Submitter : Dr. Anthony Crimaldi **Date:** 10/04/2006

Organization : Carolinas Medical Center - Dept. of Rad Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-244-Attach-1.DOC

HP 2247
249

Carolinas Medical Center

The 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

October 3, 2006

Regarding: CY 2007 OPPS Proposed Rule (CMS-1506-P)

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule filed in the Federal Register on August 23, 2006. This letter addresses a concern of mine with respect to a proposed Medicare payment reduction for Iotrex, an Iodine I-125 liquid radioisotope source, which is reported using HCPCS code, C2632.

I specialize in Radiation Oncology and routinely care for Medicare beneficiaries, some of whom are diagnosed with glioblastomas, often referred to as malignant brain tumors. Once the neurosurgeon resects the tumor and implants a balloon catheter within the cavity for purposes of receiving internal radiation, the patient, once recovered will then be cleared to start outpatient radiation therapy. The delivery of internal radiotherapy includes use of Iotrex which targets the tissue nearest the cavity where the tumor was removed. Use of Iotrex is beneficial in the treatment of brain cancer patients because it increases their survival and preserves quality of life.

CMS is proposing a significant payment change of median cost for Iotrex, along with several other radiation therapy sources. The proposed payment method impacts Medicare beneficiary access to cancer therapy as hospitals will not be able to continue offering these radiation cancer treatment options due to payment reductions. For example, right now Iotrex is paid to the hospital based on charge reduced to cost. CMS has listed a proposed payment rate of $19.32 per millicurie (mCi). This rate does not meet the per mCi cost delivered in a 1-mL single use vial (150 mCi).

I am submitting this comment letter as an appeal to CMS that the Agency will continue paying Iotrex and other radiation sources at cost to ensure all radiation oncology treatment options are available to Medicare beneficiaries diagnosed with this deadly disease. Of further note, I've learned the APC Advisory Panel has also made this recommendation to CMS of which I stand in agreement to the Panel's recommendation.

Thank you again for allowing me to share my comments and I appreciate your consideration in this very important matter.

Sincerely,

Anthony J. Crimaldi, M.D.

Anthony J. Crimaldi, M.D.
Carolinas Medical Center
Department of Radiation Oncology
P.O. Box 32861
Charlotte, NC 28232-2861
704-355-2272

cc: Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Representative Sue Myrick, Energy and Commerce Health Subcommittee; Co-Chair House Cancer Caucus

Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Dr. Robert Fraser **Date:** 10/04/2006

Organization : Carolinas Medical Center, Dept. of Rad Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED

CMS-1506-P-245-Attach-1.DOC

Attach H
245

Carolinas Medical Center

The 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

October 3, 2006

Regarding: CY 2007 OPPS Proposed Rule (CMS-1506-P)

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule filed in the Federal Register on August 23, 2006. This letter addresses a concern of mine with respect to a proposed Medicare payment reduction for Iotrex, an Iodine I-125 liquid radioisotope source, which is reported using HCPCS code, C2632.

I specialize in Radiation Oncology and routinely care for Medicare beneficiaries, some of whom are diagnosed with glioblastomas, often referred to as malignant brain tumors. Once the neurosurgeon resects the tumor and implants a balloon catheter within the cavity for purposes of receiving internal radiation, the patient, once recovered will then be cleared to start outpatient radiation therapy. The delivery of internal radiotherapy includes use of Iotrex which targets the tissue nearest the cavity where the tumor was removed. Use of Iotrex is beneficial in the treatment of brain cancer patients because it increases their survival and preserves quality of life.

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I am submitting this comment letter as an appeal to CMS that the Agency will continue paying Iotrex and other radiation sources at cost to ensure all radiation oncology treatment options are available to Medicare beneficiaries diagnosed with this deadly disease. Of further note, I've learned the APC Advisory Panel has also made this recommendation to CMS of which I stand in agreement to the Panel's recommendation.

Thank you again for allowing me to share my comments and I appreciate your consideration in this very important matter.

Sincerely,

Robert W. Fraser, M.D.

Robert W. Fraser, M.D.
Carolinas Medical Center
Department of Radiation Oncology
P.O. Box 32861
Charlotte, NC 28232-2861
704-355-2272

cc: Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Representative Sue Myrick, Energy and Commerce Health Subcommittee; Co-Chair House Cancer Caucus

Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Dr. Stuart H. Burri **Date:** 10/04/2006

Organization : Carolinas Medical Center, Dept. of Rad Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

please see attached

CMS-1506-P-246-Attach-1.DOC

Attach 11
246

Carolinas Medical Center

The 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

October 3, 2006

Regarding: CY 2007 OPPS Proposed Rule (CMS-1506-P)

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule filed in the Federal Register on August 23, 2006. This letter addresses a concern of mine with respect to a proposed Medicare payment reduction for Iotrex, an Iodine I-125 liquid radioisotope source, which is reported using HCPCS code, C2632.

I specialize in Radiation Oncology and routinely care for Medicare beneficiaries, some of whom are diagnosed with glioblastomas, often referred to as malignant brain tumors. Once the neurosurgeon resects the tumor and implants a balloon catheter within the cavity for purposes of receiving internal radiation, the patient, once recovered will then be cleared to start outpatient radiation therapy. The delivery of internal radiotherapy includes use of Iotrex which targets the tissue nearest the cavity where the tumor was removed. Use of Iotrex is beneficial in the treatment of brain cancer patients because it increases their survival and preserves quality of life.

CMS is proposing a significant payment change of median cost for Iotrex, along with several other radiation therapy sources. The proposed payment method impacts Medicare beneficiary access to cancer therapy as hospitals will not be able to continue offering these radiation cancer treatment options due to payment reductions. For example, right now Iotrex is paid to the hospital based on charge reduced to cost. CMS has listed a proposed payment rate of $19.32 per millicurie (mCi). This rate does not meet the per mCi cost delivered in a 1-mL single use vial (150 mCi).

I am submitting this comment letter as an appeal to CMS that the Agency will continue paying Iotrex and other radiation sources at cost to ensure all radiation oncology treatment options are available to Medicare beneficiaries diagnosed with this deadly disease. Of further note, I've learned the APC Advisory Panel has also made this recommendation to CMS of which I stand in agreement to the Panel's recommendation.

Thank you again for allowing me to share my comments and I appreciate your consideration in this very important matter.

Sincerely,

Stuart H. Burri, M.D.

Stuart H. Burri, M.D.
Carolinas Medical Center
Department of Radiation Oncology
P.O. Box 32861
Charlotte, NC 28232-2861
704-355-2272

cc: Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Representative Sue Myrick, Energy and Commerce Health Subcommittee; Co-Chair House Cancer Caucus

Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Kim Mcqueen **Date:** 10/04/2006

Organization : Carolina Kidney Care Procedure Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I support the position as outlined by the American Society of Diagnostic and Interventional Nephrology (ASDIN).

Submitter : Dr. Margaret Hadcock **Date:** 10/04/2006

Organization : Dr. Margaret Hadcock

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-248-Attach-1.DOC

HHS-NF
248

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 (OPPS) and CY 2007 Payment Rates

Dear Administrator,

I first want to thank you for this medium to share my remarks on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I do have many concerns with the proposed reduction of the RVUs by 4 units when CPT code 19296 is performed by the Surgeon in the Hospital as well as the proposed reduction of the conversion factor by 5.1%. I am also concerned with the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) as this is an issue due to the cost of the device (catheter) not being considered in the new Clinical APC, which will make it impossible for the hospital to purchase.

A reduction of the RVUs will not allow me to place the catheter in the hospital and will negatively affect my ability as a Physician to treat Medicare patients with this important procedure in the hospital. The hospital will be forced to not provide the catheter for Medicare beneficiaries as the catheter will be priced higher than the clinical APC rate. Access to this important technology will be severely limited for Medicare patients who are eligible for partial breast irradiation. Availability to this technology is very important as it allows radiation treatment in only 5-7 days. CMS should preserve the RVUs and continue the assignment of the New Technology APC for an additional year until more cost data and research is done.

As a Surgeon who is concerned about this proposal, I recommend that CMS maintain the current RVUs for CPT code 19296 when done in the hospital. I recommend that if you have to have a reduction, then possibly reduce the conversion factor, but not to the current degree. In support of the hospital, I further recommend that CMS keep the designation of CPT codes 19296 and 19297 to the New Technology APC for the hospital for at least another year until further research is completed.

Once again, thank you for allowing me to share my recommendations and this important issue and please continue to do further evaluation of this topic.

Sincerely,

Margaret Hadcock, MD
Surgeon
6167 N. Fresno Street, Suite 102
Fresno, CA 93710

cc: Senator Barbara Boxer, CA, (D)
Senator Diane Feinstein, CA, (D)
Congresswoman Nancy Pelosi, (D)

cc: Carol Bazell, MD, MPH, Director, Division Outpatient Services

cc: American College of Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Michael Fromke **Date:** 10/04/2006

Organization : Dr. Michael Fromke

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-249-Attach-1.DOC

1 Attachment
249

October 2, 2006

The 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 – CY 2007 Hospital Outpatient Prospective Payment System

Dear Administrator:

I would like to provide comment concerning a matter not only important to me, but most importantly on behalf of my Medicare patients diagnosed with brain cancer. I appreciate the opportunity to share my concern which has been outlined in the CMS-1506-P Proposed Rule published in the Federal Register on August 23, 2006.

I am concerned about the proposed payment method CMS is considering implementing for radiotherapy sources, one of which is Iodine I-125, a liquid radioisotope source named Iotrex. The HCPCS code used to report Iotrex is C2632.

Right now the hospitals that purchase Iotrex are reimbursed by Medicare at cost, but a new method of payment is using a median unit cost. According to your files the median unit cost is proposed at $19.32 per millicurie. This is far below the cost of each millicurie contained in the single use 1 milliliter vial of Iotrex. The proposed rate will seriously impact Medicare beneficiary outpatient access to this cancer therapy because hospitals cannot continue to afford to purchase I-125 Iodine should the payment be reduced to $19.32 per millicurie.

As a neurosurgeon and provider of care for Medicare patients, I am faced with diagnosing and performing major surgery on some Medicare beneficiaries that have malignant brain tumors. Part of the patient treatment plan not only involves removing the tumor, but following surgery, the patient must also go through radiotherapy using the radionuclide solution, Iotrex. This surgical intervention and the radiation course of therapy gives the patient an increase in survival and offers quality of life that might otherwise be unavailable.

I support and recommend that Medicare continue to pay Iotrex at charges adjusted to cost.

Again, I appreciate your time and evaluation in this matter.

Sincerely,

Michael Fromke, MD

Michael D. Fromke, M.D.
Board Certified, American Board of Neurological Surgery
Neurosurgery Clinic of Knoxville, PLLC
930 Emerald Avenue, Suite 611
Knoxville, TX 37917
(865) 633-8054

cc: Bill Frist, U.S. Senator, Tennessee
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Dr. John Fiveash **Date:** 10/04/2006

Organization : UAB-Comprehensive Cancer Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED

CMS-1506-P-250-Attach-1.DOC

Attach. H
250

October 2, 2006

The 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 – CY 2007 OPPS Proposed Rule

Dear Administrator:

I am sending this letter with the hope that Medicare will reconsider the payment method proposed in the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS 1506-P) for I-125 Iodine, a liquid radionuclide source used in patients diagnosed with brain cancer. I appreciate that CMS encourages and requests public comment and believe this an important matter to bring to your attention.

Iotrex, an Iodine I-125 liquid radioisotope source (HCPCS C2632) is infused through a catheter and into a balloon that has surgically been implanted in the cavity space where a malignant brain tumor or glioblastoma had existed before its removal by a neurosurgeon. The tumor excision and implantation of the balloon catheter is performed in the same surgical session. Once the patient is fully recovered and is discharged from the hospital, radiation therapy can begin in the outpatient setting. One of the more important benefits in using Iotrex during the internal radiation therapy course is that it provides the cancer patient an opportunity to experience a quality of life and increased survival that might not otherwise be available when faced with this devastating illness.

I urge CMS to reconsider the proposal for payment of I-125 as outlined in CMS-1506-P and respectively request continued payment based on cost following hospital charge adjustment. The proposed payment rate is insufficient in meeting the cost of the liquid source along with handling and any other administrative costs associated with the source itself. Hospitals must be able to continue offering this vital brain cancer radiotherapy option hence setting an adequate rate is imperative.

Thank you for allowing me to submit comment with respect to this serious matter – that being continued access to and the offering of cancer treatment services to Medicare beneficiaries.

In regard,

Sandra Tincher, MD

Sandra A. Tincher, M.D.
Brookwood Regional Cancer Center
2010 Brookwood Medical Center Drive
Birmingham, AL 35209
(205) 877-CARE (877-2273)

cc: Senator Jeff Sessions, State of Alabama
Senator Richard C. Shelby, State of Alabama
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Mrs. Dawn McMurray **Date:** 10/04/2006

Organization : Genesys Regional Medical Center

Category : Hospital

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

OPPS: Drug Administration Proposed rule page 315 regarding separate payment for IVIG pre-administration related services for IVIG infusions. We respectfully request that CMS continue payment for IVIG pre-administration related services as there continues to be a shortage of IVIG and other blood products. Reasons for this request and factors leading to the IVIG shortage are as follows: It requires plasma donors. There has been market consolidation. Overall production has decreased. There is increased utilization and decreased supply. IVIG is used for multiple indications. Due to the insufficient allocation of product to large hospital based systems not meeting needs, these hospitals must go outside their supply chain preferred distributors to obtain product at increased prices. This creates bidding wars between hospitals. Please reconsider allowing separate payment for IVIG pre-administration services. Signed Mr. Steve Cote, Director of Pharmacy, Genesys Regional Medical Center. Mrs. Dawn McMurray, Revenue Cycle Specialist, Genesys Regional Medical Center.

CMS-1506-P-251-Attach-1.DOC

Submitter : Dr. Meg Verrees **Date:** 10/04/2006

Organization : Dr. Meg Verrees

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

please see attached

CMS-1506-P-252-Attach-1.DOC

HHS-1506-P
252

October 2, 2006

The 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: CY 2007 Hospital OPPS System / CMS-1506-P

Dear Administrator:

I am writing this letter in comment to a proposed payment reduction for the liquid radionuclide, Iotrex, reported under HCPCS code C2632 which has been outlined in the Rule published in the Federal Register on August 23, 2006. I appreciate the opportunity the Centers for Medicare and Medicaid offer to the public in submitting comments and hope that my concern will be viewed in a manner that will cause CMS to reconsider its proposed payment of this important source utilized in brain cancer treatment.

I am a participating neurosurgeon with Medicare and am dedicated to treating and caring for those Medicare beneficiaries requiring neurological surgical needs. One type of surgery I perform involves removal of a glioblastoma or cancerous brain tumor. Following removal of the tumor, many patients can begin outpatient radiation therapy and one of the treatment options available involves the use of liquid I-125 radioisotope referred to as Iotrex.

It is my understanding that CMS is proposing a payment rate that does not meet the cost of Iotrex which will seriously impede hospitals to purchase Iotrex. This proposal worries me as I know that the course of radiotherapy treatment offered with Iotrex has produced favorable results with my patients – a better quality of life along with an increase to their survival. I do not want to minimize the option and treatment alternatives available to my glioblastoma patients because payment of the liquid isotope has been undervalued. I respectively ask that Medicare reconsider its proposal and instead maintain its current payment of charges adjusted to cost for calendar year 2007. I've learned recently that my request is in keeping with recommendations made by the APC Advisory Panel. Finally I would like to submit another alternative should Medicare not accept the first request and suggest a payment rate application of mean unit cost.

I am again appreciative to Medicare in hearing my concern and allowing me to submit comment to CMS-1506-P.

In good health,

Meg Verrees, M.D.

Meg Verrees, M.D.
Division of Neurosurgery
MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109-1998
(216) 778-7800

cc: Senator Mike DeWine, Senate Appropriations Labor-HHS Subcommittee and Senate Health, Education, Labor and Pensions Committee
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Mr. Russ Ranallo **Date:** 10/04/2006

Organization : Owensboro Medical Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-253-Attach-1.DOC

Attached
253

October 4, 2006

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Ref: [CMS-1506-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2007 Rates.

Dear Sir/Madam:

The Owensboro Medical Health System (OMHS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, which establishes new policies and payment rates for hospital outpatient services for calendar year 2006. We are pleased by CMS' openness in soliciting comments on the numerous changes it proposes to this remarkably complex and difficult payment system.

Attached are our detailed comments regarding CMS's proposed changes. We hope that CMS will consider our recommendations and make the appropriate adjustments. Please feel free to contact me at (270) 688-2855 if you have any questions or if you require additional information.

Sincerely,

Russ Ranallo
Vice President, Financial Services

Wage Index

OMHS ***continues*** to be concerned with the impact of wage index on the APCs and the inclusion of devices and technologies and former pass-throughs into the base APC system. The pass-throughs have been incorporated into the base system but it is not apparent that any review concerning the labor and non-labor split of the APCs has been performed. Currently, 60% of the APC is wage index adjusted.

We feel that in certain APCs that have high cost in technologies, implants and drugs this is too large of a labor percentage. Hospitals have roughly the same acquisition costs for these items yet the hospitals with higher wage indices are paid more for these APCs while the hospitals with lower indices are paid less.

Our internal data shows that our labor expenses on APCs that have high dollar devices or supplies included in the payment are far less than the 60% adjusted by Medicare. We are being punished with lower payments for **devices** because our wage index is below 1.0 while other hospitals are benefiting with higher payments if their wage index is greater than 1.0. This inequity could prohibit hospitals with lower wage indices from being able to offer more advance implants and devices.

For example, take a device with a pass through of $5,000 for the device and a procedure payment of $2,500(e.g. APC of 0050 Level II musculoskeletal).

During the pass through period, a hospital with a **1.2 wage index** would be paid $7,800 for this procedure ($2,800 for the procedure and $5,000 for the device).

During the pass through period, a hospital with a **0.8 wage index** would be paid $7,200 for this procedure ($2,200 for the procedure and $5,000 for the device).

After the pass through period (assuming the procedure is put into an APC with the value of $7,500) the hospital with the 1.2 wage index would be paid $8,400 while the hospital with a .80 wage index would be paid $6,600. Assuming the device costs each hospital the same, the hospital with the higher wage index is getting a premium payment for the device while the hospital with the lower wage index is getting a payment penalty.

We would recommend that CMS incorporate a different labor rate split for the APCs that carry high device, supply, or pharmaceutical costs. Our internal data shows that a labor rate split of 20% (rather than 60%) is more appropriate for these APCs.

We would recommend the change in the labor rate percentage for the following APCs:

APCs 107, 108, 222, 224, 225, 226, 227, 315, 418, 654, 655, 656 and others that CMS feels would meet the criteria outlined above.

Submitter : Dr. Kenneth Lane **Date:** 10/04/2006

Organization : Dr. Kenneth Lane

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-254-Attach-1.DOC

NAME
254

September 29, 2006

The 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

Regarding: CY 2007 OPPS Proposed Rule (CMS-1506-P)

Dear Administrator:

Thank you for the opportunity to submit comment on the Medicare Program's Proposed Rule filed in the Federal Register on August 23, 2006. My letter is written to comment on the proposed new Medicare payment methodology for a liquid radionuclide source used with internal radiation for malignant brain tumors. The radionuclide is an Iodine I-125 source sometimes referred to by its brand name of Iotrex. I believe the code used by hospitals to report use of Iotrex during outpatient radiation therapy is C2632.

As a Radiation Oncologist, I want to be able to provide my patients, many of whom are Medicare beneficiaries the benefit of different treatment options available based on the type, location and size of malignant tumors. Additionally age and general health is also factored into determining what radiation therapy treatments will best serve the patient. With respect to persons with malignant brain tumors one treatment option involves internal radiation using a balloon catheter implanted during a craniotomy. Following discharge from the hospital for surgery, a patient returns to the hospital radiation oncology department and has infused through the catheter into the balloon the liquid radionuclide, I-125 Iotrex. The patient goes home with the Iotrex remaining inside the balloon for 4-5 days. Once the patient has received the radiation, s/he returns to the hospital where the Iotrex is removed. The catheter is also explanted and the patient goes home.

I share this treatment flow with you to illustrate the value in being able to provide this effective internal radiation therapy to brain tumor patients. Benefits include an increase to survival and sustained quality of life; internal radiation targets the area most likely to contain cancer with healthy tissue around the tumor site less likely to be damaged by radiation. This is a treatment option we can give to people today, however, if Medicare moves forward in its proposed payment method for Iotrex, it will halt the treatment option as hospitals will not be able to continually afford purchasing Iodine I-125 due to its cost exceeding expected Medicare payment.

Bearing this in mind, I ask that and believe CMS should continue paying the hospitals their charges adjusted to cost for Iodine I-125. I agree with and support the APC Advisory Panel's recommendation to CMS with respect to radiopharmaceutical and brachytherapy sources. Furthermore, I also agree and support the PPAC's recommendation to CMS regarding sources, as well.

Your reconsideration and evaluation of this issue is greatly appreciated.

Sincerely,

Kenneth Lane, MD

Kenneth Lane, M.D.
MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109-1998
216.778-7800

cc: Senator Mike DeWine, Senate Appropriations Labor-HHS Subcommittee and Senate Health, Education, Labor and Pensions Committee
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : **Dr. Donald Schon** **Date: 10/04/2006**

Organization : **AKDHC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1506-P-255-Attach-1.RTF

Attach #
255

The American Society of Interventional Nephrology (otherwise referred to as ASDIN) is the society which represents over 95 % of the interventional nephrologists in the United States as well as many radiologists who specialize in interventional procedures for dialysis accesses. Because of this ASDIN represents major stake holders affected by proposal CMS1506P.

We support many aspects of this proposal by CMS. We are especially supportive of the intent to improve access for Medicare recipients to dialysis access maintenance procedures. The proposal to evolve from a list of allowed procedures to a list of disallowed procedures goes a long way towards achieving this goal. However there are several aspects of this proposal which we feel are counter productive and will have the effect of inhibiting access to appropriate care for end stage renal disease (ESRD) recipients of Medicare.

Currently access procedures are reimbursable in either the office setting or the hospital setting and, to a markedly lesser extent, in the ASC setting. Adequately and appropriately reimbursing these procedures in an ASC setting will not change the frequency of these procedures. It will however, improve patient access to care. By shifting procedures out of the hospital it will provide a net savings to the Medicare system and should rightly be encouraged.

As CMS is well aware, the state of vascular access for dialysis in the United States is such that marked improvement is necessary. To this end, the KDOQI (Kidney Disease Outcome Quality Initiative) practice guidelines were developed as a joint effort of multiple organizations and then embraced by the nephrology community. Supporting organizations include the National Kidney Foundation, the American Society of Nephrology and the Renal Physicians Association. As documented in the USRDS database, vascular access in the United States has been improving since implementation of these guidelines. KDOQI mandates the development of facilities and mechanisms to improve timely access to dialysis access maintenance procedures. In addition it was recommended that these procedures be moved to the outpatient setting. To further these goals, effective January 1, 2005 CMS changed the reimbursement guidelines for procedures done in place of service 11 (POS 11) or an extension of a physician's office setting. Since the reimbursement changes have been implemented, over 30 freestanding centers for the performance of vascular access procedures have been built by physician practices throughout the United States. These centers perform more than 50,000 access related procedures annually. All of these procedures have been moved from the hospital setting. Many more centers are currently planned. Currently, the vast majority will function in POS 11. The current proposal has the intent of similarly improving access to procedures performed in the ASC setting.

Because of the nature of dialysis access procedures, specialized radiology equipment and supplies are necessary. This equipment must be provided in an ASC dedicated to dialysis vascular access procedures. The specialized equipment and supplies are not easily transferable to other uses if dialysis access procedures are to continue to be the main focus of the ASC. This focus is necessary to achieve the desired improved access to care for ESRD patients with dialysis access problems discussed below. Because of this, these centers cannot "blend" in other procedures to counter a 38 percent decrease in reimbursement per procedure. In addition, the cost per procedure does not go down 38 percent with an increasing volume of access procedures. Also, CMS has proposed a reduction in reimbursement for multiple radiology procedures done on the same day. CMS already imposes a 50 % reduced reimbursement for multiple surgical procedures performed on the same day. If in addition to this, if the proposed reduction in reimbursement for multiple radiology procedure is superimposed the combined effect would be prohibitive.

KDOQI and the Fistula First initiative have set as goals an increase in fistula prevalence in ESRD patients to greater than 65%. To facilitate this effort the National Kidney Foundation, American Society of Nephrology, Renal Physicians

Association and Fistula First Initiative have advocated making interventional procedures more available to patients, especially in the outpatient setting. The proposed cuts will make performing access related procedures in an ASC a financially marginal endeavor from the perspective of operating revenues. This will have the effect of retarding the shift of access related procedures to the outpatient departments from the inpatient settings. It will also have the effect of reducing access to care for Medicare recipients who suffer from ESRD. Since the hospital setting is both less efficient and more expensive, the result will be an increase in Medicare expenditures.

The proposed list of procedures prohibited from reimbursement in an ASC includes 35475 and 37206. 35475 is the code used by interventional physicians performing procedures (i.e. balloon angioplasty or PTA) at the arterial anastomosis of a fistula or graft and the proximate feeding artery. When applied to the repair and maintenance of vascular access for dialysis, these procedures are very safely performed in an ASC. Indeed, they are currently frequently performed safely in POS 11. Data from three sources is provided. The first is an ASC setting with low volume of procedures coding 35475. The second is a single Access Center which performs greater than 3,000 procedures per year all on dialysis vascular access. The third is a large number of procedures from multiple access centers all functioning as POS 11 and managed by a common entity.

no. proc.% major complications 140 %4550 %1,968< 0.3 %

In each case the number of major complications is miniscule and well within the professional guidelines for each center and the national guidelines published by the Society for Interventional Radiology. Thus, excluding procedures performed on dialysis vascular access which would be coded as 35475 would be inappropriate as well as counterproductive. These procedures can be safely and effectively performed in an outpatient setting. Prohibiting this code would also have the affect of limiting access to care for ESRD patients as these patients would have to have a second procedure and anesthesia to open these lesions at a separate time. Since they would need a way to achieve dialysis access in the meantime, a large number of otherwise unnecessary catheter insertion procedures would be necessitated and the cost to the Medicare program from both additional procedures would go up significantly.

37206 is the code utilized by interventional physicians for placement of additional vascular stents in the venous system. These procedures have been safely performed in the outpatient setting for years. In addition, the initial placement of a stent in the venous system, coded 37205, is not on the list of excluded procedures. In our opinion, this prohibition is logically inconsistent, not medically indicated and would necessitate repeat and additional procedures which could otherwise be avoided.

We recommend and request that 35475 and 37206 both be removed from the list of excluded services when applied to dialysis access.

Lastly is the issue of frequent procedures and budget neutrality.

Interventional access procedures are a very cost effective means of treatment for dysfunctional dialysis accesses. They are much less costly than equivalent surgical procedures. Thus, increasing access procedures and reducing surgical and hospital based procedures will not increase overall Medicare expenditures. Therefore, reducing ASC reimbursement in the name of budget neutrality is neither appropriate nor fair. For every ASC performed procedure there is a net savings to the ESRD system as opposed to the procedure being performed within a hospital setting.

We feel that the intent of the CMS proposal CMS1506P is excellent. However, certain features of the proposed implementation will make the proposed goals elusive or impossible to achieve. To this end we have tried to make positive suggestions to further the common goal of achieving better care and better access to care for Medicare recipients with ESRD.

In summary, ASDIN respectfully suggests and requests the following.
1. We support the proposed shift from a list of approved procedures to a list of disallowed procedures.
2. We support improving access to outpatient vascular access procedures in the ASC setting for ESRD patients.
3. We maintain that shifting procedures to the ASC from the inpatient setting will not change the absolute number of procedures performed as these are essential procedures to sustain life on dialysis.
4. There will be a major savings to the Medicare system from this shift. Therefore, reducing reimbursement for budget neutrality is not logical. There will result a net savings without the reduction.
5. ASC access centers are of necessity highly specialized facilities dedicated to a specific purpose. The equipment and set up are not routinely useful to other procedures performed in the ASC setting. Thus, these centers will feel an effect from the proposed reimbursement cuts which cannot be mitigated by "blending" in other procedures.
6. CMS has also proposed reimbursement cuts for multiple radiology procedures. The combined effect, if implemented, of both the 38 % reduction in ASC reimbursement and reduction for multiple radiology procedures will severely and disproportionately penalize ASC facilities dedicated to dialysis vascular access.
7. The above proposals will retard the shift in dialysis access procedures to the outpatient setting. This will result in lost opportunity for savings to the Medicare system and reduce access to care for Medicare recipients.
8. We request the removal of codes 37206 from the list of disapproved procedures on the basis of safety and consistency. We request the removal of code 35475 from the list of disapproved procedures when applied to dialysis vascular access. Data documenting the safety of such procedures in the outpatient setting is supplied for low and high volume facilities.
9. Maintaining 37206 and 35475 on the list of disapproved procedures would result in multiple procedures which could otherwise be avoided.

Donald Schon, MD, FACP
Councilor for Regulatory Affairs
Ted Saad, MD, FACP
President ASDIN
The Committee of Officers and Councilors of ASDIN on behalf of the membership:
Arif Asif, MD
Timothy Pflederer, MD
Jack Work, MD
Gerald Beathard, MD
Michael Levine, MD
Kenneth Abreo, MD
Tom Vessely, MD
Tony Besarab, MD
Linda Francisco, MD
Rick Mishler, MD
Stephen Ash, MD
Terry Litchfield

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4 ASDIN response to CMS 1506-P

5 ASDIN response to CMS 1506-P

Submitter : Ms. Margaret Boiano **Date:** 10/05/2006

Organization : VNUS Medical Technologies,Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

ASC payment group-see attachment

CMS-1506-P-256-Attach-1.PDF

Attachment 256

VNUS®

October 5, 2006

Via Electronic
http://www.cms.hhs.gov/eRulemaking
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1506-P or CMS-4125-P**
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: CMS-1506-P- the Ambulatory Surgical Center Payment System

Dear Administrator McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS), and Ambulatory Surgical Centers using our technology, we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed Hospital Outpatient PPS and CY 2007 update to the Ambulatory Surgical Center payment System; CMS-1506-P.

Specifically, we appreciate CMS for recognizing that 36475 and 36476 Endovenous Radiofrequency (RF) requires significantly more facility resources than traditional vein removal procedures. We are pleased with your taking into consideration the associated cost of the required equipment and supplies, and support the proposed change for reassignment of the endovenous RF Ablation procedures to the higher **ASC Payment Group 9**. (Page 404 of the propose rule)

However, with references to *Addendum AA --proposed list of Medicare approved ASC procedures for CY 2007 with additions and payment rates*, on page 732;

- It wrongly reflects this change as ASC Payment Group 8 with a payment rate of $973
- In keeping with you proposed ruling it should show ASC Payment Group 9 and a payment rate of $1,339

We appreciate the opportunity to submit comments and to work with CMS to ensure Medicare patients have access to endovenous RF ablation procedures in the Ambulatory Surgical Centers setting.

Should you have any questions, please contact me at 408-360-7560. Or our reimbursement counsel, John McInnis at 202-942-6293, if we can provide further information to support the correct change to ASC payment group 9 for these procedures in CY 2007.

Sincerely,

Margaret Boiano
Director of Reimbursement
VNUS Medical Technologies, Inc.

cc: Dana Burley, CMS

Submitter : Mrs. Dixie Calhoun **Date:** 10/05/2006

Organization : Endoscopy Center of Southeast Georgia, Inc.

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am an Administrator and Clinical Nursing Director for an ASC in Southeast rural Georgia. Our ASC is a single specialty center that delivers GI endoscopy services. I would like to express my concern over the proposed changes in the ASC payment system for 2008. If implemented as proposed, the CMS rule could have a disastrous impact on single-specialty GI ASCs. The proposal is misguided, and if it were to be implemented as written, would almost certainly assure: 1) the closing of many GI ASCs, 2) reduction in access for Medicare beneficiaries, 3) reduce the levels of colorectal cancer screening, and 4) higher total costs to the Medicare program. We are totally commited to the delivery of quality care to our patients. This commitment does require adequate compensation in order to maintain the level of service that Medicare beneficiaries deserve. Medicare beneficiaries comprise 47% of out patients. The out of pocket expense will be greater and there will be a delay in their care because our local hospitals do not have the capacity, nor adequate number the qualified physicians, to accommodate the additional case load in a timely manner. We serve a 8-9 county area and perfom over 2500 procedures annually. The county, in which our ASC is located, is proud to be in the lowest 10% in Georgia and the nation, in the occurence of deaths due to colorectal cancer. This is a result of our commitment to and passion for colorectal cancer prevention. We sponsor a weekly local TV program that reaches out to the 8-9 county area we serve, with an emphasis on colorectal cancer prevention and present many educational programs for our communities. These programs also come at a cost to our Center. Research has proven that lack of public education is a strong contibutor to non-compliance in colorectal cancer screening recommendations. The proposed 62% of HOPD, for the SAME service, is not acceptable or reasonable. The elderly population is more prone to be compliant with the national recommendations for colorectal cancer screening if they do not have to go through all the "red tape" that occurs regularly in the hospital environment. I find it ironic that CMS approved colorectal cancer screening as a covered service and now are attempting to implement changes that will discourage the beneficiaries from seeking adequate screening and continued surveillance. I would like to strongly request reconsideration of CMS-1506-P to identify and document the potential devasting effects if the proposal is implemented as written now. The issue is not just "money". The real issus is Medicare beneficiaries being able to obtain quick access to high quality, cost efficient healthcare and the proposed changes will definitely effect this in a negative manner. Again, I strongly urge the powers that be to relook and rethink this proposal and adjust according to the real needs!!! Thank you for your time and consideration of this request.

Submitter : Dr. Marco Zaider **Date:** 10/05/2006

Organization : MSKCC

Category : Physician

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 Federal Register) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a device of brachytherapy and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive.

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical brachytherapy. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity brachytherapy. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year s proposed rule.

Submitter : **Tehjan Martin** **Date: 10/05/2006**

Organization : **Jennings Behavioral Health LLC**

Category : **Other Health Care Provider**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

JENNINGS BEHAVIORAL HEALTH LLC
619 North Main Street
Jennings, LA 70546
martint@jbhllc.com

October 5, 2006

FILE CODE: CMS-1506-P PARTIAL HOSPITALIZATION

Re: CMS-1506-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates Proposed Rule

In response to the Proposed Rule for Medicare Outpatient Prospective Payment for 2007, please accept the following comments and concerns.

The rate for 2007 is set at 208.27 results in a net payment of 141.49 per day for rural Louisiana providers up to 155.17 per day in New Orleans. A reduction of an additional 15% from 2006. These rates are insufficient to cover the cost of caring for an acutely ill person with mental illness. The current standard of Practice for Partial Hospitalization Programs is an average of 4-5 professional services per day. Services provided in a partial hospitalization program are provided both on a group and individual basis. Partial Hospital Programs require extensive amounts of professional services, inclusive of nursing, social work, therapy, ancillary services and psychiatry.

Lack of protection for rural providers:

I am concerned that CMS again fails to protect rural mental health providers. There has been well documented evidence, published by CMS, of the special hardships and needs of rural providers. Most other rural provider types have been recognized for this hardship and have had allowances and special provisions to ensure their viability. CMHC s have long been asking for this protection and some assistance for rural providers. We ask that you consider treating CMHC s in an equitable manner to other provider types.

It appears that CMS has concerns over the quality of services being provided in Partial Hospital Programs. My facilities are, and have been for eight years, JCAHO accredited. This is at a substantial cost to our small company. I ask that you consider increased requirements for participation in providing Medicare PHP but would ask that you provide fair compensation for such. I also request that you consider an outcome based demonstration project for Partial Hospitalization services. I think you will find that it is a valuable tool at decreasing inpatient length of stays for the chronically mentally ill population.

Thank you for your consideration of these comments.

Sincerely,

Tehjan Martin RN,C
CEO

Submitter : Dr. Edward Flotte **Date:** 10/05/2006

Organization : Coastal Neurological Institute, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-260-Attach-1.DOC

October 2, 2006

The 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 – CY 2007 Hospital Outpatient Prospective Payment System

Dear Administrator:

I would like to provide comment concerning a matter not only important to me, but most importantly on behalf of my Medicare patients diagnosed with brain cancer. I appreciate the opportunity to share my concern which has been outlined in the CMS-1506-P Proposed Rule published in the Federal Register on August 23, 2006.

I am concerned about the proposed payment method CMS is considering implementing for radiotherapy sources, one of which is Iodine I-125, a liquid radioisotope source named Iotrex. The HCPCS code used to report Iotrex is C2632.

Right now the hospitals that purchase Iotrex are reimbursed by Medicare at cost, but a new method of payment is using a median unit cost. According to your files the median unit cost is proposed at $19.32 per millicurie. This is far below the cost of each millicurie contained in the single use 1 milliliter vial of Iotrex. The proposed rate will seriously impact Medicare beneficiary outpatient access to this cancer therapy because hospitals cannot continue to afford to purchase I-125 Iodine should the payment be reduced to $19.32 per millicurie.

As a neurosurgeon and provider of care for Medicare patients, I am faced with diagnosing and performing major surgery on some Medicare beneficiaries that have malignant brain tumors. Part of the patient treatment plan not only involves removing the tumor, but following surgery, the patient must also go through radiotherapy using the radionuclide solution, Iotrex. This surgical intervention and the radiation course of therapy gives the patient an increase in survival and offers quality of life that might otherwise be unavailable.

I support and recommend that Medicare continue to pay Iotrex at charges adjusted to cost.

Again, I appreciate your time and evaluation in this matter.

Sincerely,

Edward R. Flotte, M.D.

Edward R. Flotte, M.D.
Coastal Neurological Institute, P.C.
P.O. Box 160848
Mobile, AL 36616
251.450-3700

ERF: km

cc: United States Senator Richard Shelby
United States Senator Jeff Sessions
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Mrs. Lynn Gerig **Date:** 10/05/2006

Organization : Parkview Cancer Center

Category : Nurse

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am writing to request that CMS reverse its proposal and maintain current payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery for CY2007. Image-guided robotic radiosurgery is less expensive than GammaKnife therapy which is completed in one fraction vs. one to five fractions for robotic radiosurgery. Less cost is incurred with robotic therapy which does not require headframe placement or the risk of infection to pin sites, etc. The stress to the patient is reduced as well since the patient is more comfortable. Robotic radiosurgery provides more treatment options than GammaKnife as well. Other body sites other than intracranial are being treated with good results that do not require invasive surgeries. More side effects are experienced with invasive procedures. These side effects can and often do increase the cost of treatment and patients experience more distress than from non-invasive procedures. I am requesting that CMS set reasonable reimbursement rates for image-guided robotic stereotactic radiosurgery technology, codes G0339 and G0340. Thank-you for your consideration.

Submitter : **Miss. Jugna Shah** **Date: 10/05/2006**

Organization : **Alliance of Dedicated Cancer Centers**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

Drug/Pharmacy Issues Related to ASP + 5% and packaged drugs

CMS-1506-P-262-Attach-1.DOC

Attachment
262

The Alliance of Dedicated Cancer Centers:
Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
City of Hope National Medical Center
Dana-Farber Cancer Institute
Fox Chase Cancer Center
H. Lee Moffitt Cancer Center and Research Institute
M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center
Roswell Park Cancer Institute
Seattle Cancer Care Alliance
Sylvester Comprehensive Cancer Center

October 5, 2006

By Electronic Delivery

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

Re: File Code CMS-1506-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear CMS Administrator:

On behalf of the Alliance of Dedicated Cancer Centers (the "Centers"), an alliance of ten nationally recognized institutions focusing exclusively on the care of cancer patients, I am writing to comment on the Proposed Rule that would revise the Medicare prospective payment system for hospital outpatient services, as published in the *Federal Register* on August 23, 2006 (71 Fed. Reg. 49,506) (the "Proposed Rule"). The Cancer Centers, individually listed above, appreciate the opportunity to submit these comments on the issue of reimbursement for drugs, biologicals, and radiopharmaceuticals. This letter is the second of several comments that the Centers will be submitting on the Proposed Rule.

1. Average Sales Price + 5% and Pharmacy Handling/Overhead Costs

CMS proposes to pay for specified covered outpatient drugs in 2007 on the basis of average sales price (ASP), with ASP + 5% reflecting payment for average acquisition costs and pharmacy overhead/handling costs.[1] The Centers recognize that CMS was required by the Medicare Modernization Act (MMA) to change how it pays for drugs starting in 2006 and that, in the absence of average acquisition cost data, CMS is authorized to use ASP unless Competitive Acquisition Program data is available. We commented on this issue last year when CMS proposed, and made final for 2006, that separately payable drugs would be reimbursed at ASP + 6%. The Centers believe that payment rates at this level are grossly inappropriate, because they do not begin to cover our acquisition or overhead/handling costs -- particularly since several new mandates (e.g., USP797,[2] NIOSH[3]) require the Centers to expend even more resources in our pharmacies. We provided detailed information on both of these mandates and the costs associated with them for a number of our Centers in last year's comments; thus, while we can provide these comments upon request, we will not repeat that information here.

The Centers continue to believe that CMS is incorrect in its assumption that using a percentage increase over the ASP to set payment rates for most separately payable and pass-through drugs is sufficient to cover both our drug acquisition and pharmacy overhead/handling costs. We, like many others, urged CMS to find an administratively simple solution to capture pharmacy handling data in our comments last year. At a minimum, CMS must carefully consider the impact of unfunded mandates on pharmacy overhead/handling costs and identify a

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[1] 71 Fed. Reg. 49,506, 49,585 (Aug. 23, 2006).

[2] See U.S. Pharmacopoeia, Proposed Revisions to USP Chapter 797, available at: http://www.usp.org/healthcareInfo/pharmInfo (January 2004 revisions - without opportunity for public comment – to recommendations on the preparation of sterile intravenous medications in response to isolated but highly publicized cases of patient harm resulting from contaminated medications produced outside of hospital pharmacies).

[3] See National Institute for Occupational Safety and Health Alert, September 2004, available at: http://www.cdc.gov/niosh/docs/2004-165/ (introducing new recommendations for pharmacy and nursing handling of hazardous drugs).

mechanism to factor them into the overall drug payment policy.

It is difficult to understand why CMS is suggesting decreasing the current drug APC payment rates from ASP + 6% to ASP + 5% for 2007. Given that the current rates are already inadequate, this 1% decrease in how we are currently paid is inappropriate. Therefore, we strongly oppose CMS's proposal to further reduce drug APC reimbursement rates. The Centers' oncology clinics already face increased patient loads as physicians have been forced to turn certain types of patients away from their private office practices in the face of falling drug reimbursement. At the Centers, we do not have the same ability to direct patients to another setting, and yet we face even higher pharmacy overhead/handling costs and receive lower reimbursement in the aggregate because we do not receive separate payment for packaged drugs. As such, we fail to understand how CMS can reimburse physicians in the private office setting at a higher rate for separately payable drugs, nor do we understand why CMS would reintroduce the site of service differential between the physician and hospital settings that it eliminated for 2006 by reimbursing all separately payable drugs at the same rate – ASP + 6%.

Moreover, the Centers were very disappointed that CMS did not comment in the 2006 final OPPS rule on the merits of our suggestion to review hospital cost report data as an alternative to CMS's proposal to require category C-codes to capture pharmacy overhead/handling cost data. In that comment letter, we suggested that CMS study hospital cost report data and determine if handling costs could be extracted from this existing data source. This method could potentially be used as an alternative, or just a stopgap until methodological issues can be resolved with CMS's proposal.

Alternatively, CMS could require each Fiscal Intermediary (FI) to provide a "pharmacy overhead/handling cost collection" survey to the hospitals it services, collect the completed

surveys from the hospitals, and transmit the data back to CMS. This approach has been used for a number of purposes in the past, including to collect data for the payment-to-cost ratio[4] used in the transitional outpatient payment calculations; the wage index and occupational mix information for both OPPS and IPPS; and, most recently, for the outpatient cost-to-charge-ratio.[5]. In all of these cases, hospitals submitted the requested calculations and data to their respective FIs using a very prescriptive method and the FIs, in turn, used these data for payment purposes.

The Centers believe that CMS can utilize a similar approach to obtain data on provider drug handling charges and costs. Collecting these data from all hospitals (and using the same formula, cost report line numbers, and consistent methodology) will allow CMS to establish a more realistic pharmacy/drug handling fee by creating either a flat add-on percentage or separate APC payment rates. Although the 2004 cost reports will not contain cost data related to the impact of the two unfunded mandates mentioned above, it will provide CMS a much better starting point for estimating pharmacy overhead/handling costs. As more current cost report data becomes available, CMS should continue updating its estimates of pharmacy overhead/handling costs (if this approach is selected as a method to set drug handling APC payments).

In sum, the Centers urge CMS to continue paying for all separately payable drugs according to the ASP + 6% methodology. We further urge CMS to exercise its authority and provide an add-on payment that would cover pharmacy overhead/handling costs, which would help offset our increased costs associated with the unfunded mandates discussed above. In addition, we recommend that CMS convene a special meeting of the APC Advisory Panel dedicated to the issues of pharmacy overhead/handling data capture and charge compression. To date, these issues have not been addressed by CMS and the result is continued underpayments

[4] See CMS, Program Memorandum A-01-51 (April 13, 2001).
[5] See CMS, Program Memorandum A-03-004 (Jan. 17, 2003).

and/or inappropriate payments for drug and device APCs. Clearly, there are no simple solutions to this problem. We are, however, optimistic that bringing stakeholders together would be an important starting point to discuss these issues from both a technical and hospital operations perspective.

2. Drug packaging threshold

CMS has proposed to retain the drug packaging threshold resulting in no separate APC payment for drugs with a per administration cost below the threshold. The proposed threshold for CY 2007 is increased by $5 to $55, with a provision for an annual inflationary update thereafter.[6] The Centers do not agree with the continued use of a drug packaging threshold for several reasons, which we outline below.

First, eliminating the drug packaging threshold will allow CMS to align its drug payment policy across the physician office setting and hospital outpatient departments since all drugs are reimbursed separately in the physician office setting regardless of cost, while drugs with a per administration cost of less than $55 are proposed to be "packaged" in the hospital setting. The transition away from using average wholesale price as the basis for drug reimbursement in both settings to the use of ASP is one example of how CMS has aligned payment policy across the two settings in the past. CMS eliminated the separately payable drug site of service differential for 2006 by paying for drugs in both settings using ASP + 6%. CMS also worked to create consistency across the two settings by moving towards requiring similar codes and rules for reporting drug administration services. Conversely, the 2007 proposal to pay hospitals using ASP + 5%, while continuing to pay physicians in the office setting using ASP + 6%, is a problematic divergence from that alignment.

[6] 71 Fed. Reg. at 49,582.

Second, CMS often states that the charges for packaged drugs and other packaged items (e.g., supplies and other services) are included in the development of other APC payment rates. The Centers understand that the concept of packaging is consistent with prospective payment systems; however, this concept only works if the charges associated with packaged services, including drugs, are actually being included in the APC rate-setting process. The Centers believe the majority of packaged drug charges are on multiple procedure claims, and are never factored into the payment rate of other APCs. The Centers analyzed data from the first six months of our own 2005 drug administration claims data, which showed that packaged drugs with HCPCS codes represented 5.83% of total drug charges, and only 17.91% (of the 5.83% of HCPCS coded packaged drug charges) appeared on single procedure claims. This demonstrates that the vast majority (82.09%) of packaged drug charges with HCPCS codes appear on multiple procedure claims, and thus would not be factored into the APC rate-setting process. The Centers presented the above information at the March 2006 APC Advisory Panel meeting, and we are disappointed that CMS did not respond to the Panel's recommendation that CMS should prepare an analysis that discloses the actual percentage of packaged drug charges appearing on single procedure claims used in the APC rate-setting process.

Since CMS already goes through the process of identifying single and multiple procedure claims, the Centers believe it would be relatively easy for CMS to isolate the percentage of packaged charges appearing on single procedure claims and again request that CMS disclose this information. Specifically, the Centers request that CMS release the total charges associated with all packaged HCPCS and revenue codes billed by providers. Once this number has been isolated, CMS should calculate the percentage of packaged dollars associated with single and pseudo-single procedure claims as this will inform the public of the actual percentage of packaged dollars in aggregate included in the rate-setting process. Finally, the Centers ask CMS to isolate the universe of drug administration claims and disclose the total charges associated with packaged drug HCPCS and revenue codes along with the percentage that appear on single and pseudo-single procedure drug

administration claims. This will serve to inform the public of the percentage of packaged drug charges appearing on drug administration claims that are being factored into drug administration APC payment rates.

Third, and related to the discussion above regarding packaged drug charges, the Centers are concerned that a disproportionate percentage of packaged charges, often with higher mark-ups, are being discarded and therefore not factored into the APC rate-setting process. Packaged drugs are typically older and lower in cost. Providers using a tiered mark-up structure may end up applying higher mark-ups to these drugs and lower mark-ups to their higher cost, separately payable drugs. Therefore, if a large percentage of packaged drug charges - charges that CMS and MedPAC claim reflect our pharmacy handling/overhead charges - are not being used in the rate-setting process, then CMS cannot reasonably assert that ASP + 5% is sufficient to cover both acquisition and pharmacy handling/overhead. If packaged drug charges are NOT being factored into the APC rate-setting process, then CMS's estimate of ASP + 5% for 2007 is incorrect and should be analyzed more extensively. Since CMS has not yet disclosed the percentage of total packaged drug charges that appear on single or pseudo-single procedure claims, we do not know whether (or where) the majority of packaged drug charges and hence our pharmacy overhead is being factored into the payment rates of separately payable APCs. This is another reason for CMS to conduct the analyses mentioned above and disclose the information to the public. If our hypothesis is correct and CMS is not factoring in the majority of packaged drug charges, then this is further justification for the provision of separate payment for all HCPCS coded drugs, regardless of their median cost, as this will help to offset some of our pharmacy overhead/handling expense.

Finally, in 2006, CMS eliminated separate APC payment for multiple injections of the same drug/substance. Therefore, it must be recognized that hospitals lose money on both the second and

subsequent drug administration (i.e., injections) service of the same drug and also on the drug itself when the drug administered is packaged. This results in a compounded loss in payment for hospitals. Alternatively, physicians in their office setting only have to absorb the loss of the second and subsequent administrations, as they are paid for each billed drug regardless of the median cost of the drug.

If CMS does not implement the recommendation to eliminate the drug packaging threshold, it will continue to perpetuate a site of service differential between the physician office setting and the hospital setting with respect to drug reimbursement. This disparity is unacceptable, particularly if packaged charges are not being factored into the APC rate-setting process. If CMS rejects our recommendation to pay for all HCPCS coded drugs separately, then it must find a way to truly use packaged drug charges in the APC rate-setting process, or else hospital payments will continue to be compromised. The Centers have provided CMS with packaging logic in the past to generate additional single procedure claims for drug administration and are willing to work with CMS to develop logic to isolate packaged drug charges so they can be appropriately allocated to drug administration APCs for the rate-setting process.

3. Intravenous Immune Globulin (IVIG)

IVIG (Intravenous Immune Globulin) is a blood product that is used extensively in bone marrow transplants. For 2006, CMS created a temporary HCPCS G-code, G0332 (for *pre-administration related services for IV infusion of immunoglobulin [IVIG], per infusion encounter*) in recognition of the extra resources that hospitals must expend due to the IVIG shortage and to help offset those costs. In the Proposed Rule, CMS states that its review of the IVIG marketplace indicates that a separate IVIG pre-administration payment is no longer necessary in 2007.[7]

[7] 71 Fed. Reg. at 49,604.

As CMS is aware, there continues to be an ongoing nationwide supply shortage of IVIG. Because of the Iraq war, *all* blood products continue to be in short supply. Therefore, the Centers do not understand why CMS proposes to eliminate the pre-administration IVIG G-code and associated APC payment rate.

As a result of the ongoing shortage, the Centers and other providers must purchase IVIG "off contract" (i.e., at whatever price the secondary market suppliers believe the market can bear). In this type of environment, unforeseen clinical necessity sometimes mandates that we purchase IVIG at acquisition prices that are much higher than the APC reimbursement for the product. Additionally, the IVIG shortage necessitates that the Centers' pharmacies purchase whichever formulation is available, so that this important drug therapy can be provided to our patients when they need it.

The Centers recognize that CMS has proposed paying for additional hours of infusion therapy separately beginning in 2007.[8] According to the Proposed Rule, this reimbursement is intended to cover the additional nursing resources that are incurred during additional hours of infusion therapy. CMS should not expect this payment to cover the extra facility resources expended related to the shortage of IVIG. The resources expended as a result of the IVIG shortage are completely separate from the payment for additional hours of infusion therapy, which is correlated to the nursing time and resources expended to provide this therapy.

The Centers therefore urge CMS to continue providing separate APC reimbursement for HCPCS G-code, G0332. We are very concerned about our ability to maintain beneficiary access to this important drug therapy for our bone marrow transplant, neurology, hematology, and HIV/AIDS patients.

---

[8] Id. at 49,600.

4. Radiopharmaceuticals

The Centers believe that it is important for CMS to continue paying for brachytherapy and radiopharmaceuticals at cost. The frequent code and descriptor changes have likely resulted in poor and incomplete claims data. CMS does not have the advantage of using 2006 claims data yet, where payment is based on charges reduced to cost and the revised codes. We believe this data will generate more accurate and appropriate payment rates for use in 2008. Therefore, relying on median cost data from 2005 as the basis for setting 2007 APC payment rates is premature and could impact beneficiary access to care, since the calculated payment rates are understated due to data-related issues.

The Centers recognize that OPPS is a budget neutral system and that providing separate payment for all HCPCS coded drugs, maintaining ASP + 6% for all separately payable drugs, and continuing to pay cost for brachytherapy and radiopharmaceuticals will take money away from other APCs. However, OPPS is still evolving and, over the years, much consideration has been given to developing appropriate payment rates for high-cost devices and device-related APCs, including the use of external data and dampening mechanisms even when claims data were available. The Centers ask CMS to examine the category of drugs, biologicals, and radiopharmaceuticals in the same manner. Payment policy decisions over the past few years have resulted in the continued ratcheting down of payment for cancer-related services. If CMS does not provide adequate reimbursement for drugs, biologicals, and radiopharmaceuticals, then providers who administer them in the outpatient setting will incur disproportionate losses and access to care for Medicare beneficiaries may be compromised.

* * * *

Thank you for your willingness to consider our views. We hope that CMS will address the concerns described above and make the necessary adjustments to OPPS to ensure equitable reimbursement for state-of-the-art cancer care. If you have any questions or require additional information, please contact the Cancer Centers' technical consultant on OPPS matters, Ms. Jugna Shah, at (215) 888-6037.

Sincerely,

James S. Quirk
Executive Director
Alliance of Dedicated Cancer Centers

Submitter : Dr. Ronnie Smith **Date:** 10/05/2006

Organization : Endoscopy Center of Southeast Georgia

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

October 5, 2006

I am a practicing physician in Vidalia, Georgia. I am writing to express my deep concern over Medicare s proposed rule to change the payment system for ambulatory surgery centers (ASC). Approximately 47% of the procedures that I perform every year are Medicare patients.

The Endoscopy Center of Southeast, Inc., of which I am part owner and where I perform over 2,300 endoscopy procedures every year, takes great pride promoting Colorectal Cancer Prevention. Our facility complies with the Colorectal Screening guidelines recommended by the American Cancer Society, the Center for Disease Control and Prevention (CD), the National Institute of Health, and the American Society of Gastrointestinal Endoscopy. Not only do we comply with their recommended guidelines but we also conform to the payment guidelines as set fourth by Medicare, BC/BS, United Healthcare and other major reputable insurance companies for cancer screening.

Considerable time, effort, and cost are invested not only by me but by the competent staff that makes the Endoscopy Center of Southeast Georgia successful. Great pride is taken in the fact that Toombs County s death rate from colorectal cancer has declined substantially. The CDC reported that the colorectal cancer death rate for Toombs County is among the lowest 10% in the state and nation.

One would think that a facility of this description would be located in a metropolitan area, but the fact is this facility is located in rural Toombs County. Services of this type cannot be found without leaving the area and traveling to a large city. Medicare patients tend to be older and traveling out of town for this type of medical care would be a major inconvenience.

Medicare is proposing to reduce its ASC payment for endoscopy more than 25% by 2008. The rates Medicare is currently allowing ($424.41) is already well below our cost of performing these endoscopy procedures, including screening for cancer. Our practice will lose money on every Medicare patient that comes to our ASC. The facility fees of the Endoscopy Center of Southeast Georgia are affordable and reasonable. The fee is less than 20% of the local hospitals. As an ASC we are able to provide patients with the safest, highest quality of care available.

Congress needs to change its instructions on budget neutrality to avoid cuts in payment reimbursement to ASC s. I know we can continue to provide services to Medicare patients in the ASC and save Medicare money if the reimbursement rules make sense. This proposal, however, does not pass that test.

Thank you for your careful consideration of this request. As a passionate physician in preventing Colorectal Cancer I urge you to convey these concerns to the leadership of the Committees that handle Medicare and to encourage action this year to correct this problem.

Sincerely,
Ronnie R. Smith, M.D.

Submitter : Dr. FREDERICK ELMORE **Date:** 10/05/2006

Organization : ELMORE MEDICAL VEIN

Category : Physician

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor Cl APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : **Ms. Jana Bethea** **Date: 10/05/2006**

Organization : **Blues Management, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-265-Attach-1.DOC

HH-CMS-1506-P-265

October 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

DAPA Family Recovery Center is a freestanding Community Mental Health Center near the Medical Center of Houston, Texas. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction again. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $37.64/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 99-105 describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS arbitrarily applies its' own bias assumptions and methodology on a different basis every year from CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no calculation of a methodology. It is nothing more than an arbitrary decision by CMS. We quote CMS on p. 105 to say "To calculate the CY2007 APC PHP per diem **cost,** we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

2. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

3. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

5. Based on the above issues, DAPA Family Recovery Center asks that CMS leave the per diem unchanged from the CY 2006 rate of $245.91. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 944 general adult admissions and 194 geriatric admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Jana Bethea

Submitter : Dr. Stephen B. Tatter **Date:** 10/05/2006

Organization : Wake Forest University Baptist Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

please see attachment

CMS-1506-P-266-Attach-1.DOC

October 3, 2006

The 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

Dear Administrator:

I write regarding the Centers for Medicare and Medicaid Services' proposed rule, *Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P)* to specifically address proposed Medicare payment for Iotrex®, an Iodine I-125 liquid radioisotope source assigned to HCPCS code, C2632.

I am a neurosurgeon and routinely care for Medicare beneficiaries, most of whom are diagnosed with malignant brain tumors, either glioblastomas or metastases of cancers from other organs. Generally, treatment involves surgically removing the tumor and then delivering radiotherapy. In some of these patients post-operative Iotrex (HCPCS code C2632), an Iodine I-125 radionuclide solution, is of great benefit providing an increase survival and preservation of quality of life.

My hospital has recently informed me that CMS is proposing a significant change in the payment methodology for Iotrex which will impact Medicare beneficiary access to this cancer therapy. Currently Iotrex is paid on charge adjusted to cost. CMS is proposing moving payment based on "median costs". The proposed payment rate of $19.32 per millicurie (mCi) does not meet the per mCi cost delivered in a 1-mL single use vial (150 mCI). If the rate CMS is proposing goes into effect, this will negatively impact the hospital's ability to provide Iotrex to the patients. Ultimately it is the beneficiary and his/her family that will suffer the consequences because they will no longer have access to this US FDA-approved therapy.

I am in support of the APC Advisory Panel's recommendation to continue cost payment. I, therefore request CMS continue payment for Iotrex under a cost payment method. If CMS moves ahead with an alternative payment approach then I recommend application of a "mean" unit cost as the basis for payment. The mean is a better representation of costs associated with Iotrex and consistent with the proposed payment method for other therapeutic radionuclides.

In conclusion, I strongly urge CMS to reconsider the proposed payment methodology of median unit cost and instead continue paying charges reduced to cost.

Thank you for your consideration in this important matter.

Sincerely,

Stephen B. Tatter

Stephen B. Tatter, M.D., Ph.D.
Liang Yee and Dixie Soo Professor of Neurosurgery
Wake Forest University Baptist Medical Center
Department of Neurosurgery
(366) 716-4047

cc: Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Representative Sue Myrick, Energy and Commerce Health Subcommittee; Co-chair, House Cancer Caucus
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : **Ms. Jana Bethea** **Date: 10/05/2006**

Organization : **Blues Management, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

October 5, 2006

Re: Partial Hospitalization Response on Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P.

Our agency, DAPA Family Recovery Programs is a freestanding Community Mental Health Center near the Medical Center of Houston, Texas. We serve approximately 944 general adults and 194 geriatric patients on an annual basis. We provide intensive psychiatric programs, including partial hospitalization services that are greatly needed by the severe andpersistently mentally ill in our community

We are requesting the proposed 15% cut for Partial Hospitalization Services be stopped. Coupled with last year's 12.5% reduction, the proposed rate will make it impossible to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program rate so drastically when most most medical costs are actually increasing by 4-6% annually. These programs need to be supported by reasonable reiumbursement rates that sufficiently cover the costs of providing these services to such a needy population.

Thank you for your consideration.

Sincerely,

Jana Bethea

Submitter : Mr. Wes Westfall **Date:** 10/05/2006

Organization : The Management Co.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-268-Attach-1.DOC

To Whom It May Concern:
I am greatly concerned about the recent changes in Partial Hospitalization's and wish for more discussion to be done.

Submitter : **Lori Woods** **Date: 10/05/2006**

Organization : **IsoRay Medical Inc**

Category : **Device Industry**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Please see comment letter attached

CMS-1506-P-269-Attach-1.PDF

HHS-CMS-2006-0069

350 Hills Street, Suite 106
Richland, WA 99354-5411
Phone (509) 375-1202
Fax: (509) 375-3403

October 5, 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: CMS-1506-P Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

IsoRay Medical, Inc. 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.

IsoRay Medical, Inc. began production and sales of Cesium-131 in October 2004 for the treatment of prostate cancer. Cesium-131 offers a combination of patient benefits not currently available with other brachytherapy sources. Cesium-131 is used to treat prostate cancer, but is also considered for use in other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer.

Payment Methodology for Brachytherapy Sources

IsoRay Medical believes that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source require a unique payment methodology for radioactive sources. One source may have a cost variation of over 10 times based upon the intensity of the source.

The CMS claims data shows large variations in per unit cost reported (see table below) on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007.

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

The recommended payment methodology will not appropriately capture the variation of brachytherapy source configurations. We urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device.

IsoRay recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting and the PPAC meeting on August 26, 2006.

HCPCS Codes for Stranded Sources

The claims data indicates large variances in the data for iodine, palladium and cesium sources. Some of the variance is due to the clinical distinctions among different types of brachytherapy sources. The 2005 CMS claims data does not reflect the important clinical differences that have emerged with these brachytherapy sources. The increased clinical use of stranded sources and the ability to track these costs separately will allow CMS to capture more relevant and reliable cost data for brachytherapy sources in the future.

Stranded brachytherapy sources are embedded into the stranded suture material and separated within the strand by an absorbable material at prescribed intervals based upon the patient need. This ensures the initial and long-term position of each source when implanted in and around cancerous tumors. This special stranded source is manufactured prior to delivery to the customer and is not a process which can be performed by a hospital.

The GAO survey noted that one professional society recommended that the data used to establish reimbursement rates should reflect the increased clinical use of stranded brachytherapy devices. The increased use of stranded sources and the note from the professional society underscore the need to track the cost of these stranded sources separately in the CMS data set.

Published clinical literature supports that stranded sources are distinct from traditional brachytherapy devices in a number of ways including the clinical use of this technology. In addition, stranded sources have increased costs of production and thus a higher cost to the hospital. These products are FDA approved and HCPCS codes should be established for each of these sources to permit better cost data in the CMS system.

Three brachytherapy sources are provided to hospitals in a stranded suture material; iodine, palladium and cesium. In the proposed rule, CMS requests recommendations for new codes to describe new brachytherapy sources in a manner reflecting the number, isotope and radioactive intensity of the sources.

IsoRay recommends that CMS establish three new stranded brachytherapy source codes to reflect the isotopes that hospitals currently purchase:

- *Brachytherapy device, Stranded Iodine-125, per source*
- *Brachytherapy device, Stranded Palladium-103, per source*
- *Brachytherapy device, Stranded Cesium-131, per source*

Payment for NEW Brachytherapy Sources

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

IsoRay recommends that CMS implement a three year payment policy for new brachytherapy sources at hospital's charges adjusted to cost.

Proposed Definition of Brachytherapy Source

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."

The evolution of technology and advances require that CMS keep an open mind regarding the definition of a brachytherapy source. Brachytherapy sources do not have to be radioactive to deliver a therapeutic radiation dose.

In the treatment of cancer using brachytherapy, sources give off radiation that travels only a few millimeters to kill nearby cancer cells. There are two types of brachytherapy, permanent, when the source remains inside of the body, and temporary, when the source is inside of the body and then removed. Brachytherapy is not defined by the type of source used to treat the cancer, but by the treatment that is delivered to the patient.

IsoRay recommends that CMS reconsider their definition of brachytherapy sources as consisting of a radioactive or non-radioactive sources or seeds.

Summary of Recommendations

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

In summary, IsoRay recommends that CMS:

- **continue the current HOPPS payment methodology of hospital charges adjusted to cost for <u>all</u> brachytherapy devices**
- **establish three new stranded brachytherapy source codes to reflect the isotopes that hospitals currently purchase:**
  - **Brachytherapy device, Stranded Iodine-125, per source**
  - **Brachytherapy device, Stranded Palladium-103, per source**
  - **Brachytherapy device, Stranded Cesium-131, per source**
- **implement a three year payment policy for <u>NEW</u> brachytherapy sources at hospital's charges adjusted to cost**
- **reconsider the definition of brachytherapy sources to include radioactive and non-radioactive sources**

Thank you for your consideration of these important issues.

Sincerely,

Roger Girard
President and CEO
IsoRay Medical, Inc

Lori Woods
Vice President
IsoRay Medical, Inc.

Submitter : **Ms. Jana Bethea** **Date: 10/05/2006**

Organization : **Blues Management, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

See Attachment

CMS-1506-P-270-Attach-1.DOC

Attach
270

October 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

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Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Jana Bethea

Submitter : **Dr. Anand Mahadevan** **Date: 10/05/2006**

Organization : **Beth Israel Deaconess Medical Center**

Category : **Physician**

Issue Areas/Comments

OPPS

OPPS

See Attachment

CMS-1506-P-271-Attach-1.DOC

Beth Israel Deaconess Medical Center

A teaching hospital of Harvard Medical Scho

Anand Mahadevan
MD DMRT
FRCS FRCR

Department of Radiation Oncology

Clinical Instructor Harvard Medical School

Chief of Head and Neck, Cutaneous and Neuro- Radiation Oncology

Radiation Oncologist: The Cutaneous

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

October 4, 2006

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.

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.

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

[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

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 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 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.

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 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,

Anand Mahadevan MD

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Submitter : Mrs. Catherine Morris **Date:** 10/05/2006

Organization : Diomed, Inc

Category : Nurse

Issue Areas/Comments

OPPS Impact

OPPS Impact

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.6279.

Code Descriptor C1 APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Ms. Susan Wysocki **Date:** 10/05/2006

Organization : NPWH- Nurse Practitioners in Women's Health

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-273-Attach-1.DOC

Draft NPWH Letter to CMS re: Proposed Medicare Reimbursement Cuts for PBI

September 26, 2006

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

RE: Rule: Physician Fee Schedule (CMS-1321-P); and

Rule: Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P)

Dear Administrator McClellan:

It has recently been brought to our attention that the Centers for Medicare and Medicaid Services (CMS), through the Physician Fee Schedule (CMS-1321-P) and Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P) rules, has proposed a series of payment cuts which, when taken together, would dramatically reduce Medicare reimbursement for partial breast irradiation (breast brachytherapy) in all the settings in which it is performed, including health care professional offices, freestanding radiation oncology centers, and hospital outpatient departments.

The National Association of Nurse Practitioners in Women's Health (NPWH) is perplexed by the depth of the cuts, which will have the unintended consequence of limiting, rather than expanding, Medicare patients' choice of treatments. In the course of their practice, nurse practitioners see numerous women who have been diagnosed with early-stage breast cancer and are candidates for partial breast irradiation (PBI) following lumpectomy. The American Society of Breast Surgeons and the American Brachytherapy Society have both published guidelines for selecting patients who are appropriate for partial breast irradiation. Partial breast irradiation provides a higher dose of radiation to the area immediately surrounding the lumpectomy cavity, while minimizing radiation exposure to healthy tissue. It also dramatically reduces the course of radiation therapy from 5-6 weeks to 5 days, with corresponding quality of life benefits.

The National Association of Nurse Practitioners in Women's Health knows that CMS shares our commitment to providing high quality health care to women. Breast cancer patients and healthcare providers alike are counting on CMS to honor that commitment by preserving adequate Medicare reimbursement rates

for partial breast irradiation in all delivery sites. Specifically, NPWH urges CMS to refrain from making any reductions to the relative value units (RVUs) for PBI under the physician fee schedule. If changes need to be made, limiting the decrease in practice expense RVUs to no more than 10% would seem to be a reasonable alternative. In the hospital outpatient setting, NPWH believes that CMS should maintain partial breast irradiation in the New Technology APC for another year, in order to allow additional time to collect appropriate cost data. The assignment of PBI to a Clinical APC was clearly in error, since the cost of the medical device is greater than the total proposed reimbursement rate.

The National Association of Nurse Practitioners in Women's Health appreciates the opportunity to comment on CMS' proposed rules, and urges the agency to seriously consider our recommendations and take the necessary steps to preserve Medicare women's access to partial breast irradiation.

Sincerely,

Susan Wysocki, RNC, NP
President/CEO

Cc: Herb Kuhn, Director, Center for Medicare Management, CMS
Helen Pass, MD, President, American Society of Breast Surgeons
Margaret Kirk, CEO, Y-ME National Breast Cancer Organization

Submitter : **Mr. David Hubers** **Date: 10/05/2006**

Organization : **University of Michigan**

Category : **Pharmacist**

Issue Areas/Comments

OPPS Impact

OPPS Impact

CMS,

My comments are related to the CY 2007 rates as applied to radioimmunotherapy (RIT). Proposed 2007 reimbursement for RIT treatment for non-Hodgkin's Lymphoma (both BEXXAR and Zevalin) will be significantly under-reimbursed with the proposed payment rates for 2007. This would make the delivery of this important treatment modality unfeasible for hospitals from a financial perspective, as they would lose several thousand dollars per treatment. The current 2006 rates cover the acquisition, preparation and handling of the product for delivery to the patient, which is entirely appropriate as these are all costs that the hospital incurs in delivering this treatment to patients, and therefore this principle of covering all costs should continue in 2007 and beyond.

The proposed rates for 2007 not only significantly under-reimburse below the acquisition cost of the product, they also do not cover the preparation and handling of the product for delivery to the patient. Therefore, if adopted in the final rule, the proposed 2007 payment rates will severely impact the ability of Medicare covered cancer patients to gain access to radioimmunotherapy as a treatment modality due to the fact that hospitals will be reimbursed only approximately 50% of their actual costs in acquiring, compounding and dispesning the product. The proposed reimbursement rates for 2007 above do not cover the cost of the compounding fee, which is required for delivery of the therapy to the patient. The current wholesale acquisition cost (WAC) of the drug is $26,780 As can be seen, the 2007 proposed payment rates will only cover 60% of the WAC price for the drug. Furthermore, unlike the payment rates for 2006 the compounding fee for preparation of the product for delivery to the patient are not included at all in the 2007 reimbursement structure. Clinical resutls with RIT have been good. A large percentage of NHL patients respond well to this therapy. The proposed reimbursement rates for 2007 will make RIT an unattractive option to physician, pharmacists and hospitals leading to an unfavorable impact on patient care.

Regards,

David Hubers, R.Ph., BCNP
Clinical Nuclear Pharmacist

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Submitter : **Mr. Michael Becker** **Date: 10/05/2006**

Organization : **GE Healthcare**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-275-Attach-1.DOC

GE Healthcare

Michael S. Becker
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October 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year (CY) 2007(*Federal Register*, Vol. 71, No. 163, August 23, 2006). Our comments focus on a number of issues relating to reimbursement for diagnostic imaging procedures including the following:

- PET/CT Procedures
- Myocardial Perfusion PET Procedures
- Process for New Technology Designation
- Multiple Procedure Discount Policy
- Claims Data Used to Determine Payment Rates
- Radiology Costs and Charges

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

Our detailed comments follow.

PET/CT Procedures

In the proposed rule, CMS states there is adequate claims data for CPT codes representing PET/CT procedures[1] to reassign these procedures from the New Technology APC 1514 (New Technology- Level XIV, $1,200-$1,300 with payment of $1,250) to a "clinically appropriate" APC (proposed APC 0308 with payment of $865). The proposed reassignment would result in a 30% decrease in payment for these procedures.

PET/CT is an advanced imaging modality that provides both patient physiological and anatomical information. The technology is an improvement over traditional PET and CT, providing more accurate attenuation correction and image fusion, thereby aiding in better diagnosis and monitoring. Due to its enhanced capabilities, the costs of purchasing and maintaining a PET/CT system can be 67-100% higher than that of traditional PET systems.

The proposed reassignment of PET/CT procedures would end New Technology status for these procedures after only a 21-month period. (The initial assignment of PET/CT procedures occurred in March of 2005.) CMS has stated that it expects to pay for services under a New Technology APC for at least two years, unless the agency is able to collect sufficient claims data before that time. We believe that data are insufficient to support reassignment of these procedures at this time. In fact, CMS has only nine months of claims data on PET/CT procedures upon which to base its decision to reassign these procedures. Moreover, the accuracy of these data is questionable since it is unlikely that the hospitals have uniformly updated their charge masters to account for these recent changes in costs of PET/CT during the CY 2005 period.

GEHC recommends that CMS maintain PET/CT scans in New Technology APC 1514 for at least one more year, while sufficient data is collected. As more stable hospital data regarding PET/CT payment becomes available, CMS should consider transitioning PET/CT to a different APC (other than APC 308) to better reflect the unique clinical and resource differences associated with PET/CT versus PET alone.

Myocardial Perfusion PET Procedures

In CY 2006, CMS revised its APC assignment of single and multiple myocardial PET perfusion studies based on CY 2004 claims data indicating significant differences in median costs between these procedures. Specifically, in the CY 2006 final HOPPS rule, CMS agreed with commenters that there are significant cost differences between signal study and multiple study myocardial PET imaging services, as reflected in historical hospital claims data. Further, data supported the splitting of APC 285 into two myocardial PET scan APCs in order to improve payment accuracy for these services for CY 2006. In addition, CMS stated that the splitting of APC 285 resolved the two times violation that occurred in the CY 2006 proposed rule configuration of APC 285. As a result, for CY 2006, CMS assigned multiple studies to APC 307 with a payment rate of $2,485, while single studies are assigned to APC 306 with a payment rate of $801.

For CY 2007, CMS proposes to assign multiple myocardial PET studies to the same APC as single studies -- APC 307 with a proposed payment rate of $721. The agency bases its proposal on analysis of CY 2005 claims data indicating that more hospitals are providing multiple myocardial

[1] CPT 78814, 78815, and 78816 – list descriptions...

PET studies and that the hospital resource costs of single and multiple studies are similar. For multiple myocardial PET scans, the proposed rule would reduce payment by over 240%, resulting in significant underpayment for providers of multiple scanning procedures.

We believe that the CY 2005 claims data for myocardial PET studies, upon which CMS makes it proposal, do not accurately capture differences among single and multiple imaging studies. Clearly, resources required to perform multiple scans are greater than those required for single scans. Yet, the claims data indicate that median costs for single studies are actually higher than multiple studies ($836 versus $680, respectively), making the reliability of these data highly suspect. Moreover, because myocardial perfusion PET studies underwent significant coding revisions during CY 2005, it is reasonable to raise questions regarding the validity of CY 2005 data for these procedures. Such dramatic differences in median costs over a short time period indicate that at least one more year of claims data is required before stable APC assignment can be made. Providers will have difficulty planning the provision of such services with the high degree of fluctuation in payment rates, as proposed for CY 2007.

GEHC requests that CMS maintain current payment levels and differential payment for multiple studies in CY 2007 to more accurately reflect the true costs of providing these procedures. To do so, CMS should retain the current APC assignment and relative weights for single and multiple studies in CY 2007. This approach would provide for the capture of more accurate claims data for these procedures in order to establish more appropriate APC assignment in CY2008. Our recommended approach would also provide stability in payment rates for hospitals that are adopting and integrating this important imaging advance into medical practice.

Process for New Technology Designation

GEHC is concerned by recent trends by CMS to more quickly transition procedures from New Technology APCs to clinical APCs. Moreover, we are concerned about CMS actions, in some cases, to completely bypass the use of New Technology APCs in favor of immediate assignment to permanent clinical APCs. This often involves new CPT codes, particularly CPT Category III codes. We believe that CMS's process for addressing new technology lacks transparency and results in actions that undermine the original intention of the new technology APC provisions in HOPPS.

The vehicle of HOPPS new technology payment is important for ensuring that new technologies and procedures are available to Medicare beneficiaries. The provision also enables hospitals to adopt these technologies with assurance that adequate payment will be provided. For CMS, the new technology APC approach enables the agency to collect payment data to assure that future permanent assignment to a permanent clinical APC is appropriate from both a clinical and resource homogeneity perspective.

GEHC encourages CMS to make public its criteria for accepting or denying New Technology APC applications, as well as its rationale for decision making. We also recommend that CMS refrain from the immediate assignment of new technologies to permanent clinical APCs in the absence of sufficient data to assure both clinical and resource homogeneity. Through these measures, patients, providers and manufacturers can be assured of appropriate and timely reimbursement for new technology and clinical practice advances in the hospital outpatient setting.

Multiple Procedure Discount Policy

GEHC commends CMS on its decision to postpone its proposal to reduce HOPPS payments for some second and subsequent diagnostic imaging procedures performed in the same session. We concur with commenters' contentions that existing hospital costs already reflect efficiencies in care when multiple procedures are performed. We urge CMS to continue to refrain from implementing a multiple procedure discount policy under HOPPS.

Claims Data Used to Determine Payment Rates

In the proposed rule, CMS discusses how it will expand the type of claims data that the agency will consider to set APC payment rates. Specifically, CMS has decided to bypass specific codes that do not have significant packaged costs, thereby enabling CMS to consider data from a greater number of multiple procedure claims in setting the APC rates. This new single and "pseudo" single procedure claims rate-setting method has the potential to result in data that more accurately captures the cost of procedures. **GEHC encourages CMS continue to pursue methods that improve the accuracy of APC rate setting, including the pseudo claims approach.**

Radiology Costs and Charges

In March, the APC Advisory Panel recommended that CMS request comments on how hospitals can uniformly and consistently report charges and costs for radiology services. In the proposed rule, CMS expands this request to solicit comments on ways to improve charge and cost reporting in all hospital cost centers. CMS notes the benefits and importance of internal consistency to HOPPS, as well as the potential burdens that might be created by establishing additional reporting requirements for hospitals.

As CMS addresses these issues, **GEHC urges the agency to establish a process for further consideration that is open to public comment, minimizes hospital reporting burden and charge compression to the extent possible, and appropriately recognizes the differential capital intensity associated with radiology services.** We would welcome the opportunity to work with CMS regarding this matter going forward.

*****

In summary, we urge CMS to carefully consider our recommendations which support more accurate and equitable payment for imaging services. Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,

Michael S. Becker
General Manager, Reimbursement

cc: Dr. Carol Bazell

Submitter : **Mrs. Catherine Morris** **Date: 10/05/2006**

Organization : **Diomed, Inc.**

Category : **Nurse**

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.6279.

Code Descriptor Cl APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Ms. Susan Wysocki **Date:** 10/05/2006

Organization : NPWH- Nurse Practitioners in Women's Health

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-277-Attach-1.DOC

HHS-CMS-2006-0049-0277

October 5, 2006

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

RE: Rule: Physician Fee Schedule (CMS-1321-P); and

Rule: Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P)

Dear Administrator McClellan:

It has recently been brought to our attention that the Centers for Medicare and Medicaid Services (CMS), through the Physician Fee Schedule (CMS-1321-P) and Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P) rules, has proposed a series of payment cuts which, when taken together, would dramatically reduce Medicare reimbursement for partial breast irradiation (breast brachytherapy) in all the settings in which it is performed, including health care professional offices, freestanding radiation oncology centers, and hospital outpatient departments.

The National Association of Nurse Practitioners in Women's Health (NPWH) is perplexed by the depth of the cuts, which will have the unintended consequence of limiting, rather than expanding, Medicare patients' choice of treatments. In the course of their practice, nurse practitioners see numerous women who have been diagnosed with early-stage breast cancer and are candidates for partial breast irradiation (PBI) following lumpectomy. The American Society of Breast Surgeons and the American Brachytherapy Society have both published guidelines for selecting patients who are appropriate for partial breast irradiation. Partial breast irradiation provides a higher dose of radiation to the area immediately surrounding the lumpectomy cavity, while minimizing radiation exposure to healthy tissue. It also dramatically reduces the course of radiation therapy from 5-6 weeks to 5 days, with corresponding quality of life benefits.

The National Association of Nurse Practitioners in Women's Health knows that CMS shares our commitment to providing high quality health care to women. Breast cancer patients and healthcare providers alike are counting on CMS to honor that commitment by preserving adequate Medicare reimbursement rates for partial breast irradiation in all delivery sites. Specifically, NPWH urges CMS to refrain from making any reductions to the relative value units (RVUs) for PBI

under the physician fee schedule. If changes need to be made, limiting the decrease in practice expense RVUs to no more than 10% would seem to be a reasonable alternative. In the hospital outpatient setting, NPWH believes that CMS should maintain partial breast irradiation in the New Technology APC for another year, in order to allow additional time to collect appropriate cost data. The assignment of PBI to a Clinical APC was clearly in error, since the cost of the medical device is greater than the total proposed reimbursement rate.

The National Association of Nurse Practitioners in Women's Health appreciates the opportunity to comment on CMS' proposed rules, and urges the agency to seriously consider our recommendations and take the necessary steps to preserve Medicare women's access to partial breast irradiation.

Sincerely,

Susan Wysocki, RNC, NP
President/CEO

Cc: Herb Kuhn, Director, Center for Medicare Management, CMS
Helen Pass, MD, President, American Society of Breast Surgeons
Margaret Kirk, CEO, Y-ME National Breast Cancer Organization

Submitter : Mrs. Dawn McMurray **Date:** 10/05/2006

Organization : Genesys Regional Medical Center

Category : Hospital

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

Our hospital is very concerned about the CMS interpretation of the 2006 final rule regarding IV Push administration C8952. In the federal register it stated that CMS would not change 2005 payment policies for 2006 and C8952 was created to allow straightforward billing of each push. The clarification made in transmittal 902 dated April 7, 2006 that states Additioinal iv pushes of the same substance or drug are not separately reported with multiple units of a push code because the number of units reported with the iv push code is to indicate the number of separate substances or drugs administered by iv push. This 'interpretation' has impacted our hospital revenue drastically. Hospitals used to bill for each iv push rendered without regard if it was a different substance or drug. Many hospitals and providers were not given the opportunity to comment in regards to this change due to the differences in the interpretation of the final rule. Hospitals were told in the federal register that there would be no change in reimbursement for this service. Do you realize that if a hospital gives an injection IV push and the drug that is given is a packaged drug - we now have provided that entire service for free due to this change in reimbursement. It is respectfully requested that this area of concern be revisited by CMS and hopefully ammended to prevent further financial difficulty for hospitals providing this service.
Thank you for your attention to this matter.
Signed, Dawn McMurray, Revenue Cycle Specialist- Genesys Regional Medical Center -Michigan

Submitter : **Ms. Linda Winger** **Date: 10/05/2006**

Organization : **Georgetown University Hospital**

Category : **Hospital**

Issue Areas/Comments

New Technology APCs

New Technology APCs

On behalf of Georgetown University Hospital I am responding to CMS 1506-P New Technology APCs - Section c Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

CMS-1506-P-279-Attach-1.DOC

Georgetown
University
Hospital

MedStar Health

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

On behalf of Georgetown University Hospital, one of the primary institutions in the United States that provide image-guided robotic stereotactic radiosurgery, I 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.

Georgetown University Hospital is the national capital area's most recognized academic teaching hospital. Since it's founding in 1898, the Hospital has been dedicated to promoting health through education, research and patient care. This mission is shaped by and reflects Georgetown's Catholic, Jesuit identity and heritage.

With a 609-licensed bed hospital and 1,100 physicians, Georgetown University Hospital's clinical services represent one of the largest, most geographically diverse and fully integrated healthcare delivery networks in the area.

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.

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)

CY2002

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.

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

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.

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

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

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

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

We believe that the changes proposed by CMS for CY 2007 are based on flawed methodology. 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.***

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 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. We 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 believe this for the following reasons:

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, our own 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 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 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".

G0339 and G0340 Code Descriptors

Given the confusion of some centers in determining which code to use, a further refinement of the code language might distinguish the technologies. If non-robotic stereotactic radiosurgery centers continue to use the r-SRS codes in the future, it will be impossible for CMS to determine whether and to what extent the median costs for this service exceed the median cost of radiosurgery performed using modified LINACs, as we believe they do. We suggest that a more precise and accurate descriptor of ***image-guided robotic*** stereotactic radiosurgery is:

> Delivering radiobiologically ablative doses to stationary or moving planning target volume, in 1-5 fractions, with non-ablative radiation dose to non-target tissue, regardless of proximity to planning target volume. Identifying and correcting translational and rotational planning target volume targeting inaccuracy in real-time, through automated continuous feedback loop with <=0.5mm radial targeting error for stationary targets and <=1.5 mm radial targeting error for moving targets.

If the r-SRS code descriptors are not further refined it will be virtually impossible to determine appropriate APC rates in the future.

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 w ith vastly differing resource r equirements. 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.

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 provide a similar 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 who urge you to look at external data in making your classification decisions. We have shared with you our analysis of the 2004 Identifiable Data Set Hospital OPPS file which we believe demonstrates the insufficiency of the 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.

►The code descriptor as proposed on page 6 for image-guided robotic stereotactic radiosurgery (r-SRS) could be used in a way that would promote more accurate capture of resources for all types of SRS procedures.

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

Sincerely,

Linda F. Winger, MSc, FACHE
Vice President
Georgetown University Hospital
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Washington, DC 20007
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202-444-8054