moving to cost-based DRG weights without accounting for charge compression would make this payment distortion much more acute. Combined with the problem described previously where using cost center CCRs has been shown to overestimate routine costs and underestimate ancillary costs, we have great concerns that, rather than achieve the desired goal of improving payment accuracy, the proposed cost-based methodology will create barriers to the introduction of new technologies and even reverse positive trends already underway (e.g., increased use of coronary artery stenting in place of coronary bypass graft surgery).

The problem of charge compression is compounded by the age of the cost report data used to adjust the charges to costs. Although CMS used the most recently available cost reports it had, those cost reports began during Federal fiscal year 2003. Much of these data are over 3 years old. As we have stated above, we applaud CMS for its proposal to

use the most recent claims data rather than matching old claims to cost reports. This does at least ensure the charge data reflect new technologies. However, adjusting these charges using CCRs that do not reflect the lower mark-ups hospitals generally apply to these new technologies compounds the problem of charge compression (i.e., drug-eluting stents only came onto the market at the end of April of 2003, with relatively slow uptake in the latter half of FY 2003).

The example below demonstrates how the combination of charge compression and the lag time for cost report data create a disincentive for hospitals to adopt a new technology. The example demonstrates using cost report data result in a lower cost estimate (and correspondingly lower DRG payments) when a new technology is adopted, even under a scenario where total charges are unchanged (due to higher ancillary costs from the new technology).

While total charges stay the same after introducing the new technology (resulting in no payment change under the current charge-based method), applying the historical CCRs from the cost report results in a reduced estimate of costs. This is because these historical CCRs for the cost center do not reflect the lower charge mark-up for the new technology. The new methodology could, therefore, offer an incentive to the hospital to maintain the older treatment given it would have a higher "cost-based" payment rate.

Patient Treated with High Concentration of Routine Services and Long Length of Stay

	<u>Charges</u>
Routine Services (85% CCR)	\$15,000
Ancillary Services (34% CCR)	\$5,000
Total Charges	<u>\$20,000</u>

Estimated Costs Based on Proposed CCR \$14,450

Patient Treated with High Concentration of Ancillary Services (Supplies & Equipment) with Shorter Length of Stay

	<u>Charges</u>
Routine Services (85% CCR)	\$5,000
Ancillary Services (34% CCR)	\$15,000
Total Charges	<u>\$20,000</u>

Estimated Costs Based on Proposed CCRs \$9,350

We support further development of the analysis discussed in AdvaMed's comments regarding a potential regression-based adjustment for charge compression. We agree the analysis provides a solid analytical basis for an adjustment, and hope that CMS pursues this approach. However, we would emphasize that this adjustment should be part of a

comprehensive approach to improve the payment accuracy of the DRGs no sooner than in 2008. We believe this adjustment needs to be further analyzed. In particular, we would note that it is limited in its ability to estimate charge compression associated with drug-eluting stents by the fact that the analysis to date relies on 2003 cost report data. As explained above, there would be very little data reflecting this now widespread technology in the 2003 cost reports. Nonetheless, the analysis represents a significant step toward addressing the problem of charge compression (perhaps in conjunction with developing separate cost centers on the cost report for high-cost implantables).

Finally, we would support the use of an expert panel representing all stakeholders and commissioned by CMS (within the constraints of the Federal Advisory Committee Act) to provide advice on long-term solutions to issues and providing up-to-date cost data, either through the cost reports or other means, in support of cost-based weights. We believe the problems addressed above are real and merit immediate attention prior to proceeding with cost-based weights. If such a panel were commissioned, we believe it would be reasonable to expect a report back by Spring 2007 with specific recommendations. J&J would be pleased to assist with this panel.

DRGs: Severity of Illness

CMS proposes to adopt DRGs that better reflect differences in patients' severity of illness for FY 2008, although the proposed rule also discusses and solicits comments on the option of implementing severity DRGs in 2007. The severity-adjusted DRG system described in the rule is based on 3M Health Information Systems' APR-DRGs. However, CMS would consolidate severity level 4 from all APR-DRGs within each MDC to create a single severity level 4 DRG for each MDC (with some specific, limited exceptions described in the proposed rule).

CMS provides several reasons for why it did not propose to implement what it terms 'consolidated severity-adjusted DRGs' for 2007. Chief among the reasons cited were the limited time available for hospitals to review and adopt the major changes to the coding system represented by the consolidated severity-adjusted DRGs. We support CMS' position that this is a major change to the central structure of Medicare's inpatient payment system and it is crucial that it be fully understood. Our comments below detail a number of specific areas where we think the system described in the proposed rule needs further development.

Before addressing specific concerns about the proposed severity DRG system, we would like to register our disagreement with the phased implementation of HSRV, cost-based weights, and the severity DRG system. Because the payment impacts under cost-based and HSRV weights move in different directions than under severity-adjusted DRGs for some hospitals, implementing these changes in different years would cause unnecessary payment disruptions. For example, major teaching hospitals experience a negative 1.1 percent impact from implementing HSRVcc, but a positive 0.5 percent impact from implementing consolidated severity-adjusted DRGs. Major teaching hospitals also treat large numbers of uninsured patients every year so that it is already difficult to finance

their operations. Implementing these changes to the DRGs at the same time would help to smooth out the potential negative implications on these critical safety net providers.

Consistent with our support for improving the overall accuracy of the DRG system stated above, J&J supports improving the ability of the system to differentiate between patients of varying severity. Therefore, we appreciate that CMS is describing its proposal now to allow full consideration and comment for 2008. However, because CMS did raise the possibility of implementing this system in 2007, we would like to state our emphatic objection to this idea. We believe the reasons CMS gave in the proposed rule for not implementing this year are valid. They are all the more valid because hospitals now would have even less time to prepare if CMS were to implement its proposed severity adjusted DRG this October 1. Finally, we do not believe the system as proposed is ready for implementation.

The APR-DRGs include 314 base DRGs (each divided into 4 severity categories) while the current CMS DRGs include 367 base DRGs and 526 total (e.g., reflecting split DRGs for patients with/without comorbidities and complications). In many cases, these discrepancies reflect the fact that the current CMS DRGs reflect differences in the complexity of patients apart from their severity of illness. The proposed rule points out that under the current CMS DRGs there are different DRGs for coronary angioplasty with and without the insertion of a stent. The current APR-DRGs do not make this distinction. Because the proposed consolidated severity-adjusted DRGs use the APR-DRG base DRGs, this system would not distinguish between angioplasty with or without stenting (or the insertion of a drug eluting stent rather than a bare metal stent, a distinction that is also recognized by the current DRG system).

We strongly object to the proposed consolidated severity-adjusted DRG system because it does not recognize differences in patient complexity. CMS has examined many of these issues in great detail in the past and has adopted the CMS DRGs to reflect differences in case complexity. The proposed rule would undo many of those past policy decisions that have been implemented through notice and comment rulemaking without even acknowledging this impact (see Attachment 2 to our comments for illustrative examples). Because many of these decisions have recognized the utilization of innovative medical technologies in the CMS DRGs, this proposed severity system, combined with the flaws in the HSRVcc, would reverse the current positive trends toward more effective and less invasive patient care as a result of the introduction of new technology.

Rather than revisiting past policy decisions, CMS should develop and propose a system that establishes severity adjustments for the current CMS based DRGs (after eliminating the current CC/no-CC splits), including all of those CMS DRGs that reflect complexity of treatment or increased costs for new technologies. We note that CMS indicated in the proposed rule that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." A good first step would be to continue to recognize those technologies that are already recognized under the DRG system.

The proposed rule indicates that CMS plans to “develop criteria for when it is appropriate to recognize increased complexity in the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments” (p. 24014). As a worldwide leader in the development of innovative medical technologies, J&J is keenly interested in this issue. Unfortunately, the scope of the proposed DRG changes and the many issues raised above make it impossible to conduct the analysis necessary to appropriately consider this issue during the current comment period. However, we would be eager to work with CMS on this issue.

Finally, CMS requested comments on whether it should implement the DRG changes in a phased transition. We believe it would be necessary to transition these changes over several years, after considering the issues discussed above. This would be consistent with many other major changes that have been implemented gradually over the years, including the capital prospective payment system. A phase-in allows hospitals time to adapt to the new reimbursement approach, without creating massive disruption of current arrangements and services. Further, particularly if CMS proceeds stepwise with cost-based weights followed by severity adjustors, a phase-in would reduce the “whip-saw” effect of having hospitals experience negative impacts one year followed by positive impacts the next, or vice-versa.

Transparency of Health Care Information

The proposed rule also discusses the Administration’s interest in greater transparency of health care information, including charge and pricing data. According to the rule, the Department of Health and Human Services intends to launch a major health care information transparency initiative in 2006. Several regions will be identified with high health care costs and significant interest in reducing cost and improving quality. The rule solicits comments on several approaches to increase the transparency of pricing and quality information, and how this can be used to stem the growth in health care spending.

Among the possible approaches mentioned are: publishing a list of hospital charges for every region in the country or selected regions; require posting prices or discounts for uninsured patients; or posting total Medicare payments for an entire episode of care (e.g., inpatient, outpatient, and physician payments).

We support the comments submitted by AdvaMed on this issue. We urge CMS to integrate pricing and quality information on appropriate evidence-based protocols. Patients need to know both the costs and benefits of the care they receive, in a format that is understandable and accessible. We also urge CMS to consider appropriate timeframes for measuring quality and costs, and to look across all sites of care delivery to assess efficiency. If an episode of care encompasses a too-short time frame or does not consider the avoidance of inpatient and outpatient encounters, costs and quality may be inaccurately determined.

Attachment 2: J&J's Comments
Examples of DRG Adjustments Adopted Through Notice and Comment Rulemaking That Would Be Negated If CMS Implements Severity-Adjusted DRGs in FY 2007

CURRENT CMS DRG	Date Originally Adopted by CMS Through Rulemaking	Rationale for Change	CMS Consolidated Severity- Adjusted (CS) DRG Mapping	Impact Of Severity Adjustment*
557 & 558, Drug-Eluting Stent with/without Major Cardiovascular Diagnosis	FY 2003 (original), modified in FY 2006	CMS: "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." <u>Federal Register</u> , Vol. 70, 47294, August 12, 2005	CSA-DRGs 237-242 Percutaneous Cardiovascular Procedures [all coronary angioplasty is grouped here, regardless of whether a stent is inserted]	DRG 557: -23% DRG 558: -33%
559, Acute Ischemic Stroke with Use of a Thrombolytic Agent	FY 2006	CMS: "We agree...that there is an increased cost in caring for these [stroke tPA] patients including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources. We also agree that—(1) the data indicate that patients receiving thrombolytic therapy have increased severity; and (2) reperfusion therapy is a good means to segregate these patients into a separate DRG." <u>Federal Register</u> , Vol. 70, 47288. August 12, 2005.	CSA-DRGs 56-58 CVA & Pre-cerebral Occlusion W/ Infarction. (Revert to classifying tPA back with all other stroke cases, undoing what they did just last year.)	-35%
551, Permanent Cardiac Pacemaker Implant with Major CV Diagnosis or AICD Lead or Generator	FY 2006	CMS: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly	CSA-DRGs 228-233 Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock (Reverts back to classification based on presence or absence of heart failure, AMI, or shock, rather than Major Cardiovascular	-17%

		increased resource use for nine surgical cardiovascular DRGs." <u>Federal Register</u> , Vol. 70, 47474, August 12, 2005	Diagnosis)	
545, Revision of Hip or Knee Replacement	FY 2006	CMS: "For the FY 2006 IPPS proposed rule, we examined data in the FY 2004 MedPAR file on the current hip replacement procedures (codes 81.51, 81.52, 81.53) as well as the replacements and revisions of knee replacement procedures (codes 81.54 and 81.55) in DRG 209. We found that revisions were significantly more resource intensive than the original hip and knee replacements." <u>Federal Register</u> , Vol. 70, 47305, August 12, 2005.	CSA-DRGs 414-419 Hip Joint Replacement (414-416) & Knee Joint Replacement (417-419) (Would undo last year's change to recognize the increased resources for revisions.)	-10%
496, Combined Anterior/Posterior Spinal Fusion	FY 1998	CMS: "In view of the volume of cases involved and the clear differences in resource use, we concluded that it would be appropriate to create additional DRGs to separate spinal fusion cases from the other back and neck procedures... The average charges and lengths of stay for the cases involving both anterior and posterior spinal fusion were markedly greater than for the other spinal fusion cases... [W]e concluded that the magnitude of the differences in both average charges and lengths of stay warranted a further subdivision of the spinal fusion cases." <u>Federal Register</u> , Vol. 62, 45976, August 29, 1997.	CSA-DRGs 413, 421-425, 461-463 (Combined anterior/posterior spinal fusions appear simply to be regrouped with all other spinal fusions, ignoring the greater resource intensity and LOS associated with these cases and reversing the policy from the FY 1998 final rule.)	-38%

*Weighted average reduction.

Submitter : Dr. Christine O'Meara
Organization : UNC Hospitals Department of Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine resident, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Christine O'Meara
Chief Resident, UNC Family Medicine

Submitter : Mr. J. Robert Cercek
Organization : Mr. J. Robert Cercek
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

Based on the models we are building around the proposed changes I feel that more research needs to be done to truly validate what these changes will mean to our programs. With bad debt and charity care continually on the rise we need to be sure that we are able to pay for the appropriate level of care expected by our patients.

Submitter : Dr. Mark McLoney
Organization : Dr. Mark McLoney
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Background

The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,
 Mark A. McLoney, MD

Submitter : Dr. Punnaivanam Ravisankar
Organization : Dr. Punnaivanam Ravisankar
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Theodore Shoemaker
Organization : Dr. Theodore Shoemaker
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Theodore Shoemaker, MD

Submitter : Dr. Randal Hamric
Organization : Dr. Randal Hamric
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

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I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Randal Hamric MD
Family Physician

Submitter : Dr. William Given
Organization : Braxton Health Assoc. Inc.
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

I am a family physician and i strongly urge cms to rescind the language in the proposed rule that sets up an artificial divide between resident trainging time spent in didactic activities and patient care. this rule ex ludes med resident time spent in didactics in calculataion of medicare direct graduate medical education and indirect med ed payments.

We need more physicians there is a shortage looming. these cuts will kill medical education. everything they do in residency is part of their education. this is a bad policy.

i urge cms to rescind its clarification in the proposed rule relating to countingo f didactic time for purpose of DGME and IME payments and recognize the nature of these activities to pt care experiences of residents during training.

Submitter :

Date: 06/09/2006

Organization :

Category : Individual

Issue Areas/Comments

GME Payments

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Sincerely,

KGuest, MD

Family Medicine Resident

Submitter : Dr. Carlos Gomez
Organization : Dr. Carlos Gomez
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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Submitter : Victoria Kaprielian
Organization : Victoria Kaprielian
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Victoria Kaprielian, MD

Submitter : Dr. Ryan Flint
Organization : Rose Family Medicine Residency Program
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely,
Ryan C. Flint D.O.

Submitter : Dr. E. Spencer Joslin
 Organization : Dr. E. Spencer Joslin
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

E. Spencer Joslin, MD

Submitter :

Date: 06/09/2006

Organization :

Category : Physician

Issue Areas/Comments

GME Payments

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Submitter : Dr. Meghan Gannon
Organization : Mayo Hospital
Category : Physician

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

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Sincerely,

Meghan Gannon, M.D.

Submitter : Mr. Manny Berman

Organization : Tuality Healthcare

Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

See Attachment

CMS-1488-P-908-Attach-1.DOC

ATTACHMENT TO #908

June 9, 2006

Federal Register Comments:

RE: Hospital Quality Data

Dear Sirs:

We are in receipt of the proposed FFY 2007 Medicare inpatient rule regarding hospital quality data, Federal Register pages 24091 to 24095.

We feel the chart validation requirements have a couple of significant problems that create unfairness, regarding obtaining 80% validation.

These concerns are as follows:

1. The current practice and proposed rule only reviews a sample size of 5 cases per quarter for 3 quarters. We do not believe this is a large enough sample size to provide a statistically valid evaluate the hospital's validation accuracy. The sample size needs to be expanded.
2. In some cases specific diagnosis identification, creates incidences of data sets that have "parent/child" elements. In these "parent/child" elements if the determination of the "parent" diagnosis is inaccurately determined, then the chart extraction does not allow for inclusion of "child" elements. (, i.e. Pneumonia) However, when the validation review is performed, the lack of "child" items when the "parent" was incorrect is a double jeopardy situation and inappropriately weighs too heavy against obtaining a successful validation score. This "parent/child" accounting needs to be resolved in an equitable way.

Your resolution of these two concerns should be rectified before these rules are finalized. I would be happy to discuss these concerns and provide further detail if desired.

Thank you for your consideration.

Very Truly Yours,

Manuel S. Berman
Administrator/Chief Operating Officer

cc: Kevin Earls, OAHHS

Submitter : **Dr. RICHARD HORECKA**
Organization : **AFFILIATED COOMMUNITY MEDICAL CENTERS**
Category : **Physician**

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,
RICHARD R HORECKA MD

Submitter : Dr. John Parker
 Organization : Marshall University School of Medicine
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Jeffrey Palmer
Organization : Valley Medical Group
Category : Physician

Date: 06/09/2006

Issue Areas/Comments**GME Payments**

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Sincerely,

Jeffrey Palmer MD

Submitter : Mr. Jerome Crest
Organization : Immanuel St. Joseph's-Mayo Health System
Category : Hospital

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As the administrator of an organization offering a family practice residency, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care:

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
 Jerome A. Crest
 Chief Administrative Officer
 Immanuel St. Joseph's-Mayo Health System

Submitter : Dr. Catou Greenberg
 Organization : Catou Greenberg, MD, Inc
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

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Sincerely,

Catou Greenberg, M.D.

Submitter : Dr. Howard Bassel
Organization : Dr. Howard Bassel
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Howard Bassel MD

Submitter : Mr. Edward Rozynski
Organization : Stryker Corporation
Category : Device Industry

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-915-Attach-1.DOC

ATTACHMENT TO # ~~1000~~ 915

Edward Rozynski
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June 9, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Thank you for the opportunity to provide comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed changes to the Medicare hospital inpatient prospective payment systems ("IPPS") and fiscal year ("FY") 2007 rates. We appreciate your efforts to improve the IPPS and future payment rates. We share your goal of building a better and more accurate payment system that serves both the good of its users and our citizens.

Stryker Corporation ("Stryker") is one of the world's leading medical technology companies with the most broadly-based range of products in orthopaedics and a significant presence in the other medical specialties. Stryker is committed to bringing the best possible solutions to patients, surgeons, and health care systems throughout the world. This philosophy has placed Stryker at the forefront of medicine's most promising breakthroughs in joint replacements, trauma, spine and micro implant systems, orthobiologics, powered surgical instruments, surgical navigation systems, endoscopic products, and patient handling and emergency medical equipment. Notably, Stryker's products are used in over 80 percent of the hip and knee replacement procedures performed each year in the United States.

Overview of Recommendations

Stryker commends CMS for striving to improve payment accuracy under the IPPS and for the valuable start CMS has made. Stryker believes that CMS's proposed means to reach that end – transforming Diagnosis-Related Groups ("DRGs") so that they are weighted based on costs instead of charges and capture the severity of patient illness – are laudable ones. As CMS further considers these proposed changes and decides how to proceed, our company would welcome the opportunity to work with your agency and

provide technical assistance and advice to ensure that implementation achieves the result that the agency intends – i.e. enhanced payment accuracy and increased patient access to advanced medical technologies.

In that cooperative spirit, Stryker would like to identify several major concerns with the proposed rule and, thus, makes the following recommendations to CMS:

- 1) **Implementation in FY 2008 of a DRG classification methodology that accounts for patient severity of illness, complexity, and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. We would encourage CMS to start with the current DRG system and provide overlays for severity, complexity, and patient benefit.**
- 2) **Simultaneous implementation in FY 2008 of a new DRG classification methodology *and* an estimated cost-based weight system analogous to the methodology that is currently used in the outpatient prospective payment system.**
- 3) **Beginning immediately, with continued efforts through FY 2008 and beyond, we would appreciate CMS making changes to the cost reports that would result in significantly improved timeliness and accuracy of the information used to calculate estimated costs.**
- 4) **We would appreciate CMS correcting, at a minimum, two major mathematical flaws in its HSRVcc methodology related to hospital weighting and inclusion of relevant hospital costs.**
- 5) **As part of implementing cost-based weights, we request that CMS make a full adjustment for charge compression.**

Like the American Hospital Association, Stryker therefore supports a one-year delay in the DRG-related changes proposed by CMS and opposes a two-step implementation, whereby CMS would implement the movement from charge-based weights to estimated cost-based weights in one year followed by wholesale refinement of DRGs based on patient classification reforms in a succeeding year. Making these changes simultaneously would minimize swings in payment rates for many DRGs. We are flexible on the issue of the phase-in period and would support what is deemed to be necessary or appropriate.

Background on Recommendations

CMS seeks to both develop and implement the most significant and complex changes in Medicare inpatient reimbursement since the DRG system was conceived more than 20 years ago. Stryker applauds the scale of this effort and the agency's intent to improve payment accuracy. However, the agency is attempting this undertaking in just one regulatory cycle, providing stakeholders with only one 60-day comment period to review

the regulation, analyze the methodological changes, and provide input. Clearly, CMS has been ironing out the details of its complex proposals for at least an entire year; and even so, the agency admits at various points in the proposed rule that it has not yet sorted out how all of the new pieces fit together. As you may know, other countries such as Germany took several years to make similar structural changes in their DRG systems. Given that, it would seem reasonable that stakeholders would need more than 60 days to provide the agency with proper analysis and sound advice and counsel about the proposed new system.

A decision by CMS to delay implementation of any changes until FY 2008 would afford the agency, patients, hospitals, physicians, device manufacturers, and other stakeholders the opportunity to fully assess the impact of the proposed changes before they are applied to the health care services delivered to Medicare beneficiaries. A comprehensive assessment is not possible in 60 days due to the complexity of the changes proposed, the potential overlay of a completely different DRG system, and the lack of sufficient available data in this narrow timeframe.

Stryker's Recommendations and Analysis

- 1) Implementation in FY 2008 of a DRG classification methodology that accounts for patient severity of illness, complexity, and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. We would encourage CMS to start with the current DRG system and provide overlays for severity, complexity, and patient benefit.**

Stryker supports the creation of severity stratification for DRG assignment and believes that it is an important step in improving the accuracy of hospital payments. The Medicare total joint population includes the full range of patient health issues that mirrors the spread of hospital resource consumption.

The proposed rule outlines four levels of severity adjustments within a given DRG. These levels represent varying resource intensity based on resource consumption as a function of "physiological decompensation, or organ system loss of function." With respect to primary total hip and knee replacement procedures, there are three proposed severity of illness levels, two of which represent the possible DRG assignments for revision hip and knee replacement (see Table 1).

Primary & revision total hip replacement CS-DRG's			
CS-DRG's	CMS proposed wts	2006 wts	
		Primary	Revision
414	1.8267	1.96	
415	2.0853	1.96	2.4872
416	2.5599	1.96	2.4872
Primary & revision total knee replacement CS-DRG's			
CS-DRG's	CMS proposed wts	2006 wts	
		Primary	Revision
417	1.712	1.96	
418	1.8927	1.96	2.4872
419	2.5361	1.96	2.4872

Table 1

The proposed rule suggests an 18-step process to assign patients into one of the severity-adjusted DRGs for a given procedure. Stryker is concerned that the proposed severity adjustment criterion alone does not account for surgical and/or operating room organizational complexity. Enhanced implant utility and procedure complexity are common to specific orthopaedic procedures. Without consideration of these components, the proposed criterion likely would result in hospital payment inaccuracies.

In the FY 2006 Medicare inpatient final rule, CMS eliminated DRG 209, which was largely comprised of primary and revision total knee and hip replacement procedures. DRG 209 was replaced with two new DRGs: 544 (primary total hip and knee replacement) and 545 (revision hip and knee replacement). Stryker applauded this change because it recognized the need to better align resource consumption with payment specifically for revision hip and knee replacement procedures. CMS also created new ICD-9-CM procedure codes that map to DRG 545 and more accurately describe the various permutations of potential hip and knee revision scenarios, as follows:

- 00.70, Revision of hip replacement, both acetabular and femoral components
- 00.71, Revision of hip replacement, acetabular component
- 00.72, Revision of hip replacement, femoral component
- 00.73, Revision of hip replacement, acetabular liner and/or femoral head only
- 00.80, Revision of knee replacement, total (all components)
- 00.81, Revision of knee replacement, tibial component
- 00.82, Revision of knee replacement, femoral component
- 00.83, Revision of knee replacement, patellar component
- 00.84, Revision of knee replacement, tibial insert (liner)
- 81.53, Revision of hip replacement, not otherwise specified
- 81.55, Revision of knee replacement, not otherwise specified

Unfortunately, this year's inpatient proposed rule is based on criteria that may not accurately capture the potential significant increases in complexity of revision hip and knee surgery. Often, increases in surgical complexity generate the need for additional resource consumption that is unrelated to the proposed severity adjustment criterion. Such complexity increases could include implant designs that are significantly more complex and have utility requirements beyond what is needed in primary joint replacement and/or simple revision procedures.

Surgical complexity example: ICD-9-CM code 81.54 twice (Total knee replacement, bilateral)

Under the FY 2006 inpatient final rule, bilateral total knee replacement procedures map to DRG 471 with a relative value unit assignment of 3.1391. This assignment is based upon both the additional time involved in performing two distinct replacement procedures as well as the additional implant requirement.

In this year's proposed rule, CMS's proposed severity-adjusted DRG assignments for bilateral knee replacement procedures are the following:

<u>DRG</u>	<u>RVU</u>	<u>Description</u>
417	1.7120	KNEE JOINT REPLACEMENT SOI 1
418	1.8927	KNEE JOINT REPLACEMENT SOI 2
419	2.5361	KNEE JOINT REPLACEMENT SOI 3

These severity adjusted DRGs and associated RVUs do not account for the increased resource use and procedure complexity required for a bilateral procedure. In fact, they are the same ones assigned to a single knee replacement requiring half the implant usage and significantly less operating room time. Based on today's RVU assignment of 3.1391 for bilateral procedures, this proposed change would result in the following:

Primary & revision total knee replacement		
CS-DRG's	CMS-proposed RVUs	Reduction below 2006 RVUs for DRG 471
417	1.712	45%
418	1.8927	40%
419	2.5361	19%

Given that these levels represent varying resource intensity based on resource consumption as a function of "physiological decompensation, or organ system loss of function," it may be unlikely that a bilateral knee replacement patient admission qualifies for assignment to DRG 419. Even so, this DRG represents a 19% reduction in RVU assignment. The expected volume mapping from DRG 471 results in 87% of these cases falling into DRG 417, SOI 1, and 418, SOI 2. Using this percentage of bilateral knees as

the universe of bilateral patients based on 2005 discharges, the weighted RVU equals 1.8136. *This represents an RVU that is less than the current value of a single total knee replacement today.*

Surgical complexity example: ICD-9-CM code 00.80 (Revision of knee replacement total, all components)

Pre-Operative

Total knee replacement revisions vary significantly from primary total knee replacements. The pre-operative planning and instrument demand are four times that of a primary knee replacement. (This metric is based on the average total number of instrument trays processed by central supply.) These revisions also require significant staff time in preparation of the nine instrumentation trays.

Intra-Operative

This procedure involves the complete removal of an existing implant that was originally implanted with the intent of not being removed. Consequently, significantly more instruments and time are utilized removing the existing implant. Once removed, the remaining bone defects often require additional operating room time to rebuild and remodel the joint. This correction is accomplished by utilizing autograft bone and/or a combination of autograft and implant construct. Implant trialing is then performed to evaluate the function and fit of the revision implant. Unlike a standard primary knee implant comprised of four pieces, this implant requires at least eight to ten pieces, many of which need to be assembled outside of the joint.

Surgical complexity example: ICD-9-CM code 00.70 & 00.71 (Revision of hip replacement, both acetabular and femoral components; 00.71, Revision of hip replacement, acetabular component)

ICD-9-CM code 00.70 is consistent with what has been described above but is applicable to revision hip replacement. The operating room time resource increase is significant and similar to total knee revisions. Both knee and hip revision surgeries involve complex surgical management of compromised soft tissue, as well as bone defect and loss issues. Specific to acetabular bone compromise (00.70 & 00.71), management of these revisions often includes complex implant selection. To support clinical complexity, current implant designs are equally complex and provide greater utility for this patient profile. Management of bone defects and/or bone stock compromise specifically in the acetabular area is addressed with complex bone in-growth and on-growth technology that provides greater utility and fixation properties.

Many other codes listed above demonstrate significant surgical complexity that augments hospital resource consumption from several cost centers. However, many of these patients may not have medical complication and/or co-morbidities that satisfy "physiological decompensation, or organ system loss of function" and, therefore, would map to DRG 415 for hips and DRG 418 for knees with corresponding weights 2.0853 and 1.8927. For example, a candidate for procedure codes 00.70 and 00.80 likely would not

present with "physiological decompensation, or organ system loss of function," which likely would lead to DRG assignment 415 with a proposed RVU of 2.0853. This is significantly less than the current assignment for revision of hip and knees of 2.4872.

It is difficult to understand how CMS can effectively reverse its decision to re-categorize these codes after just one year of tracking the procedures. In fact, analysis of the current DRG weights for primary and revision hips and knees demonstrates a 19% and 20% decrease in weights when comparing the proposed SOI (2)- DRG 415 and the current DRG 545, SOI (2)-418 and 545. It is also relevant to compare these two SOI (2) DRGs with the current corresponding DRG weight for primary joints. The variance represents a slight increase for 415 and a negative 3.5% for 418.

There are two other severity-adjusted DRGs to which revision hips and knees could be assigned. Table 1 (see above) identifies DRG 416 (RVU 2.5599) and DRG 419 (RVU 2.5361). These two DRGs are specific to SOI 3, which for this category represents the greatest severity adjustment that can be made for this procedure and one that would need to be supported by the greatest amount of physiological decompensation, or organ system loss of function. The RVUs for these two DRGs are much closer to what CMS has in place currently with DRG 545 and in fact are slightly higher. This is more consistent with what CMS has previously identified as the amount of resources used for revision procedures. Unfortunately, the proposed severity adjusting process would eliminate substantive aspects of increased resource consumption by not recognizing surgical complexity and how this demands increased operating room costs, instrument requirements, and implant complexity. Such a result would lead to less accurate payment for these procedures, not more as CMS intends.

Data at the aggregate level for the new ICD-9-CM codes described above will be visible at the end of 2007. The new DRG assignments effective in FY 2006 only will provide a one-year snapshot derived from the additional ICD-9-CM codes. However, CMS has used 2005 data to rebase the DRGs, thus eliminating the possibility of incorporating the data generated from these newly created codes. The opportunity to use updated MedPAR data (with a 24-month data set) would provide significant insight into the issues related to resource consumption for the various revision scenarios.¹

CMS's proposed APR-DRGs (Severity-based DRG categories, patient demand and utility issues)

One of Stryker's greatest concerns with CMS's proposed severity-adjusted DRGs is that, under the proposed rule, the patient who would qualify for the implant with the greatest utility would be expected to not have any "physiological decompensation, or organ

¹ Stryker notes that orthopaedic surgeons commonly use complexity-based categories that describe levels of complexity for both hip and knee revision scenarios. These categories look at bone defect and soft tissue compromise as critical elements that support the complexity descriptions used. Using these existing categories would allow CMS to capture complexity-based resource needs relevant to hip and knee revisions.

system loss of function” and would likely be assigned to the lowest paying DRG for the same procedure.

A subset of today’s Medicare patients who undergo total joint replacement are very active and have life expectancy rates that challenge some of the older implant designs. Additionally, implant fixation and range of motion requirements are also much more demanding today for these patients. Some surgeons and hospitals have been working together to identify patients most appropriate for these implants. For example, a surgeon may inquire about a patient’s potential life expectancy based upon family history. This information, when combined with the patient’s needs such as activity level, supports matching him with an implant that provides greater utility and/or improved range of motion. However, under the proposed rule, such a patient’s DRG would have no severity adjustment due to his or her profile and thus would result in lower payment than currently assigned for this technology and associated procedure. This could significantly reduce Medicare patient access to a technology that offers greater utility.

There are many technologies designed for patients who are healthy and expected to live a longer and more active life. The proposed rule’s severity adjustment process does not capture the resource utilizations of technologies designed for patients fitting this profile. Stryker urges CMS to recognize the need for technologies with high levels of utility for certain segments of the Medicare population and the additional resource demands that such technologies place on hospitals, and to ensure that Medicare payment levels account for this need and the corresponding resource demands.

2) Simultaneous implementation in FY 2008 of a new DRG classification methodology *and* an estimated cost-based weight system analogous to the methodology that is currently used in the outpatient prospective payment system.

As mentioned at the outset, Stryker urges CMS to implement a new DRG classification methodology in the same year as it implements a new cost-based weights system. Implementing the movement from charge-based weights to estimated cost-based weights in one year, followed by wholesale refinement of DRGs based on patient classification reforms in a succeeding year, would create large swings in payment rates for many DRGs; create an unstable payment environment for hospitals and other providers; and cause uncertainty among patients about whether or not they would be able to access advanced medical technologies.

An Alternative Cost-Based Method Should be Used to Calculate Cost-Based Weights and the Detailed Impacts Should be Provided for Public Comment (HSRV Weights)

Stryker supports efforts to improve the accuracy of inpatient hospital payments. Unfortunately, CMS’s HRSVcc methodology is overly complex, omits important data, and results in a systematic bias against the hospitals that provide patients access to many advanced medical devices. Rather than improving the accuracy of the payments, it further distorts payments by using a flawed estimate of costs. If CMS chooses to move to

a cost-based payment system, Stryker recommends a cost-based payment methodology similar to the one used to calculate the hospital outpatient prospective payment system (“OPPS”) rates.

To calculate hospital outpatient prospective payments, CMS matches outpatient hospital claims to Medicare cost reports using hospital-specific cost-to-charge ratios to determine estimated costs for each hospital encounter. These are then combined to determine the payment rates after adjusting for certain factors. While there are several issues associated with the hospital outpatient prospective payment system (including charge compression, which systematically lowers the estimated costs of new technology), the general methodology could be used for inpatient hospital payments. Despite concerns regarding the outpatient payments, Stryker supports using the OPSS methodology applied to the inpatient setting as it would provide an improvement over the proposed HSRVcc methodology in that it would produce estimated costs that would better reflect the variation in costs across hospitals and procedures. Stryker encourages CMS to model the inpatient prospective payment rates using the OPSS methodology and the latest available hospital claims and cost-report data and to provide detailed estimated impacts of this methodology for public comment.

3) Beginning immediately, with continued efforts through FY 2008 and beyond, we would appreciate CMS making changes to the cost reports that would result in significantly improved timeliness and accuracy of the information used to calculate estimated costs.

Stryker supports the goal of improving accuracy within the IPPS. As CMS considers implementing an estimated cost-based payment system, it should address a number of significant concerns raised by the use of cost-based weights.

Estimated cost-based weights would be derived, in part, from Medicare cost reports, which were not designed for use in a prospective payment system. The cost reports are a vestige of the “reasonable cost” based reimbursement system that was implemented when Medicare began in 1966. When the hospital inpatient prospective payment system was implemented in 1983, hospitals began to be paid a fixed amount based on the patient’s diagnosis, rather than incurred costs. Under the IPPS, reimbursement became independent of the actual costs incurred, and the cost report no longer played a key role in the reimbursement received by hospitals, with some limited exceptions for items such as bad debt, graduate medical education, pass-through, or outlier payments.

There are several serious problems in using cost reports to derive estimated costs – which are then used to calculate DRG relative weights – that should be carefully considered and addressed. These include: 1) the accuracy of the cost-report data and limited auditing; 2) the overall timeliness of the cost report data; 3) the omission of data on new

technologies; 4) comparability of cost reports due to variability in how hospitals allocate costs; and 5) the compression of the weights both across and within cost centers.^{2 3 4}

Accuracy of Reporting and Limited Auditing

Under prospective payment systems, providers' payments are not based on their actual incurred costs. Hospitals have little incentive to report accurately and completely for the items and services provided during the patient encounter or length of stay. The cost reports were not designed to establish payment rates for individual services and, as such, do not contain the detailed costs that are necessary to accurately determine estimated costs at the DRG level. Instead, cost reports provide payment, costs, and some reimbursement totals by department or cost center. An analyst must make several assumptions and perform complex calculations before he or she can translate cost reports into the estimated costs of individual items and services used to determine DRG payments.

CMS and fiscal intermediaries perform limited auditing of cost reports. If DRG weights are based on costs, they will be based on largely un-audited cost reports and, perhaps, extrapolation of average audit findings to un-audited cost reports. According to CMS, approximately 15% of hospital cost reports are audited each year. These audits are limited scope audits that focus primarily on factors that affect Medicare payment, such as bad debt or medical education. Full scope audits are done only rarely. Instead, audits for PPS providers mostly involve payments for one or more items including DSH, GME, IME, bad debts, and organ acquisition. The fiscal intermediary determines what issue(s) will be audited based on the desk review and experience with the particular provider. Validation audits are not conducted by fiscal intermediaries. If cost reports are to be used to calculate DRGs, additional auditing might be advised. MedPAC estimated that a full scale audit could require 1,000 to 2,000 hours from a fiscal intermediary, as well as additional time and resources from the hospital.⁵

Overall Timeliness of Cost Report Data

The cost report data are old, significantly older than the charge-based data currently used to determine payment weights under the IPPS. In the current system, the DRG weights are calculated using claims that are two years older than the payment year. Under an

² J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01, March 1993; MedPAC, "Sources of Financial Data on Medicare Providers," Report to Congress, June 2004.

³ Cost-based weights would further exacerbate the problem of "charge compression," which has been observed in the early years of IPPS (when cost-based weights were used) as well as in a number of studies and in the current OPSS. AdvaMed has conducted a study that documents the effects of charge compression using current MedPAR data.

⁴ A 1998 study by MedPAC's predecessor, ProPAC noted concerns with cost report data such that "cost report data may, in some cases, produce imprecise DRG weights." ProPAC further noted that the "Secretary [of HHS] should verify the accuracy of cost report data and implement changes as necessary."

⁵ MedPAC, op cit., p. 17

estimated cost-based IPPS system, the DRG weights would be calculated using cost report data that is three to four years older than the payment year. Because the data is outdated, the quality of the information is reduced.

Omission of Data on New Technologies

Inherent lags between the time period covered by the cost reports and the payment year mean that recent important medical technology advances are omitted from the costs, which in turn determine the cost-to-charge ratios that are used to calculate cost-based DRG weights. Data that are three to four years old would exclude many of these technological advances in the calculation of cost-to-charge ratios. This situation would translate into reduced accuracy of DRG weights.

Comparability of Cost Reports due to Variability in How Hospitals Allocate Costs

The high degree of variability of hospital cost reports is attributable to several factors, including the allocation of joint costs, such as hospital administration costs, to various revenue generating sectors. This presents a problem for the accurate measurement of other costs, such as inpatient, outpatient, and skilled nursing costs. Hospitals have a range of options by which to allocate their overhead costs. Some of the methods of allocation, such as square footage, can result in an over-allocation of costs to secondary services compared to other, core function services. These allocation decisions have a significant impact on the comparability of the cost report data across hospitals.

4) We would appreciate CMS correcting, at a minimum, the two major mathematical flaws in its HSRVcc methodology related to hospital weighting and inclusion of relevant hospital costs.

The HSRVcc methodology proposed by CMS contains two serious mathematical flaws that affect the DRG weights very materially. These problems arise due to the manner in which CMS proposes to implement the HSRVcc methodology. They can be corrected, or the problems would be removed altogether if CMS abandons the HSRVcc methodology in favor of the methodology used for the OPSS, as Stryker recommends. Fixing these flaws would have a significant impact on hospital-level payments, and hospitals that may have assumed that their payments would increase, could experience reductions.

First, in calculating the national cost-to-charge ratios (“CCRs”), CMS severely over-trimmed the data and ignored hospitals with CCRs for routine days with a value less than 0.26. These CCRs appear to be real and valid, however. They apply mostly to about 238 very large hospitals that contribute roughly one-quarter of all routine day charges. In dropping them, CMS is not only throwing out a large amount of valid data, but it is distorting the results by omission of such a significant segment of hospitals with a unique pattern of CCRs. This problem is compounded by CMS retaining these hospitals for other steps in calculating the national DRG weights. The table below shows the impact of CMS’s trimming.

Trimming of Routine Accommodation Charge Per Day				
CMS CCR trim action	Hospitals	Charges (\$ in billions)	Days (in millions)	Charge per Day
Not Trimmed	3133	\$ 34.11	39.1	\$ 873
Trimmed	238	\$ 12.37	3.3	\$ 3,723
Total	3371	\$ 46.48	42.4	\$ 1,097

Source: Direct Research. Ltd. estimate based on 2003 cost reports matched to edited 2005 MedPAR file.

Second, in calculating the national CCRs for each of the 10 cost centers, CMS uses the geometric mean of the individual hospital CCRs, after they are erroneously trimmed as discussed above. The geometric mean, however, is a statistic that gives equal weight to each hospital irrespective of the volume of charges and costs in the hospital. It is important to note that similar calculations in other CMS prospective payment systems and fee schedules use an appropriate weighting methodology rather than counting each hospital equally. Only with appropriate weighting will the calculated number actually equal the overall national average. In this case, weighting should be based on the aggregate amount of charges in each hospital. As shown in the table below, the flaw causes a substantial over-estimate of the aggregate national level of costs incurred by prospective payment system hospitals. Costs are so overstated that, compared to actual payments in the MedPAR file, hospitals would be losing \$23 billion dollars, or about 29%, on care provided to Medicare beneficiaries. We know from MedPAC and CMS reports that this is not true and that hospitals experience a small positive margin on inpatient care provided to Medicare beneficiaries. Consistent with this fact, the correct weighting methodology provides an estimated patient care margin of 2.2 percent, as shown in the table.

	With CMS CCRs	With Charge-Weighted CCRs
Total charges on MedPAR file (\$B)	\$ 315	\$ 315
Estimated raw cost (charges x CCRs, ten categories, \$B)	\$ 134	\$ 107
Estimated 2005 cost (raw cost x 0.92 to account for 2003 CCR vs 2005 charges, \$B)	\$ 123	\$ 98
Actual 2005 payment on MedPAR file, \$B.	\$ 100	\$ 100
Estimated 2005 payment-to-cost ratio	0.812	1.022

The combined effect of these two flaws significantly decreases the payments for technology-intensive cases. Stryker therefore urges CMS to fix these problems if it continues to pursue the HSRVcc methodology.

5) As part of implementing cost-based weights, we request that CMS make a full adjustment for charge compression.

To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by "backing out" the average mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of \$1,000 would be reduced to a cost of \$500.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is significantly less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock".⁶ This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and overestimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates.

Charge compression occurs when items with different markups are combined in the same cost center. CMS's proposed HSRVcc methodology would combine estimated costs into only 10 cost centers nationally, increasing the variation of items placed in a particular cost center. Modeling of the HSRVcc methodology confirms that the degree of charge compression inherent in the use of cost-based weights is exacerbated under the HSRVcc methodology.

To examine further the empirical evidence of charge compression, the Advanced Medical Technology Association ("AdvaMed") recently commissioned research to investigate whether Medicare claims data provided statistical evidence of charge compression. The results indicated a strong statistical relationship between a hospital's case-mix and the device CCR. Specifically, the study found that there is a statistically significant positive relationship between the device and supply case-mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the device case-mix increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the research also showed that basing the case-mix index on the percentage of cases with higher device and supply charges led to a stronger impact. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over \$30,000) is associated with a much larger increase in the average device and supply CCR than is a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over \$20,000), which in turn has a stronger impact

⁶ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

than a one-unit change in the lowest measure (device and supply charges exceeding \$15,000). The results of this research are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.⁷ It is significant that this study was conducted exclusively on Medicare claims data with no use of external data.⁸

As part of its movement from charge-based to cost-based weights, Stryker urges CMS to utilize the studies that have been completed on charge compression and address the distortion it causes.

Conclusion

Thank you for the opportunity to comment on the FY 2007 Medicare inpatient proposed rule. We look forward to continuing to work with your agency on this and other issues of importance to Medicare patients. If you have any questions regarding this comment letter, please feel free to contact me (ed.rozynski@stryker.com, 202-974-6222) or Eric Rugo (eric.rugo@stryker.com, 201-831-5684).

Sincerely,



Ed Rozynski
Vice President
Global Government Affairs

⁷ Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: <http://www.gao.gov/highlights/d04772high.pdf>. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

⁸ C. Hogan, Direct Research LLC., March 2005

Submitter : Ms. Anita Fisher
Organization : Benefis Healthcare
Category : Other Health Care Professional

Date: 06/09/2006

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

As an HQA-participating hospital, we have been voluntarily submitting data on 9 of the additional 11 NQF-endorsed quality measures. We have not been submitting data on the two Surgical Infection Prevention (SIP) measures. To meet the requirements of this act with regard to SIP measures, will require additional resources. Based on our surgical population, we will be required to abstract approximately 90 more cases per quarter, thus, approximately 50-60 more man hours of abstractors time (does not include time to pull records, data entry, etc.) using a vendor tool. If the CART tool is used, the amount of data entry time will more than double due to the additional data elements not automatically entered through a vendor system.

The August 15th deadline for 1st quarter 2006 discharges data submission is unrealistic. Data entry requires that abstractors be trained in a new system which became available in June 2006. With payment based on data validation scores, data abstractors must be proficient. The August 15th deadline should be changed to allow more time for data submission and/or the beginning discharge date for SIP measures should be changed to July 2006 discharges when the next version for SIP/SCIP abstraction tool is released.

Submitter : Dr. Alex Zaphiris

Date: 06/09/2006

Organization : Dr. Alex Zaphiris

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Submitter : Dr. Brent Messick
Organization : Cabarrus Family Medicine
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Brent H. Messick, MD, MS

Submitter : Dr. Jeffrey Leisring
Organization : Centerville Health Care
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Jeffrey Leisring MD FAAFP

Submitter : Denise Arcand
Organization : Denise Arcand
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Denise Arcand

Submitter : Dr. Andrey Sayko
Organization : Charlton Family Practice
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Andrey Sayko, M.D.

Submitter : Dr. Tatyana Sayko
Organization : Wester-Dudly Family Health Center
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Tatyana Sayko, M.D.

Submitter : Dr. Marsha Lavoie

Date: 06/09/2006

Organization : Dr. Marsha Lavoie

Category : Individual

Issue Areas/Comments

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Sincerely,
Marsha A. Lavoie, MD

Submitter : Dr. Amy Csorba
Organization : Dr. Amy Csorba
Category : Physician

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Amy R. Csorba MD

Submitter : Dr. sarah sciascia
Organization : american academy of family practice
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

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Sincerely,
Sarah Sciascia MD

Submitter : Dr. Jeffrey Luther
 Organization : Dr. Jeffrey Luther
 Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Jeffrey Luther, MD

Submitter : Dr. Kristin Foley
 Organization : UMass Memorial
 Category : Physician

Date: 06/09/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Kristin Foley D.O.

Submitter : Dr. Razmig Krumian

Date: 06/10/2006

Organization : Dr. Razmig Krumian

Category : Individual

Issue Areas/Comments

GME Payments

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Sincerely,

Razmig Krumian, DO

Submitter : Dr. Richard Madden
Organization : American Academy of Family Physicians
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter :

Date: 06/10/2006

Organization :

Category : Physician

Issue Areas/Comments

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Submitter : Dr. Jack Cahn
Organization : Alleghany Family Practice
Category : Physician

Date: 06/10/2006

Issue Areas/Comments**GME Payments**

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Sincerely,

Jack Cahn MD

Submitter : George Kappos
 Organization : George Kappos
 Category : Individual

Date: 06/10/2006

Issue Areas/Comments**GME Payments**

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Submitter : Dr. Katie Clubb
Organization : United Family Medicine Residency
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, THERE IS NO RESIDENCY EXPERIENCE THAT DOES NOT INVOLVE PATIENT CARE. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

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Sincerely,
Katie L. Clubb, MD
United Family Medicine Residency Program
St Paul, MN

Submitter : Dr. Catherine Sauri
Organization : Dr. Catherine Sauri
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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Submitter : Dr. Beverley Brown
Organization : Dr. Beverley Brown
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,

Beverley Brown MD

Submitter : marcy hersh
Organization : marcy hersh
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,
 Marcy Hersh

Submitter : Dr. David Marques
Organization : Grant Family Practice
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,
David R Marques, MD

Submitter : Mr. Gerald Ellis
Organization : Loma Linda University Medical Center
Category : Hospital

Date: 06/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment regarding proposed rule for IPPS FY07

CMS-1488-P-938-Attach-1.DOC

ATTACHMENT TO # 938

June 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

Dear CMS staff:

Loma Linda University Medical Center is a privately owned non-profit academic health center located in one of the nation's fastest growing regions and has a substantial elderly population within our service area. On April 12, 2006, CMS released its proposed hospital inpatient payment rule for FY 2007. The rule recommends the most significant changes to the Inpatient Prospective Payment System (IPPS, DRG) methodology since it was established more than 20 years ago. I am writing to you today to request that this proposal not be implemented in 2007 as it will have a significant negative impact on quality patient care, access to specialized care, and the financial stability of our hospital. In addition, I request one proposed change at a time in order to not destabilize our hospital and negatively impact our community.

The proposed changes are so extensive that hospitals are placed at great financial risk. First, CMS proposes to move from our current system to an estimated "cost-based" system. Second, CMS is proposing to change the method for identifying the variation in patient severity of illness. Each proposed change is quite significant by itself and together these changes would place Loma Linda University Medical Center at great risk. These proposed changes move funds away from cardiology services, including proven cost-effective therapies like implantable cardioverter defibrillators (decreased 22-24%), pacemakers (decreased 12-15%), ablations (decreased 28%) and drug-eluting stents (decreased 29%), into other hospital services. Currently, from the hospital perspective, when total cost is applied to these DRGs they perform at a loss or are barely profitable. When adjusted for volume, the overall portfolio of affected diagnoses operates at a loss. This would have a devastating impact on our ability to serve patients in our community.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. The proposed system with its sweeping changes will replace one known system with an unknown system that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. I also understand that over 225 hospitals were thrown out of the data set that included large numbers of academic health centers. As an administrator at an academic health center I am concerned that this selected data set will distort any analyses conducted by CMS and have a negative impact on our hospital.

I understand that CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

I believe CMS has failed to address issues related to "charge compression." The proposed rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures and even hospital departments are lost.

CMS proposes to implement a new system based on the severity of the patient's illness in 2007-2008. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of our patients and the community we serve, I thank you and recommend that these changes be deferred so that all concerned parties can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Gerald A. Ellis
Senior Vice President
Loma Linda University Medical Center
11234 Anderson Street
Loma Linda, CA 92354
909 558 4490

Submitter :**Date:** 06/10/2006**Organization :****Category :** Individual**Issue Areas/Comments****GENERAL**

GENERAL

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. David Holman
Organization : Dr. David Holman
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,

David O. Holman MD

Submitter : Dr. alfred tallia
Organization : UMDNJ-RWJohnson Medical School
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled /"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." /71 Fed. Reg. 23996 (April 25, 2006).

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In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Alfred F. Tallia, MD. MPH
 Chair, Family Medicine, UMDNJ-Robert Wood Johnson Medical School, New Brunswick, New Jersey

Submitter : Dr. Mary Guerrero
Organization : Univ of CT SOM, Dept of Family Medicine
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician,

I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Mary Guerrero, MD, FAAFP

Submitter : Dr. John Carroll
Organization : Dr. John Carroll
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician in a rural practice, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden. Such a concept is unique but implementation impossible and off-base with the patients' benefit from their involvement in GME!

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

John R. Carroll, M.D.

Submitter : Dr. Richard Weinberger
Organization : Dr. Richard Weinberger
Category : Individual

Date: 06/10/2006

Issue Areas/Comments**GME Payments**

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Sincerely,
Richard Weinberger, MD

Submitter : Dr. William Mendoza
Organization : Dr. William Mendoza
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Edward Platia
Organization : Dr. Edward Platia
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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See attachment

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

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

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

Submitter : Dr. Jessica Bloom-Foster
Organization : Cedar Rapids Medical Educ. Foundation
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,

Jessica L. Bloom-Foster, MD

Submitter : Dr. Frank Dania
Organization : Hennepin County Medical Center, Minneapolis, MN
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Frank Dania, M.D., M.S.

Submitter : Dr. Michael Faircloth
Organization : Palmetto Health Richland Family Medicine Center
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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Michael Faircloth, DO

Submitter : Dr. Gordon Baustian
Organization : Cedar Rapids Medical Education Foundation
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I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Gordon Baustian, MD

Submitter : Dr. Steve Bartz
Organization : Mercy Health System
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely,

Steve Bartz

Submitter : Dr. Natalie Fowler
Organization : Dr. Natalie Fowler
Category : Physician

Date: 06/10/2006

Issue Areas/Comments**GME Payments**

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Sincerely,

Natalie Fowler, MD

Submitter : Dr. Lee Carter
Organization : Tennessee Academy of Family Physicians
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Lee M. Carter, MD

Submitter : Dr. John Green
 Organization : Texas Academy of Family Physicians
 Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Jon Rich
Organization : Conroe Family Practice Residency Program
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Mary Colema
 Organization : University of Louisville
 Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. greg weckenbrock
Organization : Premier Family Medicine
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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 Gregory P. Weckenbrock M.D.

Submitter : Dr. camille salame

Date: 06/10/2006

Organization : Dr. camille salame

Category : Physician

Issue Areas/Comments

New Technology

New Technology

DEAR SIR/MS

I AM WRITING IN SUPPORT OF A NEW SPINE TECHNOLOGY KNOWN AS THE X-STOP DEVICE USED IN A SURGERY REFERED TO AS INTERSPINOUS PROCESS DISTRACTION FOR SPINAL DECOMPRESSION. THIS DEVICE AND SURGERY OCCUR IN THE SETTING OF LUMBAR SPINAL STENOSIS (LSS). LSS IS A CONDITION ENCOUNTERED MAINLY IN THE ELDERLY. IT RESULTS FROM AGING AND CAUSES LEG PAIN AND DISCOMFORT AND DIFFICULTY WITH AMBULATION. IT TAKES SOMEONE FROM A STATE OF FUNCTIONALITY TO A STAGE OF DEBILITY. THE CURE FOR SUCH CONDITION HAS BEEN MAJOR SURGERY CONSISTING OF LAMINECTOMY AND POSSILBLE FUSION WITH INSTRUMENTATION DONE UNDER GENERAL ANESTHESIA AND TAKING ANYWHERE BETWEEN 2 TO 5 HOURS. A MAJOR SURGERY INDEED FOR THE ELDERLY POPULATION. NOW COMES THE X-STOP DEVICE WITH ITS RELATED SURGERY WHICH IS MINIMALLY INVASISVE, DONE UNDER LOCAL ANESTHESIA AND TAKING LESS THAN ONE HOUR. THE AMOUNT OF SURGERY AND BURDEN ON THE PATIENT IS TYPICALLY MINIMAL.

I HAVE BEEN TRAINED IN THE X-STOP AND HAVE ALREADY DONE ONE SUCH SURGERY. I ALSO HAVE DONE MANY OF THE TRADITIONAL LAMINECTOMY AND FUSION AND WILL ATTEST TO THE STEALTH AND SIMPLICITY OF THE X-STOP PROCEDURE. MY PATIENT IN HER ADVANCED AGE TOLERATED THE PROCEDURE VERY WELL AND HAS BEEN RELEIVED OF HER SYMPTOMS (NEUROGENIC CLAUDICATION).

SIMPLICITY, SAFETY AND SIMILAR PAIN RELEIF TRANSLATE INTO A MORE FAVORABLE PROCEDURE WHICH SHOULD ALSO BE COST EFFECTIVE DUE TO LESS SURGERY, LESS INSTRUMENTATION, LESS COMPLICATIONS AND QUICK RECOVERY WITH SHORTER LOS.

I HIGHLY RECOMMED THE X-STOP FOR MY PATIENTS. A PROPER CODE FOR THE PROCEDURE WILL GO WAYS INTO BRINGING IT TO THE MAINSTREAM SPINAL ARRAY OF SURGERIES AND WILL SPEED ITS INTRODUCTION.

I HAVE NO FINANCIAL ARRENGEMENTS WITH THE PRODUCER OF X-STOP AND MY COMMENTS ARE STRICTLY MEDICAL IN NATURE. YOU MAY CONTACT ME AT 860-889-8598. C G SALAME, MD, MS.

Submitter : Dr. Marshall Prunty

Date: 06/10/2006

Organization :

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

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Submitter : Dr. Sylvia Gisi
Organization : Dr. Sylvia Gisi
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,

Sylvia A. Gisi, M.D.

Submitter : Dr. Denise Devereaux
Organization : Dr. Denise Devereaux
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,

Denise Devereaux, MD

Submitter : Dr. Eric Prystowsky
Organization : Heart rhythm Society
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

To Whom it may concern:

I am very concerned about the major proposed cutbacks in hospital reimbursement for implantation of ICDs and for catheter ablation of cardiac arrhythmias. These drastic reductions will undoubtedly result in less access to medical care for our elderly patients. During my term as president of the Heart Rhythm Society, formerly NASPE, I spoke at a congressional luncheon and explained our agenda of getting patients to 'know their ejection fraction' so that appropriate patients would receive an ICD. We are making headway on this important issue of identifying high-risk patients and giving them an ICD. Many lives have been saved by such an approach. The maked reduction in payments for ICDs will cause some programs to minimize their efforts to find high-risk patients, which is a large step backwards in this key area of medicine. Please reconsider your decision, or at least delay it for a year until the many interested stakeholders have an opportunity to evaluate the consequences of your proposal.

The proposed reductions in catheter ablations will have a particular negative effect on atrial fibrillation ablations, since the elderly are one of the largest patient pools for this arrhythmia, and the techniques are getting better with fewer complications in medicare-aged patients. Reimbursement for ablations is already low, and further reductions will shift programs from a potentially curative procedure to increaed antiarrhythmic drug use. The latter has many unacceptable side-effects, and the elderly will suffer because of this. Please reconsider these reductions and delay or negate implementation of them.

Sincerely,
Eric Prystowsky, MD

Submitter : Dr. Laurence Sharp
Organization : Dr. Laurence Sharp
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Laurence Sharp, DO, FAAFP

Submitter : Dr. Mark Rampton
Organization : Dr. Mark Rampton
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Dr. Mark E. Rampton
Corvallis, Oregon

Submitter : Dr. RADHA RAMANA MURTHY GOKULA
Organization : HARBOR BEACH COMMUNITY HOSPITAL
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
MURTHY GOKULA

Submitter : Mr. Michael Sauber

Date: 06/10/2006

Organization : Mr. Michael Sauber

Category : Individual

Issue Areas/Comments

GME Payments

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Sincerely,
Michael Sauber

Submitter : Dr. James Little
Organization : Family Physicians Group
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Jim Little, MD, FAAFP

Submitter : Dr. Marc Carey
Organization : Dr. Marc Carey
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Marc Carey, MD

Submitter : Dr. Matthew Small
Organization : South Haven Community Hospital
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Dr. Matthew G. Small

Submitter : Ms. Ana Hilde
Organization : Ms. Ana Hilde
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a medical student interested in family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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Sincerely,
 Ana Hilde
 MD/MPH candidate 2007
 OHSU
 Portland, OR

Submitter : Mr. Jean Thomas
Organization : Advantage Health
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Submitter : Dr. Michael Schultz
Organization : Michael L. Schultz, MD-PC
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Michael L. Schultz, MD

Submitter : Dr. Michael Schultz
Organization : Michael L. Schultz, MD-PC
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

I have been a practicing Family Physician for 21 years. The practice of primary care has become increasingly demanding and complex. I may work for another 15 years or so. By then many of my primary care colleagues will be retired also, and it appears that there will be an insufficient supply of more recently trained (especially US-trained) physicians to take our place. I sincerely fear for the adequacy of the primary care workforce of the near future. Please do not allow anything to occur that might reduce the attractiveness of our medical school graduates selecting a primary care speciality, or anything to reduce funding to support those educational programs for their training.

I greatly appreciate you taking time to read my concerns.

Sincerely,

Micheal L. Schultz, MD

Submitter : Dr. Joel Ang
 Organization : Dr. Joel Ang
 Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely,

Joel Ang MD
1759 Q St NW
Washington DC 20009

Submitter :

Date: 06/10/2006

Organization : University Hospital - SUNY UMU

Category : Hospital

Issue Areas/Comments

**Blood Clotting Factor Payment
Rate**

Blood Clotting Factor Payment Rate

diagnosis for the reimbursement add-on to the PPS inpatient payment.

Submitter : Dr. Rakhee Sheth
Organization : West Suburban Family Medicine Program
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To separate out CMS's newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. Sidney Jackson

Date: 06/10/2006

Organization : Dr. Sidney Jackson

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

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Submitter : Dr. Brian Finley
Organization : Dr. Brian Finley
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

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Submitter : Dr. Susan Snider
Organization : Dr. Susan Snider
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GENERAL

GENERAL

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Background The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

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Sincerely,

Susan Snider MD

Submitter : Stephanie Prior
Organization : Stephanie Prior
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely,
 Stephanie Prior

Submitter : Dr. Richard Mattison
Organization : Bayfront Medical Center
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : Dr. Walter Peterlein
Organization : Dr. Walter Peterlein
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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As the former Director of the Family Practice Residency at CMMC I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Walter R. Peterlein, M.D.

Submitter : Dr. Derek Earl
Organization : Dr. Derek Earl
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Derek T. Earl, D.O.

Submitter : Dr. John Smith
Organization : Dr. John Smith
Category : Physician

Date: 06/10/2006

Issue Areas/Comments**GME Payments**

GME Payments

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Sincerely,

John F Smith D.O.

Submitter : Dr. craig smith
Organization : Dr. craig smith
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Craig M Smith D.O.

Submitter : Dr. Jennifer smith
Organization : Dr. Jennifer smith
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Jennifer Smith D.O.

Submitter : Dr. David Weldy
Organization : Dr. David Weldy
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,
David L. Weldy, M.D., Ph.D.

Submitter : Kevin Deighton
Organization : Kevin Deighton
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Kevin Deighton

Submitter : Dr. Stanley Sagov
Organization : Dr. Stanley Sagov
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Submitter : Dr. James Shelton
Organization : Nebraska Academy of Family Physicians
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Background

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Submitter : Mark Campbell
Organization : Mark Campbell
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Submitter : Dr. Stephen Adams
Organization : Cox Health
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Stephen Adams MD
Associate Professor
Cox Family Medicine Residency

Submitter : Dr. Raymond Lewis
Organization : Brown University/Memorial Hospital of RI
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,

Raymond H. Lewis, Jr., MD
Assistant Clinical Professor
Department of Family Medicine
Brown University School of Medicine
Memorial Hospital of Rhode Island

Submitter : Dr. Bryan Lundquist
Organization : Dr. Bryan Lundquist
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Bryan J. Lundquist MD

Submitter : Dr. Thomas Scheider
Organization : HealthEast Care System
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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Sincerely,
Thomas Scheider, MD
Family Medicine Chief
Woodwinds Hospital
Woodbury, MN

Submitter : Dr. Rabin Chandran
Organization : Brown Medical School/Memorial Hospital of RI
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GME Payments

GME Payments

These changes will be devastating to the ability to train high quality primary care physicians in the future. It is very important that we improve, and not cripple Family Medicine Education. We have an aging population of seniors that need well trained physicians to care for them. Please consider revising these rules to include the coverage of didactic experiences.

Submitter :

Date: 06/10/2006

Organization :

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

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Sincerely yours,

Ronald H. Labuguen, M.D.

Submitter :**Date: 06/10/2006****Organization :****Category : Individual****Issue Areas/Comments****GME Payments**

GME Payments

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Submitter : Dr. Jacqueline Friedman
Organization : Dr. Jacqueline Friedman
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

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Sincerely,
Jacqueline Friedman, MD

Submitter : Dr. Margaret Sanderson
Organization : Dr. Margaret Sanderson
Category : Individual

Date: 06/10/2006

Issue Areas/Comments

GME Payments

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