Submitter : Mr. Cecil Terry **Date:** 10/09/2006

Organization : BJC HeathCare

Category : Hospital

Issue Areas/Comments

Packaged Services

Packaged Services

FY 2006 Correct Coding Initiative (CCI) Edits for Injections and Infusions

While this topic is not specifically addressed in the proposed rule, we request consideration of amending the final rule to address this fundamental payment problem arising from what we believe is an inappropriate and unfair application of the CCI edits for post-procedure injections and infusions.

Beginning in July 2006, intermediaries began applying CCI edits to coding pairs when one of the two codes was either an injection (e.g., C8952) or an infusion (e.g., C8950, and the other code was in broad range of procedures which included all surgical codes, and even radiology codes. While Change Request 4388, explains that intermediaries were instructed to delay application of these edits to permit payment of the injections or infusions without requiring a 59 modifier (i.e., distinct procedural service), the edits were fully implemented on July 1, 2006.

One of the more common situations where payments for injections and infusions are being denied, are those that frequently occur post-procedure (i.e., after surgery or some other complex procedure) to administer pain medication or a prophylactic antibiotic. Under the rules CMS has prescribed for the application of the 59 modifier, many of these injections or infusions do not qualify for the 59 modifier, because the need of for the injection or infusion was indirectly related to the original procedure. In a recent CMS Open Door Forum, the CMS representative explained that it was CMS intent to deny payment for these injections or infusions because payment for these has been packaged with the procedure.

We believe that this prohibition of the application of the 59 modifier to injections or infusions that are only indirectly related to the procedure overly broadens the concept of related - packaged services. While the need for these injections or infusions may have arisen from the original procedure, these injections or infusions are not administered to all patients and are not administered as a direct component of the procedure. In these cases the only comment factor between the original procedure and the injection or infusion is the diagnosis. In these situations, we believe infusions and injections that are not universal components of the actual procedure should qualify for application of the 59 modifier, and therefore payment, even when the diagnosis is the same. The injections or infusions are actually a distinct procedural service.

Beginning on July 1, 2006, the discontinuance of payments for such post-procedure injections or infusions is not actually a packaging of payments with the procedure payment, but a total denial of any payment. Except for the three exceptional diagnoses, most allowable observation services are not paid separately but are packaged in the procedural payments. Since separate payment for post-procedure injections and infusions was only discontinued recently, we do not believe that the cost for these services has been sufficiently considered in the recalibration of the procedure payments, thus denying all payment for these services.

We respectfully request that CMS reconsider its rationale and permit the application of the 59 modifier to all post-procedure injections and infusions which are not direct components of the actual procedures.

Further, if CMS would allow separate payment for such post-procedure injections and infusions, then the excessive administrative burden on hospitals to document and apply the 59 modifier for these situations could be eliminated, as well. That is, the 59 modifier should then be required only to document the administration of a different drug for an entirely different clinical reason than that for the administration of the first post-procedure medication.

Visits

Visits

Type A and Type B Emergency Departments

On page 49608 of the proposed rule, CMS distinguishes between Type A and Type B emergency departments. It is observed that many hospitals with Type A emergency departments, have a separate adjacent space that is, organizationally, part of the emergency department and which, during the day, is used to treat patients with less severe symptoms and conditions. These adjacent spaces for treating less severe patients are often closed at night, although the primary emergency area remains open and fully staffed 24/7 and these adjacent spaces (which generally share some staffing with the primary emergency area) are, in effect, a volume management tool for Type A emergency departments. While we believe that such a part-time sub-division of a Type A emergency department is an integral part of the entire department, we request that CMS clarify that these low level severity sub-divisions of Type A emergency departments will, in fact, be considered part of Type A emergency departments for application of the new visit codes, and not a separate Type B emergency department in the same hospital. This clarification is needed to ensure compliance and avoid confusion for hospitals attempting to provide Type A emergency services in the most cost efficient manner possible.

Submitter : **Date: 10/09/2006**

Organization :

Category : **Congressional**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Dear CMS:

Please find below a letter to Secretary Leavitt from every member of the Louisiana delegation regarding the critical need to avert the proposed rate cuts to PHP's (Partial Hospitalization Programs - APC Code 0033). This program serves chronically mentally ill persons and the elderly. The geriatric and disabled desperately need these services. Please know that hurricanes Katrina and Rita have taught us in a painfully acute way that these services are so very important. We are certain geriatric and disabled communities are equally in need of these vital services across the country.

Rep. Rodney Alexander
(LA-05)

October 6, 2006

The Honorable Mike Leavitt
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt,

We are writing regarding CMS proposed rate reduction for 2007 to PHP (Partial Hospitalization Program - APC code 0033) services for chronically mentally ill persons and the elderly. Should this proposed reduction go into effect, this would be the second consecutive year in which this service has been faced with double digit rate cuts. To date, we are unaware of any CMS data that shows how services have been or would be impacted by these cuts and encourage CMS to delay any further cuts until such data could be provided. Enclosed is an impact statement provided by the Association for Ambulatory Behavioral Healthcare for your review.

Providers who offer this level of mental health services faced a 13% rate reduction beginning in January 2006. While providers are still making adjustments to adapt to this cut, CMS is proposing another 15% reduction in rates for 2007. This makes for a 28% rate reduction in a short, two-year time frame.

We are concerned that this latest proposed reduction will force many providers in Louisiana, as well as other parts of the country, to close their doors to mentally ill individuals. This will create an environment in which the chronically mentally ill are not properly cared for, and this can create a potentially dangerous situation for these people and for others in Louisiana.

Additionally, we are also concerned about the wage index for Louisiana providers. With the cost of doing business in Louisiana having risen significantly following the hurricanes, the wage index proposed by CMS does not accurately reflect the cost of labor. This coupled with the proposed rate reduction will surely have a negative effect on providers who offer PHP.

Your attention to this matter is much appreciated.

Sincerely,

Senator David Vitter Senator Mary Landrieu

Congressman Jim McCrery Congressman Richard Baker

Congressman William Jefferson Congressman Bobby Jindal

Congressman Charlie Melancon Congressman Charles Boustany

Congressman Rodney Alexander

Submitter : **Date: 10/09/2006**

Organization :

Category : **Congressional**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

October 6, 2006

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U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

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Your attention to this matter is much appreciated.

Sincerely,

Senator David Vitter Senator Mary Landrieu

Congressman Jim McCrery Congressman Richard Baker

Congressman William Jefferson Congressman Bobby Jindal

Congressman Charlie Melancon Congressman Charles Boustany

Congressman Rodney Alexander

Submitter : **Date: 10/09/2006**

Organization :

Category : **Congressional**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Dear Colleague:

Please join me in signing a letter urging the Center for Medicare and Medicaid Services (CMS) to suspend a rate cut to its Partial Hospitalization Program (PHP) and to establish a behavioral health task force to establish an effective method of calculating rate changes to preserve the availability of this lower-cost benefit.

The proposed changes in reimbursement to providers of outpatient services that would have far reaching injurious effects on psychiatric service access. APC 0033 Partial Hospitalization represents an entire level of care, intensive treatment for a very special population, the severely and persistently mentally ill (SPMI) and elderly. This benefit is designed to keep beneficiaries out of higher cost institutional settings such as psychiatric hospital inpatient units, emergency rooms, nursing homes, and, in some cases, jails.

Reimbursement cuts from 2005 and 2006 resulted in the closing of many programs in Community Mental Health Centers (CMHCs) and hospitals across the nation because the reimbursement does not cover the actual costs of treatment. Surviving providers now face another 15% cut, and a potential fiscal necessity of closing their Partial Hospitalization Program (PHP) doors, threatening complete elimination of services.

The reimbursement formula employed by CMS is fatally flawed in several ways, detailed in the attached letter. If we do not correct the calculation methodology and hold the rate constant there will be dramatic increases in the higher-cost presentations to emergency rooms and inpatient units due to reduced provider participation.

Therefore I ask you to join me by signing on to the attached letter to HHS Secretary Leavitt, CMS Administrator McClellan, and the CMS Comment Office urging CMS to: (1) suspend the proposed cut and (2) create a behavioral health task force to establish an effective method of calculating rate changes to preserve the availability of this lower-cost benefit.

Sincerely,

Eddie Bernice Johnson

Member of Congress

Mr. Mike Leavitt, Secretary

U.S. Department of Health and Human Services

200 Independence Avenue SW

Washington, D.C. 20201

Dear Secretary Leavitt:

The Center for Medicare and Medicaid Services (CMS) is proposing changes in reimbursement to providers of outpatient services to be effective January 1, 2007 (PPS-CMS-1506-P). One behavioral health service, APC 0033 Partial Hospitalization Program (PHP), emerges as unique in that it does not represent a simple procedure but an entire level of care. This benefit is the delivery of four to seven whole days per week of intensive psychiatric treatment to the elderly, as well as severely and persistently mentally ill. These programs, delivered by hospital outpatient departments and Community Mental Health Centers (CMHCs), are designed specifically to keep these beneficiaries out of higher cost institutional settings.

This benefit was cut 2% in 2005 from $286.82 to $281.33, and cut again 12% for 2006, down to $245.91. The proposed cut for 2007 is another 15%, reducing the rate to $208.27. The effect of last year s cut was the closing of many programs in CMHCs and hospitals across the nation because the reimbursement covers less than actual provider costs. Further cuts threaten access to this cost-saving benefit for the mentally ill.

The reimbursement rate formula presently employed by CMS is fatally flawed in several ways, only a few of which are presented below.

MEMBERS OF CONGRESS: (signatories)

Eddie Bernice Johnson,
Barney Frank,
Marcy Kaptur,
Ron Paul,
Donald M. Payne,
Collin Peterson,
Gene Green,
Lloyd Doggett,
Patrick J. Kennedy,
Sheila Jackson Lee,
Ted Strickland,
Ruben E. Hinojosa
G.K. Butterfield
Tim Ryan
Al Green

Submitter : **Dr. Oliver Khakmahd** **Date: 10/09/2006**

Organization : **Dialysis Access Center, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I support the position as outlined by Dr. Saad from the American Society of Diagnostic and Interventional Nephrology (ASDIN) regarding 1506-P.

Submitter : Darla Perry **Date:** 10/09/2006

Organization : Darla Perry

Category : Individual

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Please review attached.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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 : **Ms. Colleen McCauley** **Date: 10/10/2006**

Organization : **Ms. Colleen McCauley**

Category : **Hospital**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Please reconsider not cutting the Partial Hospitalization Program. Many facilities will not be able to operate on the proposed rate, and this cannot justify the costs involved in operating the partial hospital programs, the mentally ill population, who desperately need these services.

I urge you to think about the break down of the operation costs of an intensive psychiatric program, including hospitalization services. The 15% cut will make it impossible for a business to run, especially with the high costs of medical.

Our Partial Hospitalization Program provides services to a needy population and cannot be sacrificed by this drastic cut.

CMS-1506-P-404 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Date & Time:** **10/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHED DAVID FERN MD

CMS-1506-P-404-Attach-1.DOC

DEKALB SURGICAL ASSOCIATES, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael T. Cornwell, M.D., F.A.C.S., David R. Fish, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Respectfully,

David McTamney MD

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

CMS-1506-P-405 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Date & Time:** **10/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"SEE ATTACHED" MICHAEL CORNWELL MD

CMS-1506-P-405-Attach-1.DOC

CMS-1506-P-405-Attach-2.DOC

DEKALB SURGICAL ASSOCIATES, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael L. Caldwell, M.D., F.A.C.S., David R. Fein, M.D., F.A.C.S., Michael S. Champney, M.D.

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Respectfully,

M. Caldwell

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Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
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Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

1705-F

DEKALB SURGICAL ASSOCIATES, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael L. Cornwell, M.D., F.A.C.S., David R. Fern, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

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M. Cornwell

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Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

CMS-1506-P-406 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Date & Time:** **10/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"SEE ATTACHED" JOHN KENNEDY MD

CMS-1506-P-406-Attach-1.DOC

DeKalb Surgical Associates, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael J. Cornwell, M.D., F.A.C.S., David R. Fern, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

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Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"SEE ATTACHED" GORDON KOLTIS MD FACRO

CMS-1506-P-407-Attach-1.DOC

Gordon G. Koltis, M.D., FACRO
Board Certified
Radiation Oncologist

Cancer Treatment Center
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Fax: (252) 329-0326
www.CarolinaRadiation.com

Andrej V. Hnatov, M.D.
Board Certified
Radiation Oncologist

Carolina Radiation Medicine, P.A.

Alex V. Hnatov, M.D.
Radiation Oncologist

LMH Cancer Center
703 Doctors Drive
Kinston, NC 28501

Phone: (252) 522-7600
1-800-Hope4Me (467-3463)
Fax: (252) 527-2476

October 4, 2006

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

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear CMS Administrator:

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am very concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs.

CMS should continue with CPT codes 19296 and 19297 being assigned to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	0030	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	0029	$1,732.69	($1,017.31)	**-37.0%**

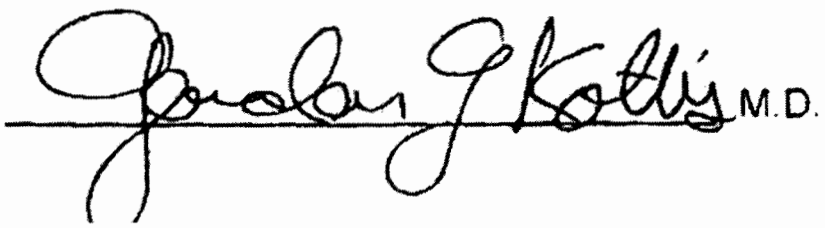
Should CMS finalize the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC assigned, must cover the cost of the device. Of note: the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Additionally, our facility purchases the radiation source to be used in breast conservation treatment. Our facility must be able to cover the costs of the radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.

Regards,



cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
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Senator Thad Cochran, Chairman, Senate Appropriations Committee
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Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Ms. Marilyn Litka-Klein **Date:** 10/10/2006

Organization : Michigan Health & Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the MHA's attached comment letter.

Thanks!

CMS-1506-P-408-Attach-1.DOC

CMS-1506-P-408-Attach-2.DOC

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attn: CMS—1540—P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2007; Proposed Rule.

Dear Dr. McClellan:

On behalf of Michigan's 145 nonprofit hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2007 proposed rule to update the Medicare outpatient prospective payment system (OPPS). The MHA is concerned about policy changes that would reduce Medicare outpatient payments to Michigan hospitals since this would further threaten the financial viability of hospitals. This is particularly concerning since the latest data available indicates that on an aggregate basis, Michigan hospitals have a negative margin of 7 percent on outpatient services and lose approximately $65 million annually on services provided to Medicare beneficiaries. Hospitals cannot sustain these financial losses and remain viable as the commercial and uninsured patients are unwilling to absorb the cost of government under financing.

HOSPITAL QUALITY DATA

The CMS proposes to require compliance with the inpatient prospective payment system (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order for hospitals to receive a full payment outpatient update in 2007. Under the IPPS, the annual payment update is linked to the collection of quality measures and hospitals that fail to comply with the program requirements receive a marketbasket update that is 2 percent less than the full update. Beginning in 2007, the CMS indicates it has the authority and proposes to also reduce the outpatient PPS conversion factor update by 2 percent for hospitals that are required to report quality data under the IPPS RHQDAPU. In addition, hospitals not submitting all of the inpatient measures required for 2008 would have their outpatient payment update for FY 2008 reduced by 2 percent. The CMS asserts that it is appropriate to link full payment for outpatient services to the submission of these inpatient measures because several of the measures assess

SPENCER JOHNSON, PRESIDENT
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care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital improves the system for delivering these medications, quality improvement to other emergency and other ambulatory services have likely occurred as well.

The MHA strongly disagrees with the CMS' proposed linkage of the reporting of the inpatient measures to payments under the OPPS for the following reasons:

- Congress has already determined the inpatient penalty for hospitals that do not submit the inpatient data. In the Deficit Reduction Act (DRA), Congress specified that the penalty would be a 2 percent reduction in the IPPS market basket update. It did not authorize additional penalties for outpatient services. If Congress had intended to authorize outpatient penalties, it would have specified those in the DRA. We conclude that Congress did not intend additional penalties for hospital outpatient services.

- The CMS' proposed rule asserts that the authority for adding the penalty to the outpatient payment comes from its "equitable payment authority". The equitable payment provision in the Social Security Act was intended to enable the CMS to eliminate inequitable impact on a particular provider or group of providers. Implementation of the equitable payment provision must be done in a budget neutral manner. For OPPS, there are no inequities in outpatient payment. Rather, application of this requirement may result in less payment to OPPS providers

- The CMS states that inpatient measures provide insight into the clinical care in the ambulatory setting. There is no relationship between the measures being used to assess the adequacy of inpatient heart attack, heart failure, pneumonia and surgical care and the care of patients receiving diagnostic, radiological, pharmaceutical and other procedures covered under OPPS.

Prior to linking any set of measures to the payment for outpatient care, there should be clear evidence that the measures specifically have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). **The MHA urges the CMS to continue working with the HQA and the AQA to identify and implement measures that truly assess important aspects of outpatient care quality.** Once appropriate measures have been identified, the CMS should work with Congress to consider how the payment system should be modified to support the provision of high quality care in the outpatient setting. Since appropriate outpatient care measures have not been identified, **the CMS should remove any link between quality measures and outpatient care payments in this rule.**

PARTIAL HOSPITALIZATION

Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care and may be provided by a hospital outpatient department or a freestanding Community Mental Health Center (CMHC). Providers are paid on a per-diem basis for these services. The MHA is concerned that an additional proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per diem rate was reduced by 15 percent and hospitals cannot sustain further reductions in the per diem rates. These services already are quite vulnerable, with many programs in recent years closing or limiting their patients.

We share the CMS's concern about volatility of the community mental health center data. However, it is inappropriate to penalize one set of providers for the performance of another.

Although the MHA recognizes that the CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per diem cost, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services.

Instead, **the MHA recommends that for 2007, the CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65.** This approach will provide payment stability for these services and protect beneficiary access to hospital-based services while allowing the CMS adequate time to address the instability in the CMHC data. **We further request that the CMS require CMHCs to improve their reporting or have that provider group face economic consequences.**

OPPS: RURAL HOSPITAL HOLD HARMLESS TRANSITIONAL PAYMENTS

The MHA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. **The MHA supports S. 3606, "Save Our Safety (SOS) Net Act of 2006" which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.**

NEW TECHNOLOGY APCS

The CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. An

example is as Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which were assigned to New Technology APC 1514 in 2005. Once approved by the CMS, there may be a delay in providing the services, resulting in less than 12 months full utilization in the first year of the CMS data files. **As a result, the MHA recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying somewhat more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs). The MHA is concerned about the CMS's proposal to reduce payments for specified covered outpatient drugs (SCODs) to ASP plus 5 percent in 2007. This represents a one percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed for the same drug paid in physician office settings. **The MHA believes that consistency in payment for drugs and biologicals across settings is important and recommends that the CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals. The CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost but instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, the CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. Due to concerns that the claims data may be incomplete due to frequent code and descriptor changes for radiopharmaceuticals, we believe that it is too soon to end the current policy of paying at hospital costs. **As a result, the MHA recommends that for 2007, the CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

EVALUATION & MANAGEMENT (E/M) CODES

Despite the CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007, the CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services. The CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, the CMS states that hospitals may continue to utilize their existing internal guidelines for determining the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The MHA continues to believe that the CMS should not implement new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. **The MHA recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.** Creating temporary G-codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G-codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. Instead, our approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus instead on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OBSERVATION SERVICES

For 2007, the CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The MHA continues to support the CMS's concept of allowing the outpatient code editor (OCE) logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, since the process for determining whether observation is separately payable is largely "automated", the MHA believes the CMS should consider expanding diagnoses for which observation may be separately paid. As a result, the MHA supports the APC Panel's recommendation that the CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment

CRITICAL ACCESS HOSPITALS: EMERGENCY MEDICAL SCREENING

The MHA supports the CMS's proposal to change the critical access hospital (CAH) conditions of participation to allow registered nurses to serve as qualified medical personnel for screening individuals who present to the CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted under facility bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. However that there is an inconsistency between the CMS's preamble language and the regulatory text being proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws. **The MHA recommends that the CMS clarify this requirement in the final OPPS rule for 2007.**

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold to $1,875 – $625, or 50 percent, more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,875 more than the APC rate.

While the MHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, the CMS proposed outlier threshold is too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the MHA is concerned that Medicare may not actually spend the outlier target set-aside. **The CMS should publish the annual outlier payments as a percent of total expenditures for 2005 and prior. The outlier threshold increase should be limited to the increase in APC rates, or 3.4 percent, unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

Proposed Critical Care Coding. The MHA is opposed to the proposed structuring of critical care coding on the basis of time. Tracking and documenting time for critical care services would pose a significant burden to hospitals and could be subject to gaming. Time has never been incorporated as a component of critical care coding and billing instructions for hospitals since the inception of the OPPS. In fact, the April 7, 2000 final rule establishing the OPPS clearly states, "In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."

While the 30-minute threshold has applied to physician professional service billing, it has long been understood that hospital resources for critical care are not linked to time, but rather reflect the immediate intensity of care provided to patients receiving these services. The goal of the ED is to stabilize the patient as quickly as possible, which involves multiple hospital staff to be simultaneously present, and may even require a multidisciplinary team. It would be extremely burdensome and confusing to track time for different individuals involved in providing critical care services. **The MHA recommends that the CMS eliminate the reference to time in the definition of the new critical care codes and instead continue with its long-standing OPPS policy concerning coding and billing for critical care services.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The MHA remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

The MHA again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, the CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the Medicare Modernization Act (MMA). Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on appropriate contractor's performance.

The MMA requires that the Secretary of the Department of Health and Human Services consult with providers of services on the MAC performance requirements and standards, and the MHA appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the MHA believes that such provider input is critical.

However, we encourage the CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may not be able to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is often used to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

The MHA also requests that the CMS to do everything within its authority to ensure that MACs are accountable to the agency and providers for the services they provide. It is critical that the selected contractors understand how hospitals and health care systems function,

and that MAC staff have the necessary technical expertise to efficiently and correctly process hospital claims.

In addition, given that each defined A/B MAC jurisdiction will include several states, the CMS **must ensure that the chosen contractor is able to maintain a significant local presence.** This includes the ability to work within different time zones, availability and accessibility within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

FY 2008 IPPS RHQDAPU

In the proposed rule, the CMS announces the measures hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to get the full inpatient payment to which they would otherwise be entitled in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would suffer a penalty of having their FY 2008 inpatient payments reduced by two percent.

The MHA is supportive of the CMS utilizing quality measures that have already been adopted as part of the Hospital Quality Alliance's efforts to promote public reporting of hospital quality data. These are well-designed measures chosen because they represent aspects of care that are important to patients, and that provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We strongly urge the CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA to provide a public accountability for quality.** This alignment will reinforce the importance of the public transparency on quality and help to focus quality improvement efforts on the chosen high priority areas of care.

We also support the CMS for publishing information on what measures hospitals will be expected to report to continue to receive their full inpatient payments early enough for them to put the proper data collection processes in place. As we said in our earlier comments on the Inpatient Prospective Payment System rule, if hospitals are not told until August what quality data they will be expected to report, they are unable to put the proper data collection processes in place quickly enough to ensure reliable abstraction of the information from patient records.

HEALTH INFORMATION TECHNOLOGY (HIT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program.

The MHA strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality

improvement strategies. They also view IT as a public good that requires a **shared investment between the providers and purchasers of care.**

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 American Hospital Association (AHA) survey noted that the median amount hospitals invested annually on health IT was greater than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts - a median of $1.7 million or 2 percent of all operating expenses - on operating costs related to IT. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.[1]

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. **However, it overlooks another of the study's major findings - that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.[2]**

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the MHA believes that the payers and purchasers of care should share in the costs of IT.**

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers - including the federal government - must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether the CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, the CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. The MHA believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

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[1] Forward Momentum: Hospital Use of Information Technology. Washington, DC: MHA (2005).
[2] R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs
Health Aff., September 1, 2005; 24(5): 1103 - 1117.

The MHA also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations - including the CMS - that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations - including expensive manual chart abstraction and use of third-party contractors - to submit quality data. The CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, the CMS **could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The MHA will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. The MHA firmly believes that **the CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.[3]

While the MHA appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives the CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

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[3] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No 06-E006 (April 2006).

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

In 2006, the Department of Health and Human Services (HHS) proposes to undertake a new effort to expand the availability of information on health care quality and pricing. The HHS intends to identify several regions in the United States with high health care costs and use its leadership role in health care policy to help lead change in those areas.

The MHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with the CMS and others to form the Hospital Quality Alliance (HQA). The work of the HQA has led to the voluntary reporting of 21 quality measures on the Hospital Compare Web site and more measures of hospital quality and patient satisfaction are planned for the future.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals, and the CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

The MHA recommends that the CMS convene a workgroup comprised of representatives from hospitals, the MHA and state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input toward resolution.

Another option the CMS offered is establishing a Medicare condition of participation to post prices on assistance programs for uninsured. While many hospitals are moving toward transparency in this area, including this as a condition of participation seems punitive and will not resolve the CMS core issue of what hospitals are doing to assist the uninsured. It is important for the CMS to understand that the income level of the uninsured varies by community and charity care policies will also vary. **Therefore, the MHA objects to the CMS expanding the conditions of participation to include posting of prices on assistance programs to the uninsured.**

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

- **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

- **Health Maintenance Organization (HMO) Insurance**. Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any need for specific price information.

- **High-Deductible or Health Savings Account (HSA) Insurance.** Individuals with HSAs have more interest regarding price information compare to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.

- **Uninsured Individuals of Limited Means.** Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Again, the MHA appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (517) 703-8608 or mklein@mha.org.

Sincerely,

Marilyn Litka-Klein

Marilyn Litka-Klein
Senior Director, Health Policy

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attn: CMS—1540—P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2007; Proposed Rule.

Dear Dr. McClellan:

On behalf of Michigan's 145 nonprofit hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2007 proposed rule to update the Medicare outpatient prospective payment system (OPPS). The MHA is concerned about policy changes that would reduce Medicare outpatient payments to Michigan hospitals since this would further threaten the financial viability of hospitals. This is particularly concerning since the latest data available indicates that on an aggregate basis, Michigan hospitals have a negative margin of 7 percent on outpatient services and lose approximately $65 million annually on services provided to Medicare beneficiaries. Hospitals cannot sustain these financial losses and remain viable as the commercial and uninsured patients are unwilling to absorb the cost of government under financing.

HOSPITAL QUALITY DATA

The CMS proposes to require compliance with the inpatient prospective payment system (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order for hospitals to receive a full payment outpatient update in 2007. Under the IPPS, the annual payment update is linked to the collection of quality measures and hospitals that fail to comply with the program requirements receive a marketbasket update that is 2 percent less than the full update. Beginning in 2007, the CMS indicates it has the authority and proposes to also reduce the outpatient PPS conversion factor update by 2 percent for hospitals that are required to report quality data under the IPPS RHQDAPU. In addition, hospitals not submitting all of the inpatient measures required for 2008 would have their outpatient payment update for FY 2008 reduced by 2 percent. The CMS asserts that it is appropriate to link full payment for outpatient services to the submission of these inpatient measures because several of the measures assess

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We share the CMS's concern about volatility of the community mental health center data. However, it is inappropriate to penalize one set of providers for the performance of another.

Although the MHA recognizes that the CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per diem cost, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services.

Instead, **the MHA recommends that for 2007, the CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65.** This approach will provide payment stability for these services and protect beneficiary access to hospital-based services while allowing the CMS adequate time to address the instability in the CMHC data. **We further request that the CMS require CMHCs to improve their reporting or have that provider group face economic consequences.**

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The MHA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. **The MHA supports S. 3606, "Save Our Safety (SOS) Net Act of 2006" which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.**

NEW TECHNOLOGY APCS

The CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. An

example is as Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which were assigned to New Technology APC 1514 in 2005. Once approved by the CMS, there may be a delay in providing the services, resulting in less than 12 months full utilization in the first year of the CMS data files. **As a result, the MHA recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying somewhat more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs). The MHA is concerned about the CMS's proposal to reduce payments for specified covered outpatient drugs (SCODs) to ASP plus 5 percent in 2007. This represents a one percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed for the same drug paid in physician office settings. **The MHA believes that consistency in payment for drugs and biologicals across settings is important and recommends that the CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals. The CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost but instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, the CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. Due to concerns that the claims data may be incomplete due to frequent code and descriptor changes for radiopharmaceuticals, we believe that it is too soon to end the current policy of paying at hospital costs. **As a result, the MHA recommends that for 2007, the CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

EVALUATION & MANAGEMENT (E/M) CODES

Despite the CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007, the CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services. The CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, the CMS states that hospitals may continue to utilize their existing internal guidelines for determining the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The MHA continues to believe that the CMS should not implement new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. **The MHA recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.** Creating temporary G-codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G-codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. Instead, our approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus instead on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OBSERVATION SERVICES

For 2007, the CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The MHA continues to support the CMS's concept of allowing the outpatient code editor (OCE) logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, since the process for determining whether observation is separately payable is largely "automated", the MHA believes the CMS should consider expanding diagnoses for which observation may be separately paid. As a result, the MHA supports the APC Panel's recommendation that the CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment

CRITICAL ACCESS HOSPITALS: EMERGENCY MEDICAL SCREENING

The MHA supports the CMS's proposal to change the critical access hospital (CAH) conditions of participation to allow registered nurses to serve as qualified medical personnel for screening individuals who present to the CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted under facility bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. However that there is an inconsistency between the CMS's preamble language and the regulatory text being proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws. **The MHA recommends that the CMS clarify this requirement in the final OPPS rule for 2007.**

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold to $1,875 – $625, or 50 percent, more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,875 more than the APC rate.

While the MHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, the CMS proposed outlier threshold is too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the MHA is concerned that Medicare may not actually spend the outlier target set-aside. **The CMS should publish the annual outlier payments as a percent of total expenditures for 2005 and prior. The outlier threshold increase should be limited to the increase in APC rates, or 3.4 percent, unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

Proposed Critical Care Coding. The MHA is opposed to the proposed structuring of critical care coding on the basis of time. Tracking and documenting time for critical care services would pose a significant burden to hospitals and could be subject to gaming. Time has never been incorporated as a component of critical care coding and billing instructions for hospitals since the inception of the OPPS. In fact, the April 7, 2000 final rule establishing the OPPS clearly states, "In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."

While the 30-minute threshold has applied to physician professional service billing, it has long been understood that hospital resources for critical care are not linked to time, but rather reflect the immediate intensity of care provided to patients receiving these services. The goal of the ED is to stabilize the patient as quickly as possible, which involves multiple hospital staff to be simultaneously present, and may even require a multidisciplinary team. It would be extremely burdensome and confusing to track time for different individuals involved in providing critical care services. **The MHA recommends that the CMS eliminate the reference to time in the definition of the new critical care codes and instead continue with its long-standing OPPS policy concerning coding and billing for critical care services.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The MHA remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

The MHA again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, the CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the Medicare Modernization Act (MMA). Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on appropriate contractor's performance.

The MMA requires that the Secretary of the Department of Health and Human Services consult with providers of services on the MAC performance requirements and standards, and the MHA appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the MHA believes that such provider input is critical.

However, we encourage the CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may not be able to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is often used to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

The MHA also requests that the CMS to do everything within its authority to ensure that MACs are accountable to the agency and providers for the services they provide. It is critical that the selected contractors understand how hospitals and health care systems function,

and that MAC staff have the necessary technical expertise to efficiently and correctly process hospital claims.

In addition, given that each defined A/B MAC jurisdiction will include several states, the CMS **must ensure that the chosen contractor is able to maintain a significant local presence.** This includes the ability to work within different time zones, availability and accessibility within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

FY 2008 IPPS RHQDAPU

In the proposed rule, the CMS announces the measures hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to get the full inpatient payment to which they would otherwise be entitled in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would suffer a penalty of having their FY 2008 inpatient payments reduced by two percent.

The MHA is supportive of the CMS utilizing quality measures that have already been adopted as part of the Hospital Quality Alliance's efforts to promote public reporting of hospital quality data. These are well-designed measures chosen because they represent aspects of care that are important to patients, and that provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We strongly urge the CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA to provide a public accountability for quality.** This alignment will reinforce the importance of the public transparency on quality and help to focus quality improvement efforts on the chosen high priority areas of care.

We also support the CMS for publishing information on what measures hospitals will be expected to report to continue to receive their full inpatient payments early enough for them to put the proper data collection processes in place. As we said in our earlier comments on the Inpatient Prospective Payment System rule, if hospitals are not told until August what quality data they will be expected to report, they are unable to put the proper data collection processes in place quickly enough to ensure reliable abstraction of the information from patient records.

HEALTH INFORMATION TECHNOLOGY (HIT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program.

The MHA strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality

improvement strategies. They also view IT as a public good that requires a **shared investment between the providers and purchasers of care.**

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 American Hospital Association (AHA) survey noted that the median amount hospitals invested annually on health IT was greater than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts - a median of $1.7 million or 2 percent of all operating expenses - on operating costs related to IT. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.[1]

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. **However, it overlooks another of the study's major findings - that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.[2]**

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the MHA believes that the payers and purchasers of care should share in the costs of IT.**

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers - including the federal government - must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether the CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, the CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. The MHA believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

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[1] Forward Momentum: Hospital Use of Information Technology. Washington, DC: MHA (2005).
[2] R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs
Health Aff., September 1, 2005; 24(5): 1103 - 1117.

The MHA also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations - including the CMS - that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations - including expensive manual chart abstraction and use of third-party contractors - to submit quality data. The CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, the CMS **could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The MHA will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. The MHA firmly believes that **the CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.[3]

While the MHA appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives the CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

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[3] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No 06-E006 (April 2006).

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

In 2006, the Department of Health and Human Services (HHS) proposes to undertake a new effort to expand the availability of information on health care quality and pricing. The HHS intends to identify several regions in the United States with high health care costs and use its leadership role in health care policy to help lead change in those areas.

The MHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with the CMS and others to form the Hospital Quality Alliance (HQA). The work of the HQA has led to the voluntary reporting of 21 quality measures on the Hospital Compare Web site and more measures of hospital quality and patient satisfaction are planned for the future.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals, and the CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

The MHA recommends that the CMS convene a workgroup comprised of representatives from hospitals, the MHA and state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input toward resolution.

Another option the CMS offered is establishing a Medicare condition of participation to post prices on assistance programs for uninsured. While many hospitals are moving toward transparency in this area, including this as a condition of participation seems punitive and will not resolve the CMS core issue of what hospitals are doing to assist the uninsured. It is important for the CMS to understand that the income level of the uninsured varies by community and charity care policies will also vary. **Therefore, the MHA objects to the CMS expanding the conditions of participation to include posting of prices on assistance programs to the uninsured.**

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

- **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

- **Health Maintenance Organization (HMO) Insurance.** Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any need for specific price information.

- **High-Deductible or Health Savings Account (HSA) Insurance.** Individuals with HSAs have more interest regarding price information compare to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.

- **Uninsured Individuals of Limited Means.** Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Again, the MHA appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (517) 703-8608 or mklein@mha.org.

Sincerely,

Marilyn Litka-Klein

Marilyn Litka-Klein
Senior Director, Health Policy

Submitter : **Date: 10/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

see attached Greg Dickerson MD

CMS-1506-P-409-Attach-1.DOC

#409

St. Dominic Hospital
SIXTY YEARS

October 10, 2006

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

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear CMS Administrator:

I am the President of the Mississippi Radiological Society, a Fellow of the American College of Radiology, and a Diplomate of the American Board of Radiology. I practice at St. Dominics / Jackson Memorial Hospital in Jackson, MS.

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am extremely concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs and the proposed new payment methodology for brachytherapy sources in 2007.

I highly recommend CMS continue with CPT codes 19296 and 19297 being assigned to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a

more appropriate APC for 2008. These CPT codes are device-dependent and the APC assigned, must cover the cost of the device. Of note: the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Additionally, our hospital purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with the cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospitals must be able to cover the costs of the radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, and as the President of the Mississippi Radiological Society, I recommend:

1. that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.

2. that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

I respectfully request that CMS heed my recommendations. I would like to continue providing this important service to your Medicare beneficiaries.

Regards,

Greg Dickerson, MD, FACR

Gregg Dickerson, M.D., FACR

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Mr. Ron Fazio **Date:** 10/10/2006

Organization : American Therapeutic Corporation

Category : Social Worker

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

This partial hospitalization provides outpatient services for mental health consumers whom are experiencing severe symptomatology such as; depression, paranoia, auditory/visual hallucinations, anxiety, and suicidal ideation, that would require inpatient hospitalization if not intervened by this program. We are staffed with highly educated and trained psychiatrists, nurses, and Master's level psychotherapists. We provide 6 days per week service and offer needed structure and learning via individual and group therapy. We provide a variety of psychotherapeutic and educational group topics to improve their coping skills and reduce the likelyhood of a relapse to the hospital. The payments for services from Medicare are expected to be cut 'again' thus would make it extremely difficult to extend the appropriate level of services to our consumers. Without the full range of services our consumers will truly suffer and be once again hidden away from society behind the walls of the hospitals. Please reconsider how 'more cuts' will be devastating to the welfare of our mental health consumers.
Thank you.
Ron Fazio, MSW, LCSW

Submitter : **Kathy Francisco** **Date: 10/10/2006**

Organization : **The Pinnacle Health Group, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Radiopharmaceutical Comments - See Attachment

CMS-1506-P-411-Attach-1.PDF

#411

THE PINNACLE HEALTH GROUP
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October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: **CMS-1506-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Submitted electronically: *http://www.cms.hhs.gov/eRulemaking/01_Overview.asp*

Dear Dr. McClellan:

The Pinnacle Health Group is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

The Pinnacle Health Group provides coding and reimbursement support for hospitals and physicians across the country. This comment letter specifically addresses the proposed payment for the diagnostic radiopharmaceutical, ProstaScint® (HCPCS A9507).

ProstaScint® (capromab pendetide) is the only FDA approved diagnostic radiopharmaceutical that targets prostate-specific membrane antigen (PSMA), a unique marker that is abundantly expressed on prostate cancer cells at all stages of prostate disease. Prior to ProstaScint, there were no reliable, noninvasive tests to identify metastatic disease in newly diagnosed and recurrent prostate cancer patients.

ProstaScint is a kit for the preparation of Indium In111 Capromab Pendetide administered by intravenous injection. The use of ProstaScint for early detection of lymph node involvement has potentially significant impact on the management of medical treatment of cancer patients and on the decrease of cost of care. ProstaScint is reported by hospitals using HCPCS A9507 and is been paid separately under the APC system.

ProstaScint is supplied one distributor as a non-radioactive agent that must be subsequently radiolabeled (combined) with Indium In-111. The Indium In-111 is provided by multiple distributors and radiolabeled by nuclear pharmacies across the country. The diagnostic radiopharmaceutical imaging agent In-111 Capromab Pendetide (Indium In-111 ProstaScint) is formed after it is radiolabeled with Indium In-111. Indium In-111 decays with a physical half-life of 67.2 hours or 2.8 days.

There are two separate components that determine the cost of this radiopharmaceutical: (1) the non-radioactive ProstaScint kit and (2) the radioactive dose of Indium In-111. The average cost of the radioactive dose of Indium In-111 alone is almost equivalent to the CMS proposed 2007 payment rate for the complete ProstaScint dose ($928.19).

It is unclear as to the reasons why CMS proposes to set fixed payment for radiopharmaceuticals in 2007 after only one year of transition to the charge adjusted to cost methodology. This payment methodology was in place for radiopharmaceuticals for claims year 2006 so CMS does not have the benefit of this useful information in which to verify costs reported by hospitals. In addition, there is support from governmental appointed advisory committees including the APC Advisory Panel on August 24, 2006 and the PPAC on August 26, 2006.

We understand that the APC initiative is to assure that hospitals are appropriately paid for products and services provided to patients. However, when a high cost product such as ProstaScint is utilized by the hospital, an appropriate payment methodology must be established to ensure payment is based upon the cost of the non-radioactive agent and the radioactive dose to prevent payment reductions that undermine the hospitals ability to provide these important diagnostic studies for Medicare beneficiaries.

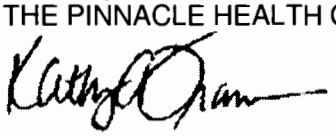
The Pinnacle Health Group supported the 2006 payment methodology change for radiopharmaceuticals to charges adjusted to cost because this offered a reliable methodology for providing appropriate payments to hospitals, and permitted CMS to collect more accurate claims data. However, this payment methodology was implemented in 2006 and the claims data utilized for the 2007 proposed payment system is the 2005 claims data. The data that CMS is collecting for 2006 should help CMS determine more appropriate payment values for radiopharmaceuticals.

Use of the median payment rate proposed for 2007 fails to reflect the average acquisition cost for ProstaScint and the radiolabeling agent Indium In-111 required to use this diagnostic imaging agent. Median payments as proposed will impose a radical reduction in the payment level, thus limiting patient access to this important diagnostic cancer study. CMS has continued to show concern when radical payment reductions are proposed and has continued to make adjustments to protect hospitals and patients under the HOPPS.

The Pinnacle Health Group respectfully recommends that CMS continue the current payment methodology of charges adjusted to cost for all radiopharmaceuticals, including ProstaScint for 2007. This will ensure that hospitals make this important diagnostic radiopharmaceutical available to patients. CMS should be aware that if the proposed payment rate for 2007 is implemented, hospitals will not be able to make this diagnostic cancer product available to Medicare beneficiaries.

Thank you for your consideration of these important issues.

Sincerely,
THE PINNACLE HEALTH GROUP, INC.



Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

Submitter : **Ms. Ann Langan** **Date: 10/10/2006**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Please see the attachment for the comments.

CMS-1506-P-412-Attach-1.TXT

#1112

October 10, 2006

Mark B. McCellan, M.D., Ph. D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 445-G
Washington, DC 20201

Re: CMS-1506-P Medicare Program; Proposed changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Rates; Proposed Rule (vol. 71 , No. 163 *Federal Register*), August 23, 2006.

Dear Dr. McClellan:

I am writing in response to the above-referenced proposed rule. In this proposed rule, the Centers for Medicare and Medicaid Services (CMS) has asked for comments on the various areas of this proposed rule. The following comments are on the section of proposed payment for Partial Hospitalization.

Partial Hospitalization:
We are writing in regard to the proposed additional 15% reduction in the partial hospitalization per diem payment as described on pages 49537 through 49539.

We have included our comment letter that we submitted in regard to the July 25, 2005 outpatient proposed rule (please see the text in the following paragraphs). We are concerned about the accuracy of the cost report data when applied to the claims data that CMS is using to compute the partial hospitalization costs per day for the community mental health centers (CMHC). If the cost report data is not matched correctly with the claims data for the same time period, an incorrect per diem cost could be computed. We ask CMS to delay the additional 15% reduction to the combined hospital-based and CMHC median per diem cost that is being proposed on page 49538 until the accuracy of the cost report data for the CMHCs can be established. Is it possible for CMS to release the detailed claims data and cost report data for both the hospital-based and the CMHC partial hospitalization programs for calendar 2005 in order for providers to review this data? For our clinicians to understand the difference between the per diem costs of other hospital-based partial hositalization programs as well as the CMHC partial hospitalization programs, this data would be very useful.

The following is the text of our comment letter to the July 25, 2005 outpatient proposed rule:
We are a hospital based partial hospitalization program (PHP) located in central Minnesota providing adolescent, adult and child PHPservices. We have recently expanded our partial hospitalization program due to the need that is present in the surrounding area. We have experienced good patient outcomes with our partial hospitalization program and have operated this program in a cost efficient manner. Our average cost per day for our PHP is approximately $300 for Medicare patients. Our inpatient psychiatric unit has an average cost per day of $1,115 for Medicare patients. We have made a significant commitment to providing a partial hospitalization program to this area since we have had success meeting the patient needs for care yet provide this care in a lower cost outpatient setting than in an inpatient setting. This program is good for the patient and good for Medicare. Therefore, we are concerned to read that CMS is proposing a 15% reduction in the PHP per diem from $289 to $245.65.

We are concerned about the Medicare cost report data that CMS is using to attempt to establish the CY 2006 per diem. CMS has described the difficulties they are having with obtaining consistent accurate cost report data from the CMHCs. In addition, we believe the hospital based

PHP cost report data is generating a low per diem because they are sharing their administrative staff between their inpatient psychiatric unit and their partial hospitalization program. The CMHCs can not share their administrative staff which results in a higher per diem.

We believe CMS should delay the 15% reduction and work with the CMHCs to improve their cost reporting data. Without consistent, accurate cost report data, we do not believe CMS has proven that a 15% reduction would ensure an adequate payment amount and continue to ensure access to the partial hospitalization benefit for the Medicare beneficiaries. We believe CMS should be rewarding the cost effective alternatives to inpatient care rather than making these alternatives like partial hospitalization less attractive by decreasing the Medicare reimbursement. If the Medicare per diem is reduced, many providers may choose to reduce their partial hospitalization programs to limit their losses.

One reason the per diem cost for the CMHCs varies so much may due to the fact some of the CMHCs are new to the partial hospitalization program. If CMS could survey their intermediaries for the diem costs for the CMHCs from their most recently filed cost report, this may provide the best per diem cost data for the CMHCs for CY 2007 per diem. By using the most recently filed Medicare cost reports for the CMHCs, CMS would obtain a cost-to-charge ratio for each CMHC that would be appicable to the same time period of the partial hospitalization charges with condition code 41 for each CMHC.

We do not believe CMS will have time to conduct such a survey in time to establish the CY 2006 per diem therefore, we again ask CMS to delay the 15% reduction until consistent, accurate cost report data can be obtained from the CMHCs.

Thank you for consideration of our comments on this proposed rule. If you have any questions about these comments, please contact me at (320) 251-2700, extension 54697.

Sincerely,

Ann Langan
Reimbursement Accountant

Submitter : Mr. Joseph Casey **Date:** 10/10/2006

Organization : Sturdy Memorial Hospital

Category : Hospital

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

For CY2007, CMS is proposing to add 14 procedures to the ASC procedure list. Further, the proposed revised ASC payment system effective January 1, 2008 would allow ASCs to perform any procedure with the exception of those included on an ASC excluded list. Sturdy Memorial Hospital opposes any additions to the ASC procedure list and would urge the continued use of an ASC approved list rather than the use of an excluded list under the any future ASC payment system. The Hospital serves seven area towns and provides 24-hour back-up coverage for its operating room. The fixed costs associated with this coverage will not diminish as procedures are moved to the ASC setting resulting in duplication of services and costs.

Device-Dependent APCs

Device-Dependent APCs

CMS proposes to reduce the APC payment for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device. CMS proposes to adjust the APC payment rate by the entire cost of the replaced device. However, CMS should recognize that hospitals incur administrative handling costs associated with a replacement device. Therefore, CMS should evaluate the proposed percentage offsets related to recalled devices to ensure that they take into account administrative resources and associated handling costs required to provide the replacement devices.

In addition, CMS should differentiate between replacements with an equivalent device and replacement with an upgraded higher functioning device. In these cases the hospital will often be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed.

GENERAL

GENERAL

See Attachment

Hospital Quality Data

Hospital Quality Data

In this proposed outpatient rule, CMS asserts that it is appropriate to link full payment for outpatient services to the submission of inpatient quality measures because several of the measures assess care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital perfects the system for reliably delivering these medications, it is likely to have improved its processes to ensure a broader array of emergency and other ambulatory services are provided consistently.

However, we strongly disagree with CMS proposed linkage of the reporting of the inpatient measures to payments under the OPPS. While we agree that the promotion of high quality care is an admirable goal, the quality of outpatient care will not be improved by linking the outpatient update to the submission of inpatient data on quality measures that are designed for acute inpatient care. Before linking any set of measures to the payment for outpatient care, there needs to be clear evidence that the measures used have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). CMS should not propose any outpatient reporting requirements until quality measures specific to outpatient services have been proposed and validated.

Further, CMS should not attempt to link the outpatient update to either inpatient or outpatient quality measures without explicit legislative authority. The update has been linked to quality reporting for both the inpatient PPS and the home health PPS. However, in both cases the link was authorized by statute. This is a clear indication that Congress regards such policies as subject to determination by legislation and does not intend that such actions be undertaken administratively. We believe that this is a misapplication the Secretary s statutory authority and that the proposal should be withdrawn.

Inpatient Only Procedures

Inpatient Only Procedures

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The Hospital remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, the Hospital recently had a case whereby during the course of a scheduled outpatient procedure, complications arose which required the performance of an inpatient only procedure. The patient was kept overnight in observation status and released the next day.

The Hospital recommends that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician s intent, patient s clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

OPPS

OPPS

The Medicare Modernization Act required that payment for specified covered outpatient drugs (SCODs) be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human Services (HHS), subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office (GAO). For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price (ASP) plus 6%. For CY 2007, CMS proposes to set payment for these drugs at the ASP plus 5%. CMS states that they believe that this payment level would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

The proposed payment reduction would result in hospital outpatient department rates that are less than the payment for the same drugs and biologicals provided in physician office settings where the rate would remain at ASP plus 6%. We believe that there is no justification for lower payments in hospital outpatient departments and we recommend that CMS maintain the payment rates for separately paid drugs and biologicals at the rate of ASP plus 6% for CY 2007.

Payment Policy for Radiopharmaceuticals. CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost and instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachtherapy sources, CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. We believe that it is too soon to end the current policy of paying at hospital costs due to concerns that the claims data are incomplete and may be incorrect as a result of frequent code and descriptor changes for radiopharmaceuticals. Therefore, Sturdy Memorial Hospital recommends that for 2007, CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.

Visits

Visits

We appreciate the depth of thought and analysis CMS has given to the issue of emergency room and clinical visit coding and payments. However, the Hospital is deeply concerned with the proposal to use five levels to describe emergency and clinic visits rather than three that had previously been presented. As background, CMS has instructed hospitals that they should code the technical side of the visit using separate criteria from that of the physician side. This requirement was in recognition of the fact that the work and resources expended by the physician may not be reflective of the work and resources consumed by the hospital in terms of staff and facility costs. In doing so, hospitals were instructed to establish their own internal guidelines for coding in the absence of national guidelines. Under HOPPS, payments to hospitals for the visits have been based on three levels. Further, AHA/AHIMA recommended guidelines were also based on three levels of care for clinic and emergency services plus a critical care level.

Despite CMS previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007 CMS is proposing the use of five levels of care through the creation of Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits in two different types of EDs and two levels of critical care services. The use of five levels of care to describe clinic and ED visits is contrary to the previous use of three levels. Sturdy Memorial Hospital, like many other hospitals, has established its internal guidelines on three levels of care using the AHA/AHIMA guidelines as a model.

To move to five levels would cause a tremendous burden on the Hospital as it would require working with all of its outpatient clinics to re-write each clinic s internal guidelines, retrain the staff with regards to the new guidelines and establish new pricing to accommodate the additional levels. All of which would need to occur within a very short time-frame (between publication of final rules in November and January 1st implementation) increasing the likelihood for confusion and inadvertent errors. CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies. However, the Hospital would have no choice but to adjust its internal guidelines in order to comply with the use of five codes instead of three. Further, when national guidelines are implemented in a subsequent year, the Hospital will yet again need to revise its guidelines and coding procedures causing further confusion for our clinical staff. Sturdy Memorial Hospital strongly opposes the creation of temporary level II G-codes while hospitals continue to use their own internal guidelines for the use of these codes. Instead, CMS should defer creation of new evaluation and management codes until such time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and published.

While the Hospital opposes the establishment of temporary level II G-codes in the absence of national coding guidelines, we support the recognition of emergency departments that operate less than 24 hours a day but meet the EMTALA definition of an emergency department. At such time that national coding definitions and guidelines are formally proposed, we would continue to support the recognition and distinct codes for use by dedicated emergency departments

CMS-1506-P-413-Attach-1.DOC

#113

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1506-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: **CMS-1506-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.**

Dear Dr. McClellan:

I appreciate this opportunity to comment on the proposed rule for the FY 2007 Outpatient Prospective Payment System (OPPS) on behalf of Sturdy Memorial Hospital. In particular, I would like to address the proposed rules on hospital coding and payments for visits.

VISITS

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HOSPITAL QUALITY DATA

In this proposed outpatient rule, CMS asserts that it is appropriate to link full payment for outpatient services to the submission of inpatient quality measures because several of the measures assess care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital perfects the system for reliably delivering these medications, it is likely to have improved its processes to ensure a broader array of emergency and other ambulatory services are provided consistently.

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subject to determination by legislation and does not intend that such actions be undertaken administratively. We believe that this is a misapplication the Secretary's statutory authority and that the proposal should be withdrawn.

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

The Medicare Modernization Act required that payment for specified covered outpatient drugs (SCODs) be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human Services (HHS), subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office (GAO). For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price (ASP) plus 6%. For CY 2007, CMS proposes to set payment for these drugs at the ASP plus 5%. CMS states that they believe that this payment level would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

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PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The Hospital remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, the Hospital recently had a case whereby during the course of a scheduled outpatient procedure, complications arose which

required the performance of an inpatient only procedure. The patient was kept overnight in observation status and released the next day.

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DEVICE DEPENDENT APCs

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In addition, CMS should differentiate between replacements with an equivalent device and replacement with an upgraded higher functioning device. In these cases the hospital will often be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed.

ASC PAYABLE PROCEDURES

For CY2007, CMS is proposing to add 14 procedures to the ASC procedure list. Further, the proposed revised ASC payment system effective January 1, 2008 would allow ASCs to perform any procedure with the exception of those included on an ASC "excluded" list. Sturdy Memorial Hospital opposes any additions to the ASC procedure list and would urge the continued use of an ASC "approved list" rather than the use of an "excluded list" under the any future ASC payment system. The Hospital serves seven area towns and provides 24-hour back-up coverage for its operating room. The fixed costs associated with this coverage will not diminish as procedures are moved to the ASC setting resulting in duplication of services and costs.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (508) 236-8150.

Sincerely,

Joseph Casey
Chief Financial Officer

Submitter : W. Robert Lee, MD **Date:** 10/10/2006

Organization : American Brachytherapy Society (ABS)

Category : Other Association

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See Attached Comment Letter

CMS-1506-P-414-Attach-1.PDF

#4/14

American
Brachytherapy
Society

12100 Sunset Hills Road, Suite 130, Reston, VA 20190 703-234-4078 fax 703-435-4390

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY07 Payment Rates

Submitted electronically: *http://www.cms.hhs.gov/eRulemaking/01_Overview.asp*

Dear Dr. McClellan:

The American Brachytherapy Society (ABS) would like to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule. This letter specifically addresses proposed changes to the hospital outpatient prospective payment that impact brachytherapy procedures.

Founded in 1978, the American Brachytherapy Society (ABS) is a nonprofit organization that seeks to provide insight and research into the use of brachytherapy in malignant and benign conditions. The organization consists of physicists, physicians, and other health care providers interested in brachytherapy.

The recommendations made by ABS for CMS consideration include the following:

- **Continue the current payment methodology of charges adjusted to cost for 2007 for brachytherapy sources;**
- **Continue to require hospitals to report the use of HDR sources per fraction;**
- **Establish a three year policy to reimburse NEW brachytherapy sources, or those with no claims data, at charges adjusted to cost; and**
- **Maintain breast brachytherapy (CPT 19296 and 19297) in the current new technology APCs.**

Proposed Payment for Brachytherapy Sources for CY2007

The proposed rule (Table 29) outlined proposed APC assignment for brachytherapy sources. Addendum A provides a proposed payment value for each of the brachytherapy source APC's listed in Table 29.

Brachytherapy Source Description	APC Assignment	Proposed Payment
Gold-198	1716	$27.65
HDR Iridium-192	1717	$134.93
Iodine-125	1718	$35.42
Non-HDR Iridium-192	1719	$31.44
Palladium-103	1720	$48.90
Yttrium-90	2616	$16,789
Iodine-125 solution	2632	$19.32
Cesium-131	2633	$90.00
High Activity Iodine-125	2634	$25.68
High Activity Pd-103	2635	$54.29
Linear Palladium-103	2636	$39.15
Ytterbium-169	2637	$25.68

We firmly believe that it would be inadvisable to implement a new payment system for 2007 that would establish prospective payment rates for brachytherapy sources based upon the listed median costs for these APCs. The data is extremely variable and it appears, to us, incorrect for many of the sources including HDR Iridium, HDR Ytterbium, high intensity Iodine, Palladium and probably other sources as well. The table below outlines the extreme range of data that was collected. Such variability alone speaks to the inaccuracy of the information. Failure to properly cover the costs of the radioactive materials would have devastating effects on the availability of brachytherapy or eliminate brachytherapy as a treatment option altogether. The only sources for which there is sufficient data is standard activity Iodine 125 (C1718) and Palladium 103 (C1720). Even in these instances there are a variety of packaging formats that have not been fully addressed or considered. For example, some practitioners use pre-sterilized and preloaded needles that have labor saving advantages even though the cost appears greater on the basis of the invoice. We would be pleased to work with CMS to evaluate the appropriate cost structure for radiation sources for brachytherapy.

HCPCS and Description	Variation of Cost per Unit (2005 Hospital Claims)
C1716 Gold-198	$3 - 943
C1717 HDR Iridium-192	$0 – 4,746
C1718 Iodine-125	$0 - 14,632
C1719 Non-HDR Iridium-192	$3 – 1,761
C1720 Palladium-103	$0 - 20,825
C2616 Yttrium-90	$1,676 - 62,071
C2632 Iodine-125 solution	$0 – 7,253
C2633 Cesium-131	$28 - 15,797
C2634 High Activity Iodine-125	$2 – 4,526
C2635 High Activity Pd-103	$3 – 5,212
C2636 Linear Palladium-103	$0 -1,690

High Dose Rate (C1717)

High Dose Rate brachytherapy utilizes a high intensity brachytherapy source that requires replacement quarterly or more often. The cost of applying this resource depends upon many things including, but not limited to frequency of utilization (case load) and the complexity of the implant procedure. It would be most detrimental to assign a particular figure for HDR source cost without careful consideration of the impact for its use at various levels of intensity. Moreover, an analysis of the top five volume hospitals (CMS claims data) indicates significant anomalies in the data. Clearly this information should cause CMS to question the validity of the data when considering payment based upon the available claims data.

In addition to the problems in HDR source cost in the CMS claims data, the GAO had an opportunity to review the HDR source cost as part of the report published by the agency earlier this year. The GAO stated *"data from 8 hospitals was determined to be usable to evaluate Ir-192 causing the GAO to recognize there was too much variability in Ir-192 source cost and therefore no recommendations could be made."*

CMS requested recommendations regarding the payment methodology for HDR sources. We have not yet been able to develop a simple and equitable system for payment of HDR source use. A change in the methodology for reporting the source at this point, would only cause further confusion in reporting requirements and further inaccuracies in the CMS claims data that would ultimately lead to unfair payments. We would be pleased to work with CMS to develop an optimal working model.

High Activity Sources (C2635 and C2634)
The proposed payment rates for High Activity sources have been established based upon claims data from a small number of hospitals. CMS data indicates rank order anomalies in proposed payments for high activity brachytherapy devices. High Activity Iodine-125 sources (C2634) always cost more than low activity sources (C1718). Typically, High Activity sources are many times more expensive than standard seed sources. CMS has paradoxically proposed to establish lower payment values for high activity sources than for standard iodine sources. This error must be corrected for High Activity sources to become clinically available.

Iodine-125 Solution (C2632)
Iodine-125 Solution is a therapeutic liquid isotope placed inside the brain tumor resection cavity through a balloon catheter to treat brain cancer. Under the proposed 2007 methodology based on median 2005 charges, CMS would set the reimbursement rate for C2632 at $19.32 per mCi.

Iodine-125 solution is supplied in a 150mCi vial, and correct coding requires reporting one unit per mCi, or 150 units per vial. Hospital confusion regarding the correct unit of billing has undermined the accuracy of data that CMS used to establish the median cost for this source. This level of payment level is again insufficient to compensate hospitals for their costs, which in turn will jeopardize access to this valuable brain cancer therapy.

Ytterbium-169 (C2637)
CMS considered four options in establishing payment for Ytterbium-169. CMS proposes to assign Ytterbium-169 (C2637) to its own APC with a payment rate set at or near the lowest proposed payment rate for any brachytherapy source paid on a per source basis (Option 2).

Ytterbium-169 is a new HDR source with unique characteristics. Ytterbium-169 has a shorter half-life than HDR Iridium 192 (C1717) and it must be replaced every 30 days compared to 90 days for HDR Iridium-192. Ytterbium-169, however, has improved shielding characteristics that may have radiation safety advantages which permit facility cost savings. We firmly believe that incorrect payment will prevent implementation of this valuable new HDR radiation source.

Since there is no comparable source, the most appropriate payment methodology for Ytterbium-169 is to establish a charge adjusted to cost methodology and to collect cost data from hospitals as it becomes available. This option would be similar to the CMS policy for New Technology APCs.

NEW Brachytherapy Sources
In the proposed rule, CMS solicited comments regarding establishing payment amounts for new brachytherapy sources eligible for separate payment when no hospital claims-based cost data are available. The only effective way for CMS to capture cost data for new brachytherapy sources is for CMS to establish payment to hospitals for new brachytherapy sources at hospital charges reduced to cost.

BREAST BRACHYTHERAPY

Breast brachytherapy codes (CPT 19296, 19297 & 19298) were implemented January 1, 2005 and were appropriately assigned to New Technology APCs. CMS proposes to reassign two of the three codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment would result in significant decreases in 2007 payment (see table below).

HCPCS	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percentage Change 2006-2007
19296	1524	$3,250.00	30	$2,508.17	**($741.83)**	**-22.8%**
19297	1523	$2,750.00	29	$1,732.69	**($1,017.31)**	**-37.0%**

Another significant concern is the proposed change in status indicator (T). Breast brachytherapy CPT codes 19296, 19297 and 19298 require the use of a high cost device that is bundled into the procedure payment (thus these procedures are classified as device-dependent). 19297 is by definition performed at the time of lumpectomy. Lumpectomy procedures map to a clinical APC that also has a T status indicator. As a consequence procedure would be reduced by 50% each time the procedure is performed as the code descriptor indicates "concurrent with partial mastectomy (list separately in addition to code for primary procedure)".

During the review of CMS claims data, it was noted that the required reporting of the catheter code (C1728) was missing on a majority of the claims used to calculate the median costs for these procedures. More accurate median costs will be acquired when single claims that include the cost of the catheter are used.

CMS has proposed to map 19296 and 19297 to clinical APCs in which the current procedures are not clinically similar or comparable in resource utilization. The selected comparison procedures do not utilize a high cost device like the breast brachytherapy (catheter cost of $2750 for both 19296 and 19297).

CPT 19296 and 19297 were new codes in 2005 so no claims were available for 2006. The number of hospital outpatient claims for 2005 is low and they are inadequate for CMS to make assumptions regarding APC assignment for these codes. We believe it is unwise to make the proposed clinical APC assignment based upon only one year of CMS claims data Since the proposed reimbursement is below the cost of the catheter, breast brachytherapy with the balloon catheter (19296 and 19297) such payment rates will very likely mean that breast brachytherapy will no longer be performed in the hospital setting.

ABS Recommends that these procedures remain in the current new technology APCs for another year to permit CMS to gather three full years of claims data prior to making a sound APC assignment.

Summary of Recommendations

Brachytherapy offers important benefits to Medicare beneficiaries. Appropriate payment for brachytherapy sources is essential to ensure that hospitals can and will continue to offer brachytherapy.

The American Brachytherapy Society appreciates that CMS will consider the following summary of recommendations:

- **Continue the current payment methodology of charges adjusted to cost for 2007 for brachytherapy sources;**
- **Continue to require hospitals to report the use of HDR sources per fraction;**
- **Establish a three year policy to reimburse NEW brachytherapy sources, or those with no claims data, at charges adjusted to cost; and**
- **Maintain breast brachytherapy (CPT 19296 and 19297) in the current new technology APCs.**

Sincerely,

W. Robert Lee

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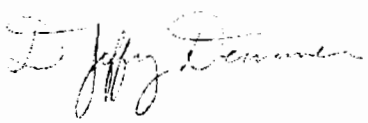

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Submitter : Dr. William Monnig **Date:** 10/10/2006

Organization : The Urology Group

Category : Physician

Issue Areas/Comments

New Technology APCs

New Technology APCs

APC 0066 and APC 0067

CMS-1506-P-415-Attach-1.PDF

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October 4, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

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We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.

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In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

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[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

[4] Federal Register November 30, 2001, page 59868

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For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that ***"any SRS code changes would be premature without cost data to support a code restructuring"***. (CMS-1506-P, page 156).

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

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There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

   Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable

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Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate reflection of the Gamma Knife, a technology

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in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	New centers treating during year	% of centers in first year
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

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Eric J. Kuhn, M.D.
Inayat K. Malik, M.D.
William B. Monnig, M.D.
Marc J. Pliskin, D.O.
Michael B. Rousseau, M.D.
B. Robert Schwartz, M.D.
Reed A. Shank, M.D.
Brian F. Shay, M.D.
Sigmund R. Sugarman, M.D.
J.D. Williams, M.D.
Dirk M. Wonnell, M.D.
Jeffrey W. Zipkin, M.D.
Urologic Pathologist -
Mark A. Weiss, M.D.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders

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who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

William Monnig, M.D.
President

Gary Kirsh, M.D.
Chairman of Board

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Submitter : **Marcia Nusgart** **Date: 10/10/2006**

Organization : **Alliance of Wound Care Stakeholders**

Category : **Other Association**

Issue Areas/Comments

OPPS

OPPS

Dear Dr. McClellan,

The Alliance of Wound Care Stakeholders (Alliance) respectfully submits the following comments on the proposed rule CMS -1506-P. The Alliance is a multidisciplinary consortium of 18 physician, clinical and patient organizations whose mission is to promote quality care and patient access to wound care products and services.

Specific Comments
CY 2007 Proposed Treatment of Guidelines- Outstanding Concerns with the AHA/AHIMA Guidelines

Under Concerns of specialty clinics on pages 351-2, it was noted that the AHA/AHIMA guidelines do not include many of the interventions commonly performed in specialty clinics.... and that the Agency would prefer to have one model that can be applied nationally to each level of clinic visit code..., the Agency is unsure whether one model can adequately address visit levels for all types of patients.

The Alliance has recognized that CMS has attempted over the years to determine the best way to capture the differences in complexity of services provided in wound care clinics. In December 2004, we met with CMS Director of Outpatient Care, Cindy Read, Deputy Director Joan Sanow, and their staff which included Dr. Carol Bazell- Director, Division of Outpatient Care to discuss our recommendations to address this issue. The Alliance presented an acuity scoring system which we believed to be a more accurate and reproducible method of measuring actual work than wound size or time. We recommended that this tool would provide an accurate assessment of the actual work involved in wound care visits that could be used as determinants for E/M level assignments. We suggested that if further data analysis was needed, CMS could utilize the Alliance s E/M services scoring sheet as a tool in the chart review. The source document and scoring sheet that we presented at the meeting are included as attachments to these comments.

We will be meeting in the next month with Director Bazell and Deputy Director Sanow to discuss the feasibility of CMS using the source documents and scoring sheets for wound care patients in the future. We would strongly encourage CMS to adopt the acuity scoring system that we presented at our December 2004 meeting and to work with the Alliance members to help implement it.

We look forward to working with the Agency on this important issue that impacts wound care patients.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

CMS-1506-P-416-Attach-1.DOC

CMS-1506-P-416-Attach-2.DOC

CMS-1506-P-416-Attach-3.DOC

#1116

Wound Care Stakeholders

Sent Via Electronic Transmission

October 9, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
PO Box 8014
Baltimore, MD 21244-8013

Re: Comments Regarding CMS-1506-P - Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates Proposed Rule

Dear Dr. McClellan,

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Specific Comments

CY 2007 Proposed Treatment of Guidelines- Outstanding Concerns with the AHA/AHIMA Guidelines

Under "Concerns of specialty clinics" on pages 351-2, it was noted that " the AHA/AHIMA guidelines do not include many of the interventions commonly performed in specialty clinics.... and that the Agency would prefer to have one model that can be applied nationally to each level of clinic visit code..., the Agency is unsure whether one model can adequately address visit levels for all types of patients."

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actual work involved in wound care visits that could be used as determinants for E/M level assignments. We suggested that if further data analysis was needed, CMS could utilize the Alliance's E/M services scoring sheet as a tool in the chart review. The source document and scoring sheet that we presented at the meeting are included as attachments to these comments.

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We look forward to working with the Agency on this important issue that impacts wound care patients.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director

#1116 - 2

Outpatient Wound Center Evaluation and Management Services Scoring Sheet

Arrival			Additional Resource Utilization		
Ambulatory	0		Isolation	10	
Wheel chair	5		Special needs patient	10	
Stretcher	10		Language; translator	15	
			Altered mentation	15	
History and Physical Examination			**Patient Process**		
Patient history	10		Patient processing: simple	6	
Review of systems	10		Patient processing: complex	12	
Chronic and inactive conditions	7		Coordination of care	8	
General physical examination	8		Development and/or Assessment of Adherence to Care Plan	4	
Risk Assessment	2				
			Patient Education	4	
Problem Focused Activities					
Wound, ulcer, burn	***Quantity***		***Edema, lymphedema***	***Quantity***	
Assessment (multiply)	4		Edema Assessment (multiply)	4	
Cleansing (multiply)	3		Circumference measurement (multiply)	5	
Area measurement (multiply)	4		Edema dressing (multiply)	10	
Undermining measurement (multiply)	2				
Volume calculation (multiply)	1				
Photography/tracing (multiply)	2		***Ostomy, continence***	***Quantity***	
Application of simple dressing (multiply)	8		Assessment and management of incontinence related skin disorders	10	
Application of moderate dressing (mult.)	13				
Application of complex dressing (mult.)	18		Assessment and management of peristomal skin disorders; repouching	20	
Hydrotherapy / Hydrodebridement	20				
Biotherapy	20		Stoma Marking	20	
Focused assessments/interventions					
Nutrition	8		Peripheral Neuropathy	10	
Diabetes management	10		Dermatology (skin care)	8	
Peripheral Arterial Disease	12		Mobility, Offloading, and Gait Assessment	15	
General Procedures			**Point of Care Testing**		
Medication: Application of a topical	5		Bedside glucose testing	8	
Medication: injection	10		Orthostatic vital signs	10	
Medication: IV management	15		Hand-held Doppler	10	
Cast removal	10		Wound culture; swab	10	
Patient transfer; hoyer lift, bariatric lift	8		Blood draw	8	
Suture/Staple removal: simple	5		Specimen collection	8	
Suture/Staple removal: complex	10				
Departure Instructions			**Departure Disposition**		
External environmental planning	15		Routine hospital admission	10	
Simple departure instructions	10		Emergency admission	20	
Complex departure instructions	15		Routine transfer to another facility	10	
			Discharge with assistance	20	

Subtotal Column A		**Subtotal Column B**	
Total Score *(Column A + B)*		**Level of Service** *(from scoring below)*	

FF 1/16-3

Outpatient Wound Center Evaluation and Management Services Scoring Sheet

Arrival			Additional Resource Utilization		
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Risk Assessment	2				
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Wound, ulcer, burn	***Quantity***		***Edema, lymphedema***	***Quantity***	
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Area measurement (multiply)	4		Edema dressing (multiply)	10	
Undermining measurement (multiply)	2				
Volume calculation (multiply)	1				
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Biotherapy	20		Stoma Marking	20	
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External environmental planning	15		Routine hospital admission	10	
Simple departure instructions	10		Emergency admission	20	
Complex departure instructions	15		Routine transfer to another facility	10	
			Discharge with assistance	20	

Subtotal Column A | **Subtotal Column B**

Total Score *(Column A + B)* | **Level of Service** *(from scoring below)*

Submitter : MARIA FIELDS **Date:** 10/10/2006

Organization : DADE FAMILY COUNSELING CMHC INC

Category : Health Care Provider/Association

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

AS A PROVIDER OF SERVICE FOR PARTIAL HOSPITALIZATION PROGRAMS I AM VERY CONCERNED REGARDING THE REDUCTIONS SEEN IN MENTAL HEALTH. WE LIVE IN AN ERA WHERE TRAGEDY, DEPRESSION,AND TRAUMA ARE THE NORM NOT THE EXCEPTION YET WE CONTINUE TO DENY AND THE END RESULTS ARE SEEN ON THE NEWS WITH INCREASED CRIME DUE TO DRUG USE,DOMESTIC VIOLENCE, SCHOOL SHOOTINGS, ETC. THERE ARE INDEED PROVIDERS WHO USE THE SYSTEM FOR THEIR OWN PERSONAL GAIN YET THEY CONTINUE TO LINE THEIR POCKETS AND THE HONEST PROVIDERS ARE ELIMINATED. NOT ALL PROVIDERS PAD THEIR COSTS TO IMPROVE THE BOTTOM LINE. WHY SHOULD THOSE PROVIDERS HURT THE REST OF US TRYING TO KEEP AMERICA MENTALLY STABLE? CMS DECIDED A FEW YEARS AGO NOT TO USE COST REPORTS ANY LONGER AND JUST PAY A DAILY RATE. I MUST ASK THEN WHY IS THE SYSTEM SO FLAWED? WE ALL THINK THAT MENTAL ILLNESS HAPPANS TO SOMEONE ELSE. MENTAL ILLNESS AFFECTS US ALL IN SOME WAY EITHER SOCIALLY ECONOMICALLY OR EMOTIONALLY. I INVITE ANY GOVERNMENT ENTITY/ REGULATORY BOARD TO SPEND A DAY IN OUR CENTER AND YOU WILL QUICKLY REALIZE THAT ELMINATING THIS NEEDED SERVICE IS A LEGAL WAY OF HASTENING DEATH AND DESPAIR TO OUR PATIENTS. AS LONG AS I AM RESPONSIBLE FOR THE CARE AND WELL BEING OF PATIENTS I ALSO FEEL IT MY RESPONSIBILITY TO PROTECT THE BENEFIT. TO THAT END I WILL CONTINUE TO CONTACT THE INTERMEDIARY AND OIG WITH SERVICES THAT ARE QUESTIONABLE. I HOPE CMS WILL DO THE SAME FOR HONEST PROVIDERS

Submitter : **Date: 10/10/2006**

Organization : **Cytyc Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

please see attachment

CMS-1506-P-418-Attach-1.DOC

#418

CYTYC

Via Electronic Submission

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Proposed Changes to Hospital Outpatient PPS for 2007

Dear Dr. McClellan:

Cytyc welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Hospital Outpatient Prospective Payment System ("HOPPS") proposed rule for calendar year 2007, published in 71 Fed. Reg. 49506 (August 23, 2006). In particular, we wish to express our concerns regarding CMS's proposal in the areas of breast and brain cancer. Specifically, we will address the following items:

1. The proposed assignment for CPT Codes 19296 and 19297 for insertion of a catheter necessary to delivery breast brachytherapy treatment
2. The proposed payment basis for C1717 for a High Dose Radiation (HDR) source used for breast brachytherapy
3. The proposed payment basis for C2632 Iotrex (Iodine –125 solution, per mCi), a radionuclide used for treatment of certain brain cancers

Cytyc will make the following recommendations at the conclusion of this letter and will ask CMS for consideration:

1. CMS should maintain CPT Codes 19296 and 19297 in New Technology APCs 1524 and 1523 respectfully to allow additional claims data to be collected through calendar year 2006. This is requested because of the low volume of procedures and accurate claims in the CMS claims database.
   Alternative Recommendation for number 1:
   Alternatively, CMS should assign breast brachytherapy to a more appropriate breast procedure APC that accurately reflects the costs of the procedure
   - APC 648 and rename 648 to Breast Level IV

2. CMS should continue current payment methodology of cost to charge ratio (CCR) for all brachytherapy sources, specifically C1717 for HDR breast brachytherapy, at hospital charges adjusted to cost calendar years 2007 and 2008.

3. CMS should continue current cost to charge ratio payment methodology for C2632 at hospital charges adjusted to cost for calendar years 2007 and 2008.

Cytyc Corporation is a medical device company that manufactures innovative therapeutic technologies for multiple areas of women's health, specifically breast cancer, as well as for patients of newly diagnosed, metastatic and recurrent brain tumors.

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Breast Brachytherapy (CPT Codes 19296, 19297 and HDR Source C1717)

Cytyc manufactures the MammoSite® Radiation Therapy System (RTS), the most widely used method of breast brachytherapy. Breast brachytherapy is targeted radiation therapy where the radiation source is placed inside the tumor cavity via a special balloon catheter, a.k.a. the MammoSite® RTS, and only delivers radiation to the area where cancer is most likely to recur. This technique limits radiation to healthy tissue, lungs and heart, thus reducing the likelihood of the possible side effects experienced during whole beam radiation. Unlike whole beam radiation where the woman requires 5-6 weeks of radiation *every day*, breast brachytherapy is *completed in 5 days*.

Approximately 80% of women diagnosed with breast cancer are detected in the early stages of the disease, when there is a 97% rate of five-year survival. The National Cancer Institute (NCI) has stated that breast-conservation therapy (lumpectomy followed by radiation therapy) is preferable to mastectomy for most early-stage cancer patients, with comparable long-term recurrence and survival rates. It is the standard of care to remove the malignant tumor and to follow up with radiation therapy.

However, according to the SEER data, up to 19% of women who undergo breast conservation surgery do not proceed to radiation therapy as is the standard of care. These women who forgo radiation have a threefold increase in risk of recurrence of the tumor according to a study published in the J. of National Cancer Institute, 2004. We know that a majority of local recurrences after breast conserving therapy occur at or near the tumor bed.

CPT Codes 19296 and 19297 for insertion of catheter used to deliver breast brachytherapy:

By way of background, on January 1, 2005, CMS implemented new breast brachytherapy CPT Codes 19296 and 19297 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS also assigned 19298 to a New Technology APC 1524 in 2005 as well. CPT Code 19298 is used when inserting multiple catheters for breast brachytherapy.

For 2007, CMS has proposed to reassign CPT 19296 and 19297 from New Technology APCs to clinical APCs. The CMS proposed APC assignment for CPT Codes 19296 and 19297 will result in significant decreases in 2007 payment well below the cost of the device. The list price for the unique cavity-conforming catheter for delivering breast brachytherapy treatment from within the breast is $2,750 and customers do not receive discounts or rebates. Additionally, whether the procedure is preformed at time of lumpectomy or during future surgery, the cost of this unique catheter is the same in both cases. The table below illustrates these reductions, ranging from **-22.8%** *or a reduction of* **-$741** *to* **-37.0%** *or a reduction of* **-$1017.31**.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	**($741.83)**	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	**($1,017.31)**	**-37.0%**

Status indicator for CPT Codes 19296 and 19297:
Compounding our concerns, is the proposed change in the status indicator for both of the CPT codes from an S to a T, should 19296 and 19297 be assigned to APC 30 and 29. The MammoSite® RTS catheter is a high-cost device and is a necessary component for breast brachytherapy and bundled in both procedures outlined in CPT 19296 and 19297, thus classifying both CPT codes as device-dependent. In the case of CPT Code 19297, this procedure, by definition (concurrent with partial mastectomy list separately in addition to code for primary procedure) is always performed at time of lumpectomy. Therefore, this 19297 procedure as proposed, because of the T status indicator, will be reduced by 50%. The CMS proposed changes in status indicators for CPT 19296 and 19297 are summarized in the table below:

HCPCS Code	2006 APC	2006 Status Indicator	2007 Proposed APC	2007 Proposed Status Indicator
19296 Breast interstitial radiation treatment, delayed	**1524**	**S**	**30**	**T**
19297 Breast interstitial radiation treatment, immediate	**1523**	**S**	**29**	**T**

Review of Claims Data for 19296 and 19297:
Cytyc Corporation contracted with The Moran Group to analyze the data used by CMS to better understand the proposed changes. Based on their report, we believe that there are an insufficient number of valid claims that may be used to substantiate the proposed assignments for 19296 and 19297.

During the review of CMS claims data, it was observed that the reporting of the required catheter code (C1728) was non-existent on a majority of the claims used to calculate the median costs for these procedures. More accurate median costs are reported when using single claims that include the cost of the catheter.

CPT Codes	Description	"Single" Frequency	Median Cost
19296	Place po breast cath for rad	491	$2,879
19296 + C1728	**Place po breast cath for rad + Cath, brachytx seed adm**	**32**	**$3,508**
19297	Place breast cath for rad	36	$1,631
19297 + C1728	**Place breast cath for rad + Cath, brachytx seed adm**	**1**	**$3,371**

CMS has proposed to map 19296 and 19297 to clinical APCs 30 and 29 respectively. The current procedures assigned to APCs 30 and 29 are not comparable clinically or in resource utilization to the procedures in 19296 and 19297. Unlike CPT Codes 19296 and 19297, these procedures do not utilize a high cost device, and the median cost of the procedures within these

APCs violate the two times rule when the device dependent median cost is utilized (19296 and 19297 + C1728).

APC 30 Level III Breast Surgery			
CPT Code	**Median Cost**	**Payment Rate**	**Median Cost 19296 + C1728**
19240	$2,479.58	$2,508	**$3,508**
19340	$1,974.69		
19380	$2,002.58		

APC 30 Level II Breast Surgery			
CPT Code	**Median Cost**	**Payment Rate**	**Median Cost 19297 + C1728**
19180	$1,942.76	$1,733	**$3,371**
19182	$1,390.91		
19316	$2,116.31		
19328	$1,397.57		
19330	$1,356.21		
19355	$1,169.32		
19366	$1,890.47		
19370	$1,875.37		
19371	$1,837.35		
19396	$38.48		

Claims data for CPT 19296 and 19297 was not available for 2006 since both codes were new in 2005. The number of hospital outpatient claims for 2005 as well as the volume of procedures is insufficient for CMS to accurately assign a valid APC for these codes in comparison to other device-dependent procedures.

CPT Code	2004 Claims - 2006 Payment (number of single frequency claims)	2005 Claims – Proposed 2007 Payment (number of single frequency claims)
19296	n/a	491
19297	n/a	36
19298	n/a	49

Should CMS proceed with the proposed clinical APC assignment for CPT 19296 and 19297, this will limit the ability for hospitals to offer breast brachytherapy as a breast cancer treatment option for Medicare eligible women since the cost of the device far surpasses the proposed payment rates. We predict that hospitals will no longer authorize the purchase of this device which is necessary in order to delivery breast brachytherapy, thus, limiting Medicare eligible women's access to this less invasive and time consuming breast cancer treatment.

However, should CMS require the reassignment of CPT 19296 and 19296, we recommend a more appropriate APC for both codes. APC 648, Breast Reconstruction, contains procedures that more accurately reflect both the clinical utilization as well as the required high-cost devices to perform these procedures.

APC 648 – Breast Reconstruction				
HCPCS	Description	APC Value	Single Frequency	Median Cost
19357	Breast reconstruction	$3,002	200	$3,016
19296	**Post-op implant of breast cath**	**$3,002**	**491**	**$2,879**
19342	Delayed breast prosthesis	$3,002	65	$2,775
19325	Enlarge breast with implant	$3,002	6	$2,414
19297	**Implant of breast cath for rad**	**$3,002**	**36**	**$1,631**

We also would recommend that CMS change the name of APC 648 to Breast Surgery Level IV.

High Dose Brachytherapy Iridium 192 (C1717) Payment Methodology
A High Dose Rate (HDR) brachytherapy source is necessary to provide breast brachytherapy treatment. The HDR source used for breast brachytherapy is HDR Iridium 192 (C1717) which is delivered twice a day through the balloon catheter for breast brachytherapy treatment. In addition to the balloon catheter, hospitals must purchase HDR Iridium 192 quarterly in order to make breast brachytherapy available for Medicare eligible women. The actual cost of the Iridium 192 source is based upon the number of treatments or fractions that are administered to patients over the life of the source. CMS claims data shows a huge variation in cost per unit reported on claims data across hospitals for the source:

APC	Number of Hospitals	Number of Claims	Variation of Cost Per Unit
1717	283	4740	$0 – 4,746

The proposed payment methodology for HDR source Iridium 192 will severely limit the hospitals ability to offer breast brachytherapy since the proposed payment method will not cover the cost of the source. Therefore, it is necessary to continue with the current cost to charge ratio payment methodology.

Brain Cancer therapy (C2632 Iotrex Radionuclide Iodine I-125 solution, per mCi)
Cytyc manufactures the GliaSite® Radiation Therapy System (RTS), an innovative system to treat individuals with malignant brain cancer. Designed to be placed inside the tumor resection cavity, the GliaSite RTS delivers radiation with Iotrex®, Iodine I-125 therapeutic liquid radionuclide placed inside a balloon catheter. The targeted tissue receives a high dose of radiation, while exposure to healthy tissue is minimized. Treatment with Iotrex has demonstrated improved median survival time, preservation of cognitive function and improvement of overall quality of treatment in patients with malignant brain cancers. In addition, the GliaSite® RTS allows for treatment with Iotrex to be completed within three to six days, often as an outpatient therapy.

Brain cancer is considered to be one of the most de-habilitating diseases for individuals to experience. With many therapies, patients suffer the loss of cognitive skills and suffer from many side effects of treatment. The GliaSite® RTS improves the treatment experience for these patients by minimizing radiation exposure to healthy brain tissue, limiting potential side effects associated with external beam radiation and by providing a 387 day median survival from time of treatment for recurrent primary tumor as published in the Journal of Neurosurgery, Aug. 2003.

C2632

CMS currently classifies Iotrex as a brachytherapy solution (C2632). Since January 1, 2004, CMS has established Medicare HOPPS reimbursement for this treatment based on a hospital's charges for the service, adjusted to cost, as mandated by the Medicare Modernization Act of 2003. This payment policy has been successful in safeguarding patient access to this important treatment for malignant brain cancer, while providing a workable policy for hospitals and the Medicare program.

CMS is proposing to discontinue its current payment policy for 2007. Instead, CMS proposes to set payment rates for C2632 in CY 2007 using the CY 2005 claims-based median cost per source. We have a number of concerns about the reliability of the data on which such payments would be based and the impact of the proposed policy change on Medicare beneficiaries. Even though the statutory requirement for payment based on hospital charges adjusted to cost expires at the end of 2006, there are important policy reasons for CMS to maintain this payment policy at least through 2007.

The Advisory Panel on Ambulatory Payment Classification ("APC Panel") adopted a recommendation at its August 23-24, 2006 meeting that "CMS continue using the current CY 2006 methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources for 1 year." This is an important development since the issuance of the Proposed Rule, in which CMS states that the APC Panel had "made no specific recommendations about a specific HOPPS CY 2007 payment methodology for brachytherapy sources."

Accordingly, we feel strongly that CMS should abide by the APC Panel's expert recommendation in this area and defer adoption of the proposed payment change for 2007.

Under the proposed 2007 methodology based on median 2005 charges, CMS would set the reimbursement rate for C2632 I-125 (Iotrex) solution at $19.32 per mCi. According to our analysis, this reimbursement level is *less than half* of the actual hospital charge for Iotrex I-125 iodine solution. The cost for a 1 mL vial (150 mCis) of I-125 Iotrex is $5,900 (without factoring in pharmacy handling, overhead, and special licensing and compliance costs). This breaks down to, at minimum, a unit cost per mCi of approximately $39.33 per mCi.

CMS's proposed payment level is insufficient to compensate hospitals for their costs, which in turn would jeopardize access to this critical therapy for beneficiaries with brain cancer.

We wish to emphasize that hospital confusion regarding the correct unit of billing undermines the accuracy of data on which CMS is relying in establishing the proposed payment this therapy. In fact, CMS itself noted this confusion at the March 1-2, 2006 meeting of the APC Panel. Specifically, the final report from this meeting highlights CMS staff review of the available hospital data, noting that: "some sources (e.g., HCPCS codes C1717, C1719, **C2632**, and C2633) demonstrate relatively inconsistent mean and median numbers of sources used." Moreover, the CMS staff "spoke about some of the concerns surrounding the variability between the mean and median numbers of sources, such as possible coding confusion regarding billing of units."

Cytyc contracted with The Moran Group to analyze the claims data used by CMS to substantiate the proposed payment method for C2632. According to their analysis of the HOPPS 2005 data regarding hospital charges for C2632 there are wide variances in how hospitals billed for units of Iotrex, which points to unreliable cost data on which to base median payments for 2007.

For example, we note that 50% of the 30 hospitals that submitted claims for Iotrex reported only "one" unit per line. As we noted above, Iotrex is supplied in a "one" milliliter vial with 150 mCi per vial. Thus, in order to be correctly coded, at minimum, every claim should have reported 150 mCis based on the current code descriptor. While we are not proposing that CMS ignore all the incorrect claims, we recommend that CMS trim/eliminate the following claims from its "cost" calculations:

- Claims with charges and costs per unit equal to or less than $1.00 *and*
- Claims with cost per unit of $20.00 or less

We feel claims with charges and costs per unit of $20.00 or less should be considered erroneous and therefore, these claims should be trimmed from the data file before calculating the costs and establishing payment for Iotrex. For Iotrex, as with most radionuclides, the costs related to pharmacy handling and overhead alone far exceed $20.00 and thus, $20.00 is an appropriate point to trim the claims.

Looking ahead, we are working with hospitals and specialty societies to educate them about billing for Iotrex. In addition, to simplify billing for Iotrex in 2007, we submitted a request for a new HCPCS code with a descriptor of one milliliter vial (up to 150 mCi). We understand the HCPCS Panel will be issuing an HCPCS coding update for 2007 in the next few weeks and we hope that the coding request is approved. We believe that a billing code based on the one milliliter vial with help simplify and clarify billing and result in hospital charge data for Iotrex that is more consistent with the hospitals' actual costs.

Continuation of the current CCR payment methodology would comply with the Congressional intent to ensure that Medicare payment policy supports access to the most appropriate treatment for Medicare beneficiaries with cancer.

If CMS does not continue the current CCR payment methodology, we strongly recommend that CMS re-examine the hospital data and establish the payment rate for Iotrex radionuclide based on the mean cost (rather than the median cost) consistent with CMS's proposal to pay for radiopharmaceuticals and radionuclides using mean cost. CMS acknowledged that mean cost is more closely aligned with hospitals average acquisition cost which is the statutory standard for payment of specified covered outpatient drugs.

Recommendations

Cytyc respectfully requests that CMS consider and implement the following recommendations:

1. CMS should maintain CPT Codes 19296 and 19297 in New Technology APCs 1524 and 1523 respectfully to allow additional claims data to be collected through calendar year 2006. This is requested because of the low volume of procedures and accurate claims in the CMS claims database.
   Alternative Recommendation for number 1:
   Alternatively, CMS should assign breast brachytherapy to a more appropriate breast procedure APC that accurately reflects the costs of the procedure
   - APC 648 and rename 648 to Breast Level IV

2. CMS should continue current payment methodology of cost to charge ratio (CCR) for all brachytherapy sources, specifically C1717 for HDR breast brachytherapy, at hospital charges adjusted to cost calendar years 2007 and 2008.

3. CMS should continue current cost to charge ratio payment methodology for C2632 at hospital charges adjusted to cost for calendar years 2007 and 2008.

CYTYC

Cytyc appreciates the opportunity to provide comments during this proposed rule period as well as the opportunity to meet with your office and discuss our concerns about brachytherapy. Should you have any questions or need additional information, please do not hesitate to contact me at 508-263-8958 or via email at margaret.eckenroad@cytyc.com.

Sincerely,

Margaret Eckenroad

Margaret Eckenroad
Senior Director, Women's Health
and Professional Relations

cc: Carol Bazell, MD, Acting Director, Division of Outpatient Care (via email)
Edith Hambrick, M.D., J.D., CMS Medical Officer; Chair, Advisory Panel on APC Groups
Robert Lee, MD, President American Brachytherapy Society
Helen Pass, MD, President, American Society of Breast Surgeons

Submitter : **Mr. Michael Pelc** **Date: 10/10/2006**

Organization : **Detroit Medical Center**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1506-P-419-Attach-1.DOC

-H419

October 6, 2006

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

Administrator, Centers for Medicare & Medicaid Services

Attn: CMS–1540–P

Room 445-G

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2007; Proposed Rule.

Dear Dr. McClellan:

On behalf of the Detroit Medical Center's (DMC)six member hospitals- Children's Hospital of Michigan, Detroit Receiving Hospital, Harper-Hutzel Hospital, Huron Valley Hospital, Rehabilitation Institute of Michigan and Sinai-Grace Hospital- the DMC appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2007 proposed rule to update the Medicare outpatient prospective payment system (OPPS).

HOSPITAL QUALITY DATA

The CMS proposes to require compliance with the inpatient prospective payment system (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order for hospitals to receive a full payment outpatient update in 2007. Under the IPPS, the annual payment update is linked to the collection of quality measures and hospitals that fail to comply with the program requirements receive a marketbasket update that is 2 percent less than the full update. Beginning in 2007, the CMS indicates it has the authority and proposes to also reduce the outpatient PPS conversion factor update by 2 percent

for hospitals that are required to report quality data under the IPPS RHQDAPU. In addition, hospitals not submitting all of the inpatient measures required for 2008 would have their outpatient payment update for FY 2008 reduced by 2percent. The CMS asserts that it is appropriate to link full payment for outpatient services to the submission of these inpatient measures because several of the measures assess care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital improves the system for delivering these medications, quality improvement to other emergency and other ambulatory services have likely occurred as well.

The DMC strongly disagrees with the CMS' proposed linkage of the reporting of the inpatient measures to payments under the OPPS for the following reasons:

• Congress has already determined the inpatient penalty for hospitals that do not submit the inpatient data. In the Deficit Reduction Act (DRA), Congress specified that the penalty would be a 2 percent reduction in the IPPS market basket update. It did not authorize additional penalties for outpatient services. If Congress had intended to authorize outpatient penalties, it would have specified those in the DRA. We conclude that Congress did not intend additional penalties for hospital outpatient services.

• The CMS' proposed rule asserts that the authority for adding the penalty to the outpatient payment comes from its "equitable payment authority". The equitable payment provision in the Social Security Act was intended to enable the CMS to eliminate inequitable impact on a particular provider or group of providers. Implementation of the equitable payment provision must be done in a budget neutral manner. For OPPS, there are no inequities in outpatient payment. Rather, application of this requirement may result in less payment to OPPS providers

• The CMS states that inpatient measures provide insight into the clinical care in the ambulatory setting. There is no relationship between the measures being used to assess the adequacy of inpatient heart attack, heart failure, pneumonia and surgical care and the care of patients receiving diagnostic, radiological, pharmaceutical and other procedures covered under OPPS.

Prior to linking any set of measures to the payment for outpatient care, there should be clear evidence that the measures specifically have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). **The DMC urges the CMS to continue working with the HQA and the AQA to identify and implement measures that truly assess important aspects of outpatient care quality.** Once appropriate measures have been identified, the CMS should work with Congress to consider how the payment system should be modified to support the provision of high quality care in the outpatient setting. Since appropriate outpatient care measures have

not been identified, **the CMS should remove any link between quality measures and outpatient care payments in this rule.**

NEW TECHNOLOGY APCS

The CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. An example is as Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which were assigned to New Technology APC 1514 in 2005. Once approved by the CMS, there may be a delay in providing the services, resulting in less than 12 months full utilization in the first year of the CMS data files. **As a result, the DMC recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying somewhat more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs). The DMC is concerned about the CMS's proposal to reduce payments for specified covered outpatient drugs (SCODs) to ASP plus 5 percent in 2007. This represents a one percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed for the same drug paid in physician office settings. **The DMC believes that consistency in payment for drugs and biologicals across settings is important and recommends that the CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals. The CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost but instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, the CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. Due to concerns that the claims data may be incomplete due to frequent code and descriptor changes for radiopharmaceuticals, we believe that it is too soon to end the current policy of paying at hospital costs. **As a result, the DMC recommends that for 2007, the CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

EVALUATION & MANAGEMENT (E/M) CODES

Despite the CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007, the CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services. The CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, the CMS states that hospitals may continue to utilize their existing internal guidelines for determining the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The DMC continues to believe that the CMS should not implement new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. **The DMC recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.** Creating temporary G-codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes - G-codes for Medicare and CPT codes for non-Medicare payers - without the benefit of a standardized methodology or better claims data. Instead, our approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus instead on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OBSERVATION SERVICES

For 2007, the CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The DMC continues to support the CMS's concept of allowing the outpatient code editor (OCE) logic todetermine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, since the process for determining whether observation is separately payable is largely "automated", the DMC believes the CMS should consider expanding diagnoses for which observation may be separately paid. As a result, the DMC supports the APC Panel's recommendation that the CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold to $1,875 - $625, or 50 percent, more than in 2006 - to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,875 more than the APC rate.

While the DMC supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, the CMS proposed outlier threshold is too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the DMC is concerned that Medicare may not actually spend the outlier target set-aside. **The CMS should publish the annual outlier payments as a percent of total expenditures for 2005 and prior. The outlier threshold increase should be limited to the increase in APC rates, or 3.4 percent, unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

Proposed Critical Care Coding. The DMC is opposed to the proposed structuring of critical care coding on the basis of time. Tracking and documenting time for critical care services would pose a significant burden to hospitals and could be subject to gaming. Time has never been incorporated as a component of critical care coding and billing instructions for hospitals since the inception of the OPPS. In fact, the April 7, 2000 final rule establishing the OPPS clearly states, "In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."

While the 30-minute threshold has applied to physician professional service billing, it has long been understood that hospital resources for critical care are not linked to time, but rather reflect the immediate intensity of care provided to patients receiving these services. The goal of the ED is to stabilize the patient as quickly as possible, which involves multiple hospital staff to be simultaneously present, and may even require a multidisciplinary team. It would be extremely burdensome and confusing to track time for different individuals involved in providing critical care services. **The DMC recommends that the CMS eliminate the reference to time in the definition of the new critical care codes and instead continue with its long-standing OPPS policy concerning coding and billing for critical care services.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The DMC remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

The DMC again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, the CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the Medicare Modernization Act (MMA). Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on appropriate contractor's performance.

The MMA requires that the Secretary of the Department of Health and Human Services consult with providers of services on the MAC performance requirements and standards, and the DMC appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the DMC believes that such provider input is critical.

However, we encourage the CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the

introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may not be able to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is often used to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

The DMC also requests that the CMS to do everything within its authority to ensure that MACs are accountable to the agency and providers for the services they provide. It is critical that the selected contractors understand how hospitals and health care systems function, and that MAC staff have the necessary technical expertise to efficiently and correctly process hospital claims.

In addition, given that each defined A/B MAC jurisdiction will include several states, the CMS must ensure that the chosen contractor is able to maintain a significant local presence. This includes the ability to work within different time zones, availability and accessibility within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

FY 2008 IPPS RHQDAPU

In the proposed rule, the CMS announces the measures hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to get the full inpatient payment to which they would otherwise be entitled in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would suffer a penalty of having their FY 2008 inpatient payments reduced by two percent.

The DMC is supportive of the CMS utilizing quality measures that have already been adopted as part of the Hospital Quality Alliance's efforts to promote public reporting of hospital quality data. These are well-designed measures chosen because they represent aspects of care that are important to patients, and that provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We strongly urge the CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA to provide a public accountability for quality.** This alignment will reinforce the importance of the public transparency on quality and help to focus quality improvement efforts on the chosen high priority areas of care.

We also support the CMS for publishing information on what measures hospitals will be expected to report to continue to receive their full inpatient payments

early enough for them to put the proper data collection processes in place. As we said in our earlier comments on the Inpatient Prospective Payment System rule, if hospitals are not told until August what quality data they will be expected to report, they are unable to put the proper data collection processes in place quickly enough to ensure reliable abstraction of the information from patient records.

HEALTH INFORMATION TECHNOLOGY (HIT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program.

The DMC strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a **shared investment between the providers and purchasers of care.**

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 American Hospital Association (AHA) survey noted that the median amount hospitals invested annually on health IT was greater than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts - a median of $1.7 million or 2 percent of all operating expenses - on operating costs related to IT. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.1

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. **However, it overlooks another of the study's major findings - that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.2**

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the DMC believes that the payers and purchasers of care should share in the costs of IT.**

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1. Forward Momentum:Hospital use of Information Technology. Washington, DC: MHA (2005)
2. R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs.
Health Aff., September 1, 2005; 24(5): 1103-1117.

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers - including the federal government - must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether the CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, the CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. The DMC believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

The DMC also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations - including the CMS - that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations - including expensive manual chart abstraction and use of third-party contractors - to submit quality data. The CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, **the CMS could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The DMC will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. **The DMC firmly believes that the CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does

not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.3

While the DMC appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives the CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

In 2006, the Department of Health and Human Services (HHS) proposes to undertake a new effort to expand the availability of information on health care quality and pricing. The HHS intends to identify several regions in the United States with high health care costs and use its leadership role in health care policy to help lead change in those areas.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider.

Providing meaningful information to consumers about the price of their hospital care is the most significant challenge hospitals, and the CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

• Presenting information in a way that is easy for consumers to understand and use;

• Making information easy for consumers to access;

• Using common definitions and language to describe pricing information for consumers;

• Explaining to consumers how and why the price of their care can vary; and

• Encouraging consumers to include price information as just one of several considerations in making health care decisions.

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3 "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication
No 06-E006 (April 2006).

The DMC recommends that the CMS convene a workgroup comprised of representatives from hospitals, the DMC and state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input toward resolution.

Another option the CMS offered is establishing a Medicare condition of participation to post prices on assistance programs for uninsured. While many hospitals are moving toward transparency in this area, including this as a condition of participation seems punitive and will not resolve the CMS core issue of what hospitals are doing to assist the uninsured. It is important for the CMS to understand that the income level of the uninsured varies by community and charity care policies will also vary. **Therefore, the DMC objects to the CMS expanding the conditions of participation to include posting of prices on assistance programs to the uninsured.**

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

• **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

• **Health Maintenance Organization (HMO) Insurance.** Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any need for specific price information.

• **High-Deductible or Health Savings Account (HSA) Insurance.** Individuals with HSAs have more interest regarding price information compare to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.

• **Uninsured Individuals of Limited Means.** Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Again, the DMC appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (313) 578-2820 or mpelc@dmc.org

Sincerely,

Michael A.Pelc
Vice President, Finance