Submitter : Dr. Robert Rosenbloom **Date:** 09/21/2006

Organization : Dr. Robert Rosenbloom

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-107-Attach-1.DOC

Attach ff
107

September 20, 2006

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

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

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

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

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

Robert David Rosenbloom, MD
1555 Barrington Road
Suite 2550
Hoffman Estates, IL 60194
847-884-7700

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

Submitter : Dr. William Bodner **Date:** 09/21/2006

Organization : Our Lady of Mercy

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-108-Attach-1.DOC

HHS-CMS
108

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing our facility the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Two areas of concern in the HOPPS proposed rule. Specifically, the proposed assignment of 19296 and 19297 to new APCs and the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

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

Our Lady of Mercy Hospital recommends that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, we recommends that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

William R. Bodner MD

Our Lady of Mercy Medical Center
600 East 233rd St
Bronx, NY 14466

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Submitter : Dr. Aaron Feliz **Date:** 09/21/2006

Organization : Our Lady of Mercy Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-109-Attach-1.DOC

Attach # 109

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing our facility the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Two areas of concern in the HOPPS proposed rule. Specifically, the proposed assignment of 19296 and 19297 to new APCs and the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

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

Our Lady of Mercy Hospital recommends that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, we recommends that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Submitter : **Mr. Michael Becker** **Date: 09/21/2006**

Organization : **GE Healthcare**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1506-P-110-Attach-1.PDF

Attach #
110

GE Healthcare

Michael S. Becker
General Manager, Reimbursement

3000 N. Grandview Blvd., W-400
Waukesha, WI 53188

T 262-548-2088
F 262-544-3573
michael.becker@med.ge.com

September 21, 2006

The Honorable Mark McClellan, MD
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 2007 (*Federal Register,* Vol. 71, No. 163, August 23, 2006). Our comments presented herein focus on the proposed payment rates for Magnetic Resonance Guided Focused Ultrasound ("MRgFUS") procedures for the treatment of symptomatic uterine fibroids. GEHC plans to submit additional comments on other issues addressed in the proposed regulation in a separate letter prior to the conclusion of the comment period.

GE Healthcare is a $15 billion unit of General Electric Company 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. In 1999, GEHC transferred its proprietary MRgFUS technology to InSightec, Ltd. GEHC currently owns approximately 20% of InSightec and continues to have an interest in the development and adoption of this important technology. GEHC is the exclusive distributor for InSightec in the United States and elsewhere and also sells the magnetic resonance imaging equipment required for use with InSightec's MRgFUS.

Background on MRgFUS for the Treatment of Uterine Fibroids

Magnetic Resonance Guided Focused Ultrasound integrates magnetic resonance imaging with focused ultrasound energy to create a non-invasive method for ablating targeted tissue without harming surrounding healthy tissue. During the procedure, ultrasound energy is focused electronically into an intense beam to heat small areas to a temperature that destroys targeted cells. Continuous MR imaging throughout the procedure allows for precise visualization of the ultrasound beam using MR thermal mapping to continuously measure temperature changes inside the body in real time during the treatment. This visualization enables targeted treatment without destroying or harming healthy surrounding tissues or organ structures. Following treatment, anatomical MR contrast-enhanced imaging is used to evaluate treatment outcome.

MRgFUS was approved by the FDA in October 2004 for treatment of uterine fibroids, a common non-cancerous tumor of the uterus. These fibroids can cause heavy bleeding, pelvic discomfort and pain. They can create pressure on other organs and result in infertility and urinary complications. The primary treatment option for uterine fibroids is surgery (hysterectomy). About 250,000 women undergo surgery for fibroids each year. MRgFUS provides a non-invasive alternative to such surgery, thereby reducing the risks associated with surgery and providing for faster recovery.

MRgFUS for uterine fibroids is performed under conscious sedation and the treatment takes anywhere from 120-300 minutes, depending on a number of factors. Data from two leading hospital providers of MRgFUS, as reported by InSightec, indicate that the average per procedure cost for simple cases is $4,960, and for complex cases is $7,037.[1]

The vast majority of women with uterine fibroids requiring treatment are not Medicare beneficiaries, as this problem generally does not afflict post-menopausal women. Nevertheless, Medicare payment rates are often a benchmark for private insurer rate setting. Thus, CMS payment amounts have widespread effect on overall rate setting for this procedure.

HOPPS Payment History for MRgFUS

In July 2004, the AMA awarded two CPT category III codes to report MRgFUS procedures:

- **CPT 0071T** *Focused ultrasound ablation of uterine leiomymata, including MR guidance; total leiomyomata volume less than 200cc of tissue*
- **CPT 0072T** *Focused ultrasound ablation of uterine leiomymata, including MR guidance; total leiomyomata volume greater or equal to 200cc of tissue*

It is important to note that these were entirely new codes created for these procedures, as no existing codes were suitable.

Both of these codes were assigned initially by CMS to clinical APC 0193 with a payment rate of $758, notably without input from InSightec or GEHC. In August 2005, the APC Panel reviewed a request by InSightec to reassign MRgFUS procedures to New Technology APCs, based on information the company provided to the panel. The panel concurred with InSightec and recommended that CMS work with stakeholders to assign 0071T and 0072T to an appropriate New Technology APC(s).

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[1] Insightec comments to the APC Advisory Panel, August 2005, page 2.

Contrary to the APC panel's recommendation, however, CMS determined that MRgFUS is not a new technology, but rather a new and integrated application of existing MRI and ultrasound technologies. Based on this distinction, the agency concluded that MRgFUS procedures are not necessarily most accurately assigned to New Technology APCs.[2] We disagree with this CMS assessment and conclusion. MRgFUS is described with CPT category III codes which are specifically designated by the American Medical Association (AMA) to report new and emerging technology. CPT category III codes 0071T and 0072T were issued by the AMA to report MRgFUS procedures because such services are not described by existing CPT codes.

Rejecting the APC panel's recommendation, CMS assigned MRgFUS procedures to two clinical APCs -- APC 0195 (for simple procedures with a payment rate of $1,595) and APC 0202 (for complex procedures with a payment rate of $2,454) -- for CY 2006. This reassignment occurred in the absence of any claims data to determine the appropriateness of the APC payment rate for MRgFUS procedures. Moreover, the payment rates are far below the estimated costs of providing simple and complex procedures based on InSightec data referenced previously.

For CY 2007, CMS proposes to maintain the same APC assignment for these procedures (APC 0195 and 0202), with 2007 proposed payment rates of $1,769 and $2,639, respectively. As has been the case in previous years, claims data remain insufficient to support clinical APC assignment. In fact, CMS data indicate that only 2 claims for simple procedures were reported; none were reported for complex procedures. GEHC is unable to validate the accuracy of these claims data.

Recommendation

We strongly urge CMS to reassign MRgFUS procedures to more appropriate APCs that accurately reflect the clinical characteristics and provider costs for these procedures.

The current APCs to which MRgFUS procedures are assigned (APC 0195 and 0202) consist primarily of procedures involving surgical excision or repair of female reproductive organs. Although MRgFUS is treating the same anatomical site, the resources used differ dramatically. The surgical procedures included in these APCs do not use imaging technology, and are typically much shorter in duration than MRgFUS procedures. In many ways, MRgFUS is not similar clinically or from a resource perspective to other procedures assigned to either APC 0195 or 0202.

Given the paucity of hospital claims data for this new procedure, **we recommend that CMS assign MRgFUS procedures to New Technology APCs.** The payment rate for these APCs should more closely reflect the estimated costs of providing MRgFUS procedures, based on the InSightec data. After sufficient claims data are obtained for these procedures, they can be reassigned to a permanent clinical APC based on clinical characteristics and resource requirements.

Assignment of MRgFUS procedures to New Technology APCs is consistent with the APC panel recommendation, particularly with consideration of the continued absence of Medicare claims data. Moreover, we believe that such assignment provides for equitable payment for this innovative new procedure until such time as it can be appropriately assigned to a permanent clinical APC.

Finally, if CMS believes that assignment to a permanent clinical APC is appropriate, then we strongly urge the agency to **assign MRgFUS procedures to an alternative permanent clinical APC that more accurately reflects these procedures from both a clinical and a resource utilization perspective.**

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[2] *Federal Register*, Bol.70, No. 217, November 10, 2005, pp 68600-01.

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In summary, we urge CMS to carefully consider the assignment of MRgFUS procedures and to more accurately reflect the clinical characteristics and resources required to provide this valuable treatment for patients. 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

Submitter : **Mrs. Denise Merlino** **Date: 09/21/2006**

Organization : **Nuclear Medicine APC Task Force**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1506-P-111-Attach-1.PDF

Attachment
III

NUCLEAR MEDICINE APC TASK FORCE

1850 Samuel Morse Drive
Reston, VA 22090-5316
(703) 708-9000
Fax: (703) 708-9015

Academy of Molecular Imaging
American College of Nuclear Physicians
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides and Radiopharmaceuticals, Inc.
National Electrical Manufacturers Association
Society of Nuclear Medicine
Society of Nuclear Medicine - Technologist Section

September 21, 2006

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

Administrator Mark McClellan M.D. PhD
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; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the proposed 2007 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 71 Fed. Reg. 163, August 23, 2006. The Nuclear Medicine APC Task Force appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. We appreciate CMS' willingness to understand and account for the unique and varying attributes of Nuclear Medicine (NM) procedures provided to Medicare beneficiaries. We look forward to working with the CMS collaboratively as you respond to our concerns and recommendations herein.

Our comments on the Proposed Rule will address proposed CMS reassignment of procedures to new or different APCs (specifically, CPT 78811- 13 PET to APC 0308; proposal to lump all non-myocardial PET studies into one non-homogeneous APC; CPT 78814-16 PET/CT tumor procedures from New Technology APCs 1513-4 to APC 0308; CPT 78608 Brain Metabolic PET procedure from New Technology APC 1513 to APC 0308; CPT 78491-2 and CPT 78459 Cardiac Procedures from 0306 to 0307; and CPT 78804 from APC 1513 to 0408, and CPT 78806 from 0406 to 0408, the procedures differ only that one is a multi-day study and the other a single day study), as well as reimbursement for radiopharmaceuticals and drugs (specifically, the proposed increase of a threshold for payment to $55; and the proposed payment for radiopharmaceuticals based on 2005 mean cost data).

New Technology & Two Times Rule
APC Assignment for Nuclear Medicine Procedure CPT Codes

The policy of CMS is to keep a procedure in a New Technology APC until sufficient claims data has been collected in order to assign it to a clinical APC [November 30, 2001 final rule (66 FR 59897)]. In instances where CMS believes the original New Technology APC assignment was based on inaccurate or inadequate information, or when the New Technology APCs are restructured, CMS may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC bands, reassign the procedure or service to a different appropriate New Technology APC.

Tumor PET CPT codes 78811, 78812 and 78813

For CY 2007, CMS is proposing assignment of non-myocardial PET procedures to a clinical APC based on what CMS believes to be several years of robust and stable data. The proposal is to assign tumor PET scans, **CPT codes 78811, 78812, and 78813**, to new APC 0308 (Non-myocardial PET Imaging) with a median cost of $865.30 for CY 2007.

The Task Force agrees with CMS and the Society of Nuclear Medicine (SNM) that claims data acquired over the past several years using G codes crosswalked to the current PET Tumor codes, plus the 9 months of experience with the current CPT codes, is adequate to move CPT 78811-13 from a new technology APC to a homogeneous clinical APC with a reimbursement such as APC 0308.

Like the SNM, the **APC Task Force does not agree with the proposal to lump several organ and disease categories into the same NM APC**, such as the proposal for APC 0308, where all "non-myocardial" PET procedures are proposed to be placed. The nuclear medicine community worked with CMS in developing a process for categorizing clinically homogeneous APCs during the initial years of HOPPS. For example, we agree that Cardiac PET procedures should be placed in an APC separate from Tumor PET studies.

Specifically, the APC Task Force requests that the Tumor PET procedures be placed in an APC separate from Brain PET to maintain clinical homogeneity.

Tumor PET/CT CPT codes 78814, 78815 and 78816

For CY 2007, CMS is proposing the assignment of concurrent PET/CT scans, specifically, CPT codes 78814, 78815, and 78816, to a clinical APC because it believes it has adequate claims data from CY 2005 upon which to determine the median cost of performing these procedures.

The new PET/CT technology codes were introduced in January 2005. Therefore, the new APC assignment appears to be based on a full year or less of CMS claims data. Like the SNM, the **APC Task Force does not support CMS' decision to move Tumor PET/CT codes out of the New Technology APC and into a clinical APC at this time.** The Task Force believes

CMS' reassignment of PET/CT to be premature and inconsistent with the published policy for moving a procedure out of a new technology APC. **Consistent with the APC panel recommendation numbers 7 and 17 at the August 2006 Panel meeting, as well as recommendations from the SNM and the Academy of Molecular Imaging, the APC Task Force strongly recommends that CMS keep CPT codes 78814, 78815 and 78816 in the New Technology APC 1514 at a rate of $1,250.**

Further, like the SNM, the **APC Task Force strongly disagrees with the proposal to lump Tumor PET/CT procedures into the same APC as Tumor PET studies**. Different and more expensive resources than those of pure PET scans are required when performing PET/CT scans (e.g. specially trained and licensed technologists, higher maintenance costs, and higher equipment costs), and these additional costs should be reflected in the reimbursement for PET/CT.

Brain PET CPT Code 78608

The NM APC Task Force, therefore, agrees with CMS' proposal that this procedure be moved from APC 1513 to a clinical APC. As stated earlier, the Task Force recommends that Brain PET be placed in its own APC and not lumped with other PET studies. Based on the published CMS claims data, the payment for this brain PET procedure-APC should be greater than that proposed for APC 0308.

Myocardial PET CPT Codes 78491, 78492 and 78459

For CY 2007, CMS is proposing to move all myocardial PET studies into one APC 0307. This proposal includes lumping single and multiple studies based on CMS' statement that "our data do not support a resource differential that would necessitate the placement of these single and multiple scan procedures into two separate APCs. As myocardial PET scans are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly." The **Task Force strongly disagrees with this conclusion.** First, for other cardiac NM studies, CMS recognizes, and its claims data supports, separating those that require multiple imaging sessions (CPT 78460-1, 78464-5, 78472-3, 78481-3). Second, by stating that "it is possible that" hospitals performing multiple studies are more efficient (and, thus, less costly), CMS is assuming that single studies are done primarily in hospitals that do not do multiple studies. The Task Force, however, has not seen any data to confirm that inference, nor are we aware of data that would diminish the doubling of time and effort to acquire multiple studies over single studies. CMS' claims data has considerably less single frequency claims data for single versus multiple studies, thus signifying that the cost conclusions are not indicative of real costs and only statistical in nature. The Task Force points out that that the mean claims cost of multiple studies 78492 is $1422 (872 single frequency claims), where as the mean cost of the single PET myocardial study 78491 is $927 (single frequency only 44). (We recognize that the "true" median costs are $660 and $1014, respectively.)

Further, the **APC Task Force disagrees with the proposal to lump both the single and multiple PET myocardial studies into one APC and recommends that there be Level I and Level II Cardiac PET APCs. Level I for CPT 78459 and 78491, and Level II for CPT 78492. Further CMS should consider dampening options similar to previous device APC for ICD and blood products to ensure adequate rate setting absent good CMS claims data. The TF will work to assist CMS in identifying external or alternate CMS claims analysis to set 2007 rates for myocardial PET APCs.**

APC Reassignment of Procedures CPT 78804 (multiple days whole body) and CPT 78806 (single day whole body study) from APC 1513 to 0408

The proposed rule reassigns CPT 78804 (a multi-day study for tumor or radiopharmaceutical distribution) from a new technology APC to a clinical APC 0408, which will include one other NM procedure, CPT 78806, a single day study. As stated previously, the **Task Force does not agree with CMS' decision to combine single and multiple studies in the same APC. More time and work are used for multiple studies compared with single studies. Reimbursement and APC placement need to reflect that added cost. Placing these two procedures in the same APC would be an aberration for the NM APC structure.**

The **APC Task Force strongly urges CMS to maintain the single day study CPT 78806 in APC 406 and to create a new APC for the multiple day study CPT code 78804. We recommend that the reimbursement for CPT 78804/APC 0408 be based on the current claims data for the procedure.**

Reimbursement for Radiopharmaceuticals

CMS threshold for drugs and radiopharmaceuticals changed from $50 to $55

During CYs 2005 and 2006, CMS set the threshold for establishing separate APCs for drugs and biologicals to $50 per administration. Because this packaging threshold will expire at the end of CY 2006, CMS evaluated four options for packaging levels so that they could determine what the appropriate packaging threshold proposal for drugs, biologicals, and radiopharmaceuticals would be for the CY 2007 OPPS update.

For CY 2007, CMS is proposing to update the packaging threshold using an inflation adjustment factor based on the Producer Price Index (PPI) for prescription preparations. For each year beginning with CY 2007, CMS is proposing to adjust the packaging threshold by the PPI for prescription drugs and to round the adjusted dollar amount to the nearest $5 increment in order to determine the new threshold. The adjusted amount for CY 2007 was calculated to be $55.99, which was rounded to $55.

At the recent August 2006 APC Panel meeting, the Panel recommended (No. 19) that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes. The **APC Task Force supports this August Panel recommendation and strongly recommends that CMS eliminate the $55 threshold for all drugs and**

radiopharmaceuticals. The Panel also recommended (No. 28) and reaffirmed their prior request for CMS to provide claims analyses of the contributions of packaged costs (considering packaged drugs and other packaging) into the median cost of each drug administration service. *We respectfully request CMS provide analysis of the contributions of each packaged radiopharmaceutical into the median cost of each nuclear medicine APC.*

Radiopharmaceutical Payment Methodology change from CCR to mean hospital data

For CY 2007 CMS is proposing to establish prospective payment rates for separately payable radiopharmaceuticals using mean costs derived from the CY 2005 claims data, where the costs are determined using CMS' standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

The Task Force is concerned that the current method that CMS has chosen to set payments is **inconsistent** with CMS 2006 clarification to hospitals. CMS was clear that hospitals would be paid based on the *hospital overall CCR* times the *hospital charge in 2006*. Therefore, hospitals in 2006 began to develop charge description master rates for radiopharmaceuticals consistent with setting their charges high enough to be adjusted by the overall *hospital* CCR and NOT the *department* CCR. Historically, a nuclear medicine department CCR is lower than an overall hospital CCR. Consequently CMS' decision to use the same methodology for drugs to set mean and median radiopharmaceutical costs is flawed, as it is likely not to capture hospital actual costs appropriately.

HCPCS Level II descriptors changed significantly for many radiopharmaceuticals effective January 1, 2006. CMS clarified their intentions for radiopharmaceutical payments by specifically directing hospitals to adjust charges to ensure that overhead and handling costs were included in the charge for the radiopharmaceuticals only in 2006. Therefore, this data is not yet available in CMS 2005 claims data. Hospitals are traditionally slow in adopting changes, and we believe this policy is no exception. Some hospitals appear to be making changes, but it is clear that all the necessary adjustments have not been made.

The Task Force agrees with the APC Panel (recommendations Nos. 18 and 20) that CMS is premature in moving to a new payment methodology for radiopharmaceuticals for FY2007. While the Task Force understands that CMS only intended to have the cost-to-charge (CCR) payment methodology in place for CY 2006, **we, like the APC panel, urge CMS to continue with the current CCR payment methodology for one more year (CY 2007) in order to establish good data, and also to explore alternative methods for capturing hospital costs for radiopharmaceuticals**.

Like CMS, the Task Force believes that it is critical to come forth with an equitable solution for **all** radiopharmaceuticals based on acquisition and handling costs. ***The proposed CMS 2007 radiopharmaceuticals payment policy does not work for all radiopharmaceuticals especially those with higher acquisition costs, because of cost compression.*** Therefore, the Task Force would like to discuss possible alternatives for payments of radiopharmaceuticals when we meet with you on September 28, 2006.

We thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the Nuclear Medicine Procedure and Radiopharmaceutical APCs. If you need additional information, please contact the APC Task Force staff, Emily Gardner at 703-652-6760 or egardner@snm.org.

Respectfully Submitted,

Kenneth McKusick, M.D., FACR, FACNP
Chairperson, NM APC Task Force

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Carol Bazell, MD, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

Submitter : **Ms. Elizabeth Funk** **Date: 09/21/2006**

Organization : **Mental Health and Substance Abuse Corps. of MA**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

See Attachment.

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

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

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

Submitter : Dr. Kevin Bethke **Date:** 09/21/2006

Organization : Dr. Kevin Bethke

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-113-Attach-1.DOC

Attach #
113

September 15, 2006

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

RE: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System

Dear Administrator:

This letter is written to express my concern regarding the proposed RVU reduction for CPT 19296 and CPT 19297 as well as the APC reassignment of CPT 19296 from the 'New Technology' to the 'Clinical' payment rate as explained in the Federal Register on August 23, 2006.

The reductions and reassignment as proposed will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to accelerated partial breast irradiation is a valuable option for my patient population. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide this option to my Medicare patients, as my hospital may decide to no longer offer this service. The proposed clinical APC payment rate is lower than the price of the catheter used to deliver the radiation, creating a significant financial challenge. As a result, we will be limiting Medicare patients' access to treatments for those patients who are clinically eligible for breast conservation surgery and accelerated partial breast irradiation.

As a busy breast surgeon significantly impacted by these changes, I urge CMS to reconsider the proposed RVU reduction and

the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for at least another year so that CMS can collect adequate data. I urge CMS to reconsider the significant impact the proposal outlines. Thank you for this opportunity to provide my comments.

Sincerely,

Name
Title
Address

cc. Senator Dick Durbin, Senate Appropriations Labor HHS Sub-Committee
Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : Dr. Kevin Bethke **Date:** 09/21/2006

Organization : Dr. Kevin Bethke

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-114-Attach-1.DOC

Attach H
114

September 15, 2006

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

RE: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System

Dear Administrator:

This letter is written to express my concern regarding the proposed RVU reduction for CPT 19296 and CPT 19297 as well as the APC reassignment of CPT 19296 from the 'New Technology' to the 'Clinical' payment rate as explained in the Federal Register on August 23, 2006.

The reductions and reassignment as proposed will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to accelerated partial breast irradiation is a valuable option for my patient population. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide this option to my Medicare patients, as my hospital may decide to no longer offer this service. The proposed clinical APC payment rate is lower than the price of the catheter used to deliver the radiation, creating a significant financial challenge. As a result, we will be limiting Medicare patients' access to treatments for those patients who are clinically eligible for breast conservation surgery and accelerated partial breast irradiation.

As a busy breast surgeon significantly impacted by these changes, I urge CMS to reconsider the proposed RVU reduction and

the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for at least another year so that CMS can collect adequate data. I urge CMS to reconsider the significant impact the proposal outlines. Thank you for this opportunity to provide my comments.

Sincerely,

Kevin P. Bethke, MD

Kevin P. Bethke, MD
Assistant Professor of Clinical Surgery,
Northwestern University Feinberg School of Medicine
676 North St. Clair, Suite 1525
Chicago, IL 60611

cc. Senator Dick Durbin, Senate Appropriations Labor HHS Sub-Committee
Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : Dr. Barry Rosen **Date:** 09/21/2006

Organization : Dr. Barry Rosen

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-115-Attach-1.DOC

Attach #
115

September 18, 2006

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

RE: CMS-1506-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B
Federal Register publication of August 23, 2006

Dear Administrator:

Allow me to express my concern regarding two proposed changes:

- The RVU reduction for CPT 19296 and CPT 19297
- the APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

The proposed reductions and reassignment will significantly impact my ability to care for Medicare patients. Access to partial breast irradiation is an important option for my patient population. With a breast cancer diagnosis, it is important that the tumor is removed and radiation therapy start as quickly as possible. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as it is entirely possible my hospital may decide to eliminate this service. The catheter itself (at $2750) is priced higher than the proposed clinical APC payment rate. As a result, we will be limiting Medicare patients' access to treatments for those patients who are clinically eligible for breast conservation surgery and partial breast irradiation. I am certain that is not Medicare's intent.

As a surgeon focused on offering the best care to my Medicare patients, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Barry S. Rosen, MD, FACS

Barry S. Rosen, MD, FACS
Vice President, Medical Management
Advocate Good Shepherd Hospital
450 West Highway 22
Barrington, IL 60010

cc. Senator Dick Durbin, Senate Appropriations Labor HHS Sub-Committee
Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Joubin Khorsand **Date:** 09/21/2006

Organization : Dr. Joubin Khorsand

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-116-Attach-1.DOC

Attach #
116

September 20, 2006

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

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

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

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

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

Joubin Khorsand, MD

Joubin Khorsand, MD
Yacktman Pavilion/Breast Center
1675 Dempster
1st floor
Park Ridge, IL 60068
847-723-3100

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

Submitter : **Dr. John Jones** **Date: 09/21/2006**

Organization : **Virginia Breast Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-117-Attach-1.DOC

Attachment 117

September 20, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 and CPT 19297 from the New Technology to the Clinical payment rate.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by radiation therapy; however, the statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation (PBI) for carefully selected breast cancer patients, in which radiation is completed in five days. If the proposed reduction takes place, my hospital and I may no longer be able to provide PBI to Medicare patients, as the procedure requires a device costing $2750. As a result, Medicare will be limiting access to its beneficiaries.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

John Jones, MD

John Jones, MD
Virginia Breast Care
Charlottesville, VA

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

Submitter : Dr. Linda Sommers **Date:** 09/21/2006

Organization : Virginia Breast Care

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-118-Attach-1.DOC

Attachment 118

September 20, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 and CPT 19297 from the New Technology to the Clinical payment rate.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by radiation therapy; however, the statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation (PBI) for carefully selected breast cancer patients, in which radiation is completed in five days. If the proposed reduction takes place, my hospital and I may no longer be able to provide PBI to Medicare patients, as the procedure requires a device costing $2750. As a result, Medicare will be limiting access to its beneficiaries.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

John Jones, MD

John Jones, MD
Virginia Breast Care
Charlottesville, VA

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

Submitter : Dr. Fred Vernacchia **Date:** 09/21/2006

Organization : San Luis Diagnostic Center

Category : Physician

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

Your proposed cuts in payments will end any aquistion of new equipment or research to make new equipment. Specifically, the proposed decrease in payments for PET imaging will place payments below costs. I will do everything I can, should the cuts be implemented, to send all PET patients to my competitors so you can drive them out of business instead of me. It is impossible to perform a PET scan for the proposed payment.

Submitter : **Dr. Jay Harness** **Date: 09/22/2006**

Organization : **Dr. Jay Harness**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-120-Attach-1.DOC

Attachment
120

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,

Thank you for the forum in which I can express my opinion on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I am very worried about the proposed reduction of the RVUs by 4 units when CPT code 19296 is performed by the Surgeon in the Hospital. It is also a concern that there is a proposed reduction of the conversion factor by 5.1%. Further the proposed APC reassignment for the hospital of CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) is also a significant issue as the cost of the catheter will be more expensive than the proposed Clinical APC payment allows for the hospitals.

The reduction of the RVUs will make it difficult for me to offer this procedure in the hospital to Medicare patients with breast cancer who desire partial breast irradiation therapy. This will deprive your beneficiaries of this option and possibly delay radiation treatment. For the hospital the current proposal will have the catheter priced higher than the clinical APC rate and this may lead the hospital to not offer this procedure to Medicare beneficiaries and not allowing me to place the Mammosite catheter in the hospital. Access and availability to this procedure for Medicare patients with breast cancer will be severely impacted due to the reduction of RVUs for the Surgeon and the reassignment of the APC from New Technology to Clinical for the hospital. For those Medicare beneficiaries who are eligible for breast conserving surgery the ability to provide them with partial breast irradiation is important and beneficial to their treatment. CMS needs to keep the current RVUs and continue the assignment of the New Technology APC (1524 & 1523) for an another year.

My recommendation is for CMS to retain the current RVUs for CPT code 19296 when done in the hospital and lower the reduction of the conversion factor. I further recommend that CMS maintain the designation of CPT codes 19296 and 19297 to the New Technology APC for the hospital for at least another year as more research of cost data is needed. Otherwise you will impede the access to partial breast irradiation for Medicare patients.

Thank you again for the opportunity to comment on this proposed rule and I hope that CMS will consider my recommendations. Please contact me if there are any questions that may arise on this topic.

Sincerely,

Jay Harness, M.D.
Surgeon
St. Joseph Hospital Comprehensive Breast Center
1140 W. LaVeta, Ste. 460
Orange, CA 92868

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congressman Henry Waxman CA (D)

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

Submitter : Dr. Kristi Harrington **Date:** 09/22/2006

Organization : Dr. Kristi Harrington

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-121-Attach-1.DOC

Attach #
21

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 am grateful for the opportunity to share my insights on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I am have significant concerns 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%. Further the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) will impact services due to the cost of the device (catheter) not being adequately captured in the clinical APC payment rate.

My ability to place the Mammosite catheter in the hospital for Medicare patients who are eligible for partial breast irradiation is severely compromised by this proposal of not only reducing the RVU values by 4 units for the Surgeon, but also assigning the CPT codes from New Technology APC to Clinical APCs for the hospital. At issue is the fact that at the new APC the hospital would not be able to offer the procedure because the catheter will be more expensive than the APC payment rate. Partial breast irradiation is a very important therapy for Medicare patients with breast cancer and unfortunately with these proposed changes it will negatively affect their opportunity to receive this standard of care technology.

I want to offer my recommendation for a solution to this issue. I recommend that CMS maintain the current RVUs for CPT code 19296 when done in the hospital and lessen the degree of reduction of the conversion factor as well. I also strongly recommend that CMS maintain 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.

I appreciate your diligent review of this situation and urge CMS to reconsider the significant impact the proposal may have for your Medicare beneficiaries. Thank you for your time.

Sincerely,

Kristi Harrington, M.D.
Surgeon
1135 116th Avenue, NE, Suite 180
Bellevue, WA 98004

cc: Senator Maria Cantwell WA (D)
Senator Patty Murray WA (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. James Pelton **Date:** 09/22/2006

Organization : Dr. James Pelton

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-122-Attach-1.DOC

Attach# 122

September 21, 2006

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

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

Dear Administrator:

I appreciate the forum to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed change in APC codes for the hospital for radiation/oncology brachytherapy services.

There are two areas of issue in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. Now CMS is proposing to reassign these codes from New Technology APCs to clinical APCs in 2007. This proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, which would result in the hospital not being able to make this service available to Medicare patients. The table below illustrates the reductions, ranging from –22.8% to –37.0%. This is truly significant.

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

If CMS finalizes the proposed APC assignments, then it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device exceeds the proposed payment rate.

CMS should preserve 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may continue to collect claims data and other cost data through calendar year 2006. This will allow CMS to more accurately re-evaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned to must cover the cost of the device. The cost of the

brachytherapy device is the same when implanted at time of lumpectomy or at a separate procedure done at a later time.

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

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

James Pelton, M.D.
Radiation Oncologist
Overlake Hospital Cancer Center
1135 116th Avenue NE, Suite 160
Bellevue, WA 98004

cc: Senator Maria Cantwell WA (D)
Senator Patty Murray WA (D)

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

cc: American Society of Therapeutic Radiation and Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. James Hanson** **Date: 09/22/2006**

Organization : **Dr. James Hanson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-123-Attach-1.DOC

Attach H
123

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 appreciate the chance to share my observations on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I very concerned with the proposed reduction of 4 units for the RVUs for CPT code 19296 when performed by the Surgeon in the Hospital. Equally concerning is the proposed reduction of the conversion factor by 5.1%. I would also like to comment on 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 will impact services due to the cost of the device (catheter) not being adequately captured in the clinical APC payment rate.

Access and availability to this procedure for Medicare patients with breast cancer will be severely hampered because of the reduction of RVUs for the Surgeon and the reassignment of the APC from New Technology to Clinical for the hospital. For the hospital the current proposal will have the catheter priced higher than the clinical APC rate and this may cause the hospital to not offer this procedure to Medicare beneficiaries, which in turn will not allow me to place the Mammosite catheter in the hospital. Availability to this technology is very important as it allows radiation treatment in only 5-7 days. It is important that Medicare patients with breast cancer have access to this technology and have quick access to partial breast irradiation therapy. CMS should preserve the RVUs and continue the assignment of the New Technology APC for an additional year. I will not be able to provide Medicare patients with the benefits of partial breast irradiation due to the reduction of RVUs and the conversion factor.

I absolutely recommend that CMS uphold the current RVUs for CPT code 19296 when done in the hospital and maintain the current conversion factor as well. I also recommend that CMS maintain the assignment of CPT codes 19296 and 19297 to the New Technology APC for the hospital for at least another year until further research is completed.

Thank you again for seeking my opinion and I appreciate your considerate appraisal of this matter and strongly advocate CMS to reconsider this proposal.

Sincerely,

James Hanson, M.D.
Surgeon
Swedish Cancer Institute
1221 Madison St.
Seattle, WA 98104

cc: Senator Maria Cantwell WA (D)
Senator Patty Murray WA (D)

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

Submitter : Dr. Michele Carpenter **Date:** 09/22/2006

Organization : Dr. Michele Carpenter

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-124-Attach-1.DOC

Attach # 124

Michele Carpenter, MD
Surgeon
230 S. Main St. Ste. 100
Orange, CA 92868

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 appreciate the opportunity to share my concerns on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I would like to share my concerns regarding 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%. Also the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) will severely impact services due to the cost of the device (catheter) not being adequately covered in the clinical APC payment rate.

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. Partial breast irradiation is a very important therapy option for Medicare patients with breast cancer and unfortunately with these proposed changes, it will affect their opportunity to receive this standard of care technology. Please realize the value of this procedure and the need for Medicare patients to have ease of access and availability to partial breast irradiation therapy, which first begins with placement of the catheter after lumpectomy. I will not be able to perform this procedure in the hospital for Medicare patients if CMS upholds this current proposal.

I strongly recommend that CMS keep the current RVUs and with only a slight reduction in the conversion factor. I also maintain that you must delay your reassignment of the CPT codes 19296 and 19297 from New Technology APC to Clinical APC for at least another year as it is investigated more and you seek more data.

Thank you for allowing me to address this issue and provide you with feedback on the proposal. I appreciate your time and efforts on this issue.
Sincerely,

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congressman Henry Waxman

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 : Mr. James Jaacks **Date:** 09/22/2006

Organization : Sisters of Mercy

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-125-Attach-1.DOC

Attach 17
125

MERCY

SISTERS OF MERCY
HEALTH SYSTEM

September 22, 2006

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

Submitted Electronically: http://www.cms.hhs.gov/eRulemaking

Re. CMS-1506-P, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar 2007 Payment Rates

The Sisters of Mercy Health System (Mercy) is a 19-hospital system operating in Missouri, Kansas, Oklahoma, and Arkansas. We perform a significant number of outpatient procedures and rely heavily on Medicare as a major payor for those services. The following comments are respectfully submitted by Mercy on the 2007 Outpatient Prospective Payment System (OPPS) proposed rule, as published in the Federal Register on August 23, 2006. We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time. Thank you for considering our comments as listed below.

Section II.A.1.c - Proposed Revision to the Overall Cost-to Charge Ratio (CCR) Calculation

Currently, CMS's CCR calculation (used to model OPPS) differs from the fiscal intermediaries (FI) CCR calculation (used to identify outlier and other payments). CMS proposes to change the methodology for calculating the overall CCR so there is consistency used in modeling OPPS and the related payments. We agree that the calculations of CCRs used for modeling and payments should be consistently applied. What is unclear is the methodology used by CMS to achieve this consistency. CMS implies the major differences between their calculation and the FIs are 1) the inclusion of allied health costs and 2) the weighting added by Medicare Inpatient Part B charges. The FI's calculation includes both of these factors. CMS asserts the median overall CCR using their calculation would be .3040, however the FI's would be .3309 (the difference then is assumed to be attributable to the above two factors). This represents a decrease in the CCR of 8.13% from the FI's calculation. We **agree** with CMS's proposal that the allied health costs should **not** be included. However, we believe Medicare Inpatient Part B charge weighting should be

included in the OPPS CCR calculation. Incorporating the weighting from Medicare Inpatient Part B charges in CMS's current CCR calculation boosts the median overall CCR to .3081 from .3040 (a 1.35% increase). This suggests allied health costs represent 6.78% of the CMS and FI CCR calculation variance (8.13% minus 1.35%). It seems difficult to correlate this large percentage variance (6.78%) solely to the removal of nursing and allied health costs. Utilizing the *2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, we estimate total Medicare Part A (acute only) and Part B expenditures for calendar year 2005 to be $134 billion. At 6.78%, allied health costs would need to total approximately $9.1 billion to have this kind of impact. From *Program Memorandum*, Transmittal No. A-03-043, dated May 23, 2003, nursing and allied health education payments were $204,780,092 for cost reporting periods ending in fiscal year 1999. Even with an annual increase of 10% through 2005, nursing and allied health education payments would only be projected to reach $362 *million* (well below the estimated $9.1 billion noted above). Mercy is concerned the CCR calculation differences between CMS and FIs could be due to additional factors other than allied health costs and the weighting of Medicare Inpatient Part B charges. If the methodology used by CMS to calculate a CCR of .3081 is flawed, the proposed overall CCR of .2999, based on updated cost report data, could also be flawed. We urge CMS to revisit the calculation to ensure the CCR methodology currently being used (as well as the calculation being proposed) appropriately includes/excludes all variables referenced.

As stated on page 49528 of the *Hospital Outpatient Prospective Payment Federal Register*, dated August 23, 2006, CMS' "traditional" CCR calculation excludes selected ancillary cost centers, such as 5700 Renal Dialysis (due to these costs being reimbursed under "other" payment systems). Mercy agrees with CMS' rationale for excluding these types of ancillary cost centers from the calculation. A specific list of ancillary cost centers included in CMS's "traditional" calculation is available in a revenue center-to-cost crosswalk workbook from the CMS website. This crosswalk indicates revenue codes for Renal Dialysis are used in CMS's CCR calculation (contradictory to what is stated in the proposed rule). It also appears revenue codes paid under other payment systems, such as Organ Acquisition, are also used in the OPPS calculation. We request CMS clarify these discrepancies (and update the crosswalk if deemed appropriate), so the provider community has a clear understanding of how these ratios are being calculated.

Section II. G – Proposed Updates Affecting OPPS Payments for CY 2007

Outliers

If the costs of a particular Medicare case exceed 1.75 times the APC payment amount and the APC payments rate plus a $1,250 fixed-dollar threshold, the hospital will receive an outlier payment. This payment equals 50% of the case's cost above the multiple threshold calculation.

CMS proposes to increase the fixed-loss cost threshold for outlier payments from the CY 2006 rate of $1,250 to $1,825. This represents a 46% increase from the CY 06 level. The

46% increase in the fixed-loss threshold will exclude high cost claims that should be receiving additional payments in the form of outliers.

We request that CMS increase the CY 2006 threshold of $1,250 by the change in the CPI (Consumer Price Index) for a CY 2007 fixed-dollar threshold of $1,300 (change in CPI for all urban consumers from July 2005 to July 2006 unadjusted was 4.1%).

Section IV. A – Proposed OPPS Payment Changes for Devices

Device Dependant APC's

Over the past several years CMS has employed a variety of methodologies to set rates for device-dependent APCs. This has been necessitated because providers have historically not reported charges and CPT/HCPCS codes for procedures and devices appropriately on the same claim. By using 2005 claims data, CMS faces the obstacle of setting 2007 payments without complete and accurate information for device-dependent APCs. The mandatory device codes was implemented in April 2005 and October 2005, but for a very small line of business, thus requiring providers to "unbundle" procedures and devices and show these charges separately on UB92 claims. Thus, CMS does not have adequate claim data from 2005 to use in creating the payment rates for device-dependant APCs for 2007.

We urge CMS to consider expanding the 19 devices from table 20 which must be billed with associated CPT procedure codes. There are other high cost devices such as Brachytherapy sources, EP Ablation catheters, Implantable Joint Devices and many more that should always be billed with CPT procedure codes not listed in Table 20. Expansion of the edits to include numerous other devices will ensure CMS has sufficient data for future rate setting.

Section V - Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Radiopharmaceuticals

Due to numerous changes in HCPCS code descriptors from CY 2005 to CY 2006, along with doses administered for several drugs and radiopharmaceuticals, the appropriate units hospitals are required to bill have been incomplete. Hospitals often order and contract with multiple radio pharmacies due to what they supply and each radio pharmacy has their own charge structure. Radio pharmacies often contract a charge "per study dose". Each provider may have a different dose protocol for the same study which then results in a different charge per study dose. For example, if one provider uses 6 mCi's and another provider uses 8 mCi's for a study, they may each pay 12.00 for the study dose which results in a per mCi cost variance as well as a per study dose cost variance.

Unlike most drugs, some radiopharmaceuticals are not stocked because of their half lives and volatile characteristics. This prevents most facilities from being able to recognize any volume discounts that may otherwise have been available for these types of supplies.

We urge CMS to consider eliminating the proposed $55.00 threshold on all HCPCS drugs and radiopharmaceuticals so applicable costs may be tracked accordingly. It would benefit all providers for CMS to expand the device edits to include drugs and radiopharmaceutical edits for the presence of these HCPCS codes on claims with nuclear medicine procedures so they may correlate the cost with each particular radiopharmaceutical and associated CPT procedure.

Currently (for CY 2006) hospitals are being reimbursed for separately payable drugs and biologicals at a combined rate of ASP (average wholesale price) plus 6%. CMS proposes to reduce that payment for CY 2007 to ASP plus 5%. Hospitals already face reimbursement constraints in relation to drug payments as many of our drugs are packaged (and therefore are not reimbursed separately). Physicians currently receive ASP plus 6% as payment from Medicare for CY 2006. Per review of recent physician payment regulations, no payment percentage reduction was referenced for payment of drugs. Therefore, physicians would continue to receive ASP plus 6% in CY 2007. We do not believe a site of service differential is reasonable or appropriate in this situation.

We urge CMS to reconsider the proposed 1% decrease in payment for drugs. Mercy requests CMS continue to reimburse hospitals for separately payable drugs using ASP plus 6% as is done today (CY 2006) and as is consistent with the proposed physician payment rates for CY 2007.

Section IX. B.2 - Proposed **Hospital Coding and Payment for Visits**

Visits

CMS is proposing the use of 17 new G codes with hospitals using their own internally developed guidelines, along with distinguishing hospital-based emergency departments as Type A, and others not meeting the 24-hour criteria as Type B. EMTALA requires providers to assess any person who presents for Emergency Department services. If the patient subsequently does not require any additional interventions, providers would receive no payment for the required assessment. The very requirements of EMTALA force a facility (Type A) to utilize its resources, yet there is no provision to reimburse facilities in the current proposed CMS OPPS rule.

We believe CMS should adopt national guidelines for hospitals and DED's (dedicated emergency departments) to properly report all visit levels the same way as outlined in the proposed rule. This would give CMS the appropriate claims data from CY 2006 and CY 2007 that would reflect the resource consumption being utilized in setting appropriate APC rates for CY 2008 and 2009 consistently.

In September 2003 the GAO released a report (GAO 03-986), in which they stated that the per visit cost of providing ambulance services in sparsely populated areas are significantly

higher than the cost of providing these services in other areas. These additional costs are typically attributed to higher "readiness" costs that are incurred as a result of being in a less densely populated area. We believe these same "location" factors directly correlate to emergency room costs also. Providers located in less densely populated areas incur costs of minimum staffing (24 hours 7 days a week), while experiencing a significantly lower volume of patients. Current reimbursement methodology, for providers in sparsely populated areas, does not consider the higher cost associated with "readiness" experienced in these locations. We respectfully request CMS consider studying the emergency room costs for these provider types.

We urge CMS to derive a more "accurate" payment structure that would more adequately reimburse facilities for the costs associated with providing emergency room services in less densely populated locations.

Section X – Proposed Payment for Blood and Blood Products

We thank CMS for their continuing efforts to implement payment revisions which would more fully reflect the hospitals' true costs of providing blood and blood products. In our experience, the American Red Cross charges up to $ 215.00 per unit for Red Blood Cells Leukoreduced. This product is assigned HCPCS Code P9016 and the proposed APC rate for 2007 is $ 176.89. This means that each time our facility administers a unit of P9016, in calendar year 2007, to a Medicare beneficiary, our cost will exceed our reimbursement by $ 38.11. Since the inception of the APC system, Medicare reimbursement for blood and blood products continues to present us with significant concerns.

Additionally, while instructions from CMS speak to reporting blood administration service for OPPS, it is hard to determine what the intent is for inpatients. Medicare retains the cost apportionment rule in the Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, 2203) which states: "so that its charges may be allowable for use in apportioning costs under the program, each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient. The Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, 2204) states: "Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients, must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. (See 2202.4.)"

Some hospitals do not separately charge blood administration service to inpatients per guidelines from their Fiscal Intermediary's revenue code manual. Some FIs consider this service to be included in the room and board rate charged to Inpatients. Medicare OPPS rules, however, clearly delineate how these services must be coded and charged for outpatients, including observation patients. These patients are often in a bed next to an inpatient on a nursing floor. Based upon the above, CMS should provide reimbursement of

blood administration services performed in nursing units for inpatients as they do for outpatients.

We urge CMS to continue examining current external data to set rates for blood and blood products.

Section XII - Proposed Procedures That Will Be Paid Only as Inpatient Procedures

We appreciate CMS' proposal to remove procedure codes from the Inpatient- only list. We continue to strongly support the elimination of the list altogether. Rather than using an Inpatient-only list, we suggest that CMS rely on its Peer Review Organizations (PROs) or Quality Integrity Organizations (QIOs) to examine any questionable cases. These organizations are best equipped to handle issues related to care provided in inappropriate sites of service.

Admittance of a patient is a medical determination made by a physician based on an individual set of variables surrounding each specific case. CMS continues to focus on "medically necessary" services, and hospitals continue to work diligently on educating physicians regarding inpatient admission criteria, providing medically necessary services, and appropriately documenting each encounter. The Inpatient-only list can cause confusion when making medically necessary decisions about which patients require hospital admission. We believe physicians should be made aware of Medicare "guidelines" regarding admission decisions. However, we believe the ultimate decision of admission should be left to the physician. We also believe hospitals should not be negatively impacted financially based on a physician's decision to admit or not, while the physician received payment for his/her services regardless of admission status.

In the event CMS chooses not to eliminate the Inpatient-only list, we request CMS post the Inpatient-only list on the physicians' (carrier) web-page of the CMS web-site and provide background on the intent of Inpatient-only list. We also respectfully request CMS discuss this issue in the Physician Open Door Forum and in the MPFS proposed and final rules. We believe this more uniform approach by CMS will educate physicians while facilitating hospitals' education efforts.

Thank you again for considering my comments. Should you have additional questions you may contact Ron Trulove at 314-364-3561 or myself at 314-628-3685.

Sincerely,

James Jaacks
Sr. Vice President/CFO

Submitter : **Date: 09/22/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 19, 2006

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

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

Dear Administrator,

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

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

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

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

Respectfully,

Charles E. Cox, M.D., F.A.C.S.
Comprehensive Breast Program
H. Lee Moffitt Cancer Center & Research Institute

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

CMS-1506-P-126-Attach-1.DOC

Attach #
126

H. LEE
MOFFITT
Cancer Center & Research Institute
The End Of Cancer Begins Here.
A National Cancer Institute
Comprehensive Cancer Center
At the University of South Florida

September 19, 2006

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Submitter : **Bruce Waring** **Date: 09/22/2006**

Organization : **Foothills Surgical Assoc., PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

September 14, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Bruce J. Waring, MD

Bruce J. Waring, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

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

Submitter : **William Schuh** **Date: 09/22/2006**

Organization : **Foothills Surg. Assoc., PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

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September 14, 2006

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3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

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Helen Pass, MD, President, American Society of Breast Surgeons

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

Submitter : **Date: 09/22/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 21, 2006

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

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

Dear CMS Administrator:

As a Diplomate in the American Board of Radiology practicing at Cedars Medical Center Cancer Center in Miami, FL, I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am very concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs and the proposed new payment methodology for brachytherapy sources in 2007.

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

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

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

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

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

In closing, I recommend:

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

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

I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.

Regards,

Martin Edward Keisch, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
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Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women s Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women s Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Services
Jame

CMS-1506-P-129-Attach-1.DOC

HHCC # 129

CHCA
Cancer Healthcare Associates

Martin Keisch, M.D.
Radiation Oncologist
Diplomate American Board of Radiology

Cedars Medical Center
1400 N.W. 12th Ave. Suite 104
Miami, FL 33136

September 21, 2006

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

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CHCA
Cancer Healthcare Associates

Martin Keisch, M.D.
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Cedars Medical Center
1400 N.W. 12th Ave. Suite 104
Miami, FL 33136

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

I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.

Regards,

Martin Edward Keisch, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Dr. Ben Furman **Date:** 09/22/2006

Organization : Nashville Breast Center, PC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-130-Attach-1.DOC

Attachment
130

September 18, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Ben Furman, MD

Ben Furman, MD, FACS
Nashville Breast Center
Nashville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Laura Lawson **Date:** 09/22/2006

Organization : Nashville Breast Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-131-Attach-1.DOC

Attach H
131

September 18, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by radiation therapy; however, the statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation (PBI) for carefully selected breast cancer patients, in which radiation is completed in five days. If the proposed reduction takes place, my hospital and I may no longer be able to provide PBI to Medicare patients, as the procedure requires a device costing $2750. As a result, Medicare will be limiting access to its beneficiaries.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Laura Lawson, MD

Laura Lawson, MD
Nashville Breast Center
Nashville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Pat Whitworth** **Date: 09/22/2006**

Organization : **Nashville Breast Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-132-Attach-1.DOC

Attachment
132

September 18, 2006

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

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

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Partial breast irradiation (PBI) allows the breast cancer treatment process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Pat Whitworth, MD

Pat W. Whitworth, MD, FACS
Nashville Breast Center
Nashville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Laura Dunbar** **Date: 09/22/2006**

Organization : **Nashville Breast Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-133-Attach-1.DOC

Attach H
133

September 18, 2006

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

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

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As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Laura L. Dunbar, MD

Laura L. Dunbar, MD, FACS
Nashville Breast Center
Nashville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Hershey Garner **Date:** 09/22/2006

Organization : Northwest Arkansas Radiation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-134-Attach-1.DOC

HHaw1A
134

September 21, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. I have two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and second, the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from –22.8% to –37.0%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

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

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Hershey Garner, MD

Hershey Garner, MD
Northwest Arkansas Radiation
Springdale, AR

Cc. Senator Blanche Lincoln, Senate Finance Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Dr. Joe Ross **Date:** 09/22/2006

Organization : Northwest Arkansas Radiation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-135-Attach-1.DOC

Attachment
135

September 21, 2006

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

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

Dear Administrator:

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CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from –22.8% to –37.0%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

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

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Joe Ross, MD

Joe Ross, MD
Northwest Arkansas Radiation
Springdale, AR

Cc. Senator Blanche Lincoln, Senate Finance Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Dr. Arnold Smith** **Date: 09/22/2006**

Organization : **Northwest Arkansas Radiation**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-136-Attach-1.DOC

HHaCH
136

September 21, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. I have two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and second, the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from -22.8% to -37%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

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

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Arnold Smith, MD

Arnold Smith, MD
Northwest Arkansas Radiation
Springdale, AR

Cc. Senator Blanche Lincoln, Senate Finance Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Date: 09/22/2006**

Organization :

Category : Physician

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 14, 2006

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

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

Dear Administrator,

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

At Presbyterian Hospital, we take pride in the services offered to Medicare beneficiaries. We are very adept in administering brachytherapy services in a very professional, comfortable environment.

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

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Donna Girard, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

CMS-1506-P-137-Attach-1.DOC

Timothy E. Cloninger, M.D.
Robert W. Fraser, III, M.D., F.A.C.R.
Mark Kirsch, M.D., F.A.C.R.
Steven R. Plunkett, M.D.
Mark J. Liang, M.D.
John B. Konefal, M.D.
Michael R. Haake, M.D.
Donna J. Girard, M.D.
Cathy H. Seymore, M.D.
L. Scott McGinnis, III, M.D.
Charles J. Meakin, III, M.D.
Bradley T. McCall, M.D.
Yvonne Mack, M.D.

SERO
SOUTHEAST RADIATION ONCOLOGY GROUP P.A.

200 Queens Road, Suite 400 • Charlotte, N.C. 28204
Phone (704) 333-7376 • Fax (704) 333-7386 • www.treatcancer.com

Thomas G. Troutmann, M.D.
Scott P. Lankford, M.D.
Robert M. Doline, M.D.
Stuart H. Burri, M.D.
Arthur W. Chaney, III, M.D.
Gregory C. Mitro, M.D.
Helen R. Maboux, M.D.
William B. Warlick, M.D.
William E. Bogo, M.D.
Kevin S. Roof, M.D.
B. Zach Fowler, M.D.
Heather D. Pacholke, M.D.
Anthony J. Grimaldi, II, M.D.

Paul A. Williams, M.S.P.H.
Administrator

September 20, 2006

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

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

Dear Administrator,

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

At Presbyterian Hospital, we take pride in the services offered to Medicare beneficiaries. We are very adept in administering brachytherapy services in a very professional, comfortable environment.

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

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Donna J. Girard, MD

Donna J. Girard, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 09/22/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 14, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
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Attention: CMS-1506-P - Rule: Hospital Outpatient Prospective Payment System (OPPS)

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At Presbyterian Hospital, we take pride in the services offered to Medicare beneficiaries. We are very adept in administering brachytherapy services in a very professional, comfortable environment.

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

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Robert W. Fraser, MD, FACR

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Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

CMS-1506-P-138-Attach-1.DOC

Attach #
138

TIMOTHY E. CLONINGER, M.D.
ROBERT W. FRASER, III, M.D., F.A.C.R.
MARK KIRSCH, M.D., F.A.C.R.
STEVEN R. PLUNKETT, M.D.
MARK J. LIANG, M.D.
JOHN B. KONEFAL, M.D.
MICHAEL R. HAAKE, M.D.
DONNA J. GIRARD, M.D.
CATHY H. SEYMORE, M.D.
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YVONNE MACK, M.D.

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THOMAS G. TRAUTMANN, M.D.
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ARTHUR W. CHANEY, III, M.D.
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HELEN R. MADDUX, M.D.
WILLIAM B. WARLICK, M.D.
WILLIAM E. BOBO, M.D.
KEVIN S. ROOF, M.D.
B. ZACH FOWLER, M.D.
HEATHER D. PACHOLKE, M.D.
ANTHONY J. CIMALDI, II, M.D.

Paul A. Williams, M.S.P.H.
Administrator

September 20, 2006

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

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

Dear Administrator,

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

At Carolinas Medical Center, we take pride in the services offered to Medicare beneficiaries. We are very adept in administering brachytherapy services in a very professional, comfortable environment.

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

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Robert W. Fraser, MD, FACR

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 09/22/2006**

Organization :

Category : Physician

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 14, 2006

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

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We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Donna Girard, MD

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Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

CMS-1506-P-139-Attach-1.DOC

Attach FF
139

TIMOTHY E. CLONINGER, M.D.
ROBERT W. FRASER, III, M.D., F.A.C.R.
MARK KIRSCH, M.D., F.A.C.R.
STEVEN R. PLUNKETT, M.D.
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HEATHER D. PACHOLKE, M.D.
ANTHONY J. CRIMALDI, II, M.D.

Paul A. Williams, M.S.P.H.
Administrator

September 20, 2006

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

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

Dear Administrator,

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

At Gaston Memorial Hospital, we take pride in the services offered to Medicare beneficiaries. We are very adept in administering brachytherapy services in a very professional, comfortable environment.

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

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Charles J. Meakin, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

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

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : Dr. Editha Krueger **Date:** 09/22/2006

Organization : Thedacare

Category : Physician

Issue Areas/Comments

Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

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. Should you have any questions please do not hesitate to email me at editha.krueger@thedacare.org

Respectfully,
Editha Krueger M.D.
Medical Director of Radiation Oncology Services
Thedacare Hospitals, Appleton, WI

CMS-1506-P-140-Attach-1.DOC

CMS-1506-P-140-Attach-2.DOC

Attach
140

September 22, 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
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

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. Should you have any questions please do not hesitate to email me at Judith.Krueger@mhsdacare.org
Respectfully,

Judith Krueger M.D.
Medical Director for Radiation Oncology Services
ThedaCare Hospitals, Appleton, WI 54913

Deleted: mklein@xoftinc.com. ¶

Deleted: Your Name Here¶
Your Title and Affiliation Here

Submitter : Dr. Katherine Barton **Date:** 09/22/2006

Organization : Dr. Katherine Barton

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-141-Attach-1.DOC

Attach #
141

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

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

Dear Administrator,

I appreciate the opportunity to share my comments on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I would like to share my concerns regarding the proposed reassignment of CPT codes 19296 and 19297 to a different APC code.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%. This will have a significant impact on my ability to treat Medicare patients in the hospital setting.

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

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. The hospital will be forced to not allow Surgeons to place the catheters for Medicare patients breast desiring breast brachytherapy.

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

Thank you again for providing me the means to voice my concerns and recommendations.

Sincerely,

Katherine Barton, MD

Katherine Barton, M.D.
Surgeon
2161 Colorado Ave, Suite A
Turlock, CA 95382

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

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

Submitter : Dr. Paul Carmichael **Date:** 09/22/2006

Organization : Dr. Paul Carmichael

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-142-Attach-1.DOC

Attach
142

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

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

Dear Administrator,

I appreciate the occasion to relay my thoughts on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I have some concerns regarding the proposed reassignment of CPT codes 19296 and 19297 to a different APC code. This could have negative affects on my ability to provide brachytherapy services at the hospital.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data and charge data through calendar year 2006 and reevaluate the intended reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. Unfortunately the current proposal will not cover the costs associated with the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I strongly recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data from the hospital to better understand the true costs associated with these codes.
Once again, thank you for giving me a forum to express my concerns with this issue and the proposal at hand.

Sincerely,

Paul Carmichael, MD

Paul Carmichael, M.D.
Surgeon
2161 Colorado Ave, Suite A
Turlock, CA 95382

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

Congresswoman Nancy Pelosi (D)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

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

Submitter : Ms. Linda Martin **Date:** 09/22/2006

Organization : Vanderbilt University Medical Center

Category : Hospital

Issue Areas/Comments

Visits

Visits

We ask that CMS delay the implementation of the new E&M "G" codes until criteria are established for use with these codes. Changing codes results in additional expenses for hospitals. Forms will have to be modified, changes made to the charge description master and education of numerous staff about the use of the "G" codes. We can't simply add the codes and expect staff to understand their usage. We request that you delay implementation of the "G" codes and require the new codes only after you have finalized criteria to describe each code. By introducing the codes and the criteria simultaneously we can eliminate the duplicative costs associated with a "two step" process

Submitter : **Date: 09/23/2006**

Organization :

Category : **Physician Assistant**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 19, 2006

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

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

Dear Administrator,

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

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

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

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

Respectfully,

April Slone, PA
Comprehensive Breast Program
H. Lee Moffitt Cancer Center & Research Institute

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

CMS-1506-P-144-Attach-1.DOC

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

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

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

Submitter : **Date: 09/23/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 19, 2006

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

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

Dear Administrator,

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

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

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

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

Respectfully,

Peter W. Blumencranz, MD

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

CMS-1506-P-145-Attach-1.DOC

Attach #
145

Surgical Associates of West Florida

General, Vascular, Thoracic, Oncologic and Endocrine Surgery
Laparoscopy and Gastrointestinal Endoscopy
Colorectal Surgery

David G. Berry, M.D.
Peter W. Blumencranz, M.D.
Robert S. Davidson, M.D.
William S. Mastrellis, M.D.
Allan H. Haydon, Ph.D., M.D.
Rick J. Schmidt, M.D.
Farnsworth R. May, M.D.
Gregg I. Shore, M.D.
Theodore R. Small, M.D.
Kurt V. Erickson, M.D.
Richard Rodriguez, D.O., M.P.H.
Mark A. Zuzga, D.O.

September 19, 2006

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

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

Dear Administrator,

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

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

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

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

Respectfully,

Peter W. Blumencranz, M.D.

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

303 Pinellas Street, Suite 310 • Clearwater, Florida 33756
(727) 462-2131 • Fax (727) 462-2115
email: info@westfloridasurgery.com

Submitter : Dr. William McGinnis **Date:** 09/23/2006

Organization : Dr. William McGinnis

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-146-Attach-1.DOC

ATTACH #
146

September 20, 2006

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

RE: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System

Dear Administrator:

This letter is written to express my concern regarding the proposed APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate. Thank you for this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule, as per the Federal Register publication on August 23, 2006.

The proposed reassignment will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is important that the tumor is removed and radiation therapy start as quickly as possible. Unfortunately, if the proposed reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital may decide to decline to offer this service. The catheter itself (at $2750) is priced higher than the proposed clinical APC payment rate. As a result, we will be limiting Medicare patients' access to treatments for those patients who are clinically eligible for breast conservation surgery and PBI. I am certain that is not Medicare's intent.

As a radiation oncologist focused on offering the best care to my Medicare patients, I urge CMS to reconsider the proposed reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

William McGinnis, MD

William McGinnis, MD
Iowa Methodist Medical Center
Radiation Oncology
1221 Pleasant Street, Suite A11
Des Moines, IA 50309
515-241-4330

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Date: 09/24/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"SEE ATTACHEMENT" FROM CHRIS HAWK MD CHARLESTON SC

CMS-1506-P-147-Attach-1.DOC

Attach #
147

CHARLESTON SURGICAL ASSOCIATES
General Surgery Surgical Oncology Laparoscopy

J. Chris Hawk, III, M.D., F.A.C.S.
Stanley M. Wilson, M.D., F.A.C.S.
Telephone: 843-577-7550

125 Doughty Street, Suite 660
Charleston, SC 29403
Fax: 843-853-5588

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

Dear Administrator:

We appreciate the opportunity to provide comments on CMS-1506-P. We would like to highlight the negative impact these proposed rates will have on breast conservation therapy. We have two major areas of concern in the HOPPS proposed rule, specifically:

1) the proposed assignment of 19296 and 19297 to new APCs
2) the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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

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

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

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures. The codes rely on the use of a high-cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities are not only clinical but also similar in device cost. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery.

Thank you in advance for your assistance.

J. Chris Hawk, III, M.D.

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

Submitter : **Date: 09/24/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"see attachement" Stanley Wilson, MD Charleston SC

CMS-1506-P-148-Attach-1.DOC

HHaciff
148

CHARLESTON SURGICAL ASSOCIATES
General Surgery Surgical Oncology Laparoscopy

J. Chris Hawk, III, M.D., F.A.C.S.
Stanley M. Wilson, M.D., F.A.C.S.
Telephone 843-577-7550

125 Doughty Street, Suite 660
Charleston, SC 29403
Fax 843-853-5588

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

Dear Administrator:

We appreciate the opportunity to provide comments on CMS-1506-P. We would like to highlight the negative impact these proposed rates will have on breast conservation therapy. We have two major areas of concern in the HOPPS proposed rule, specifically:

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

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures. The codes rely on the use of a high-cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities are not only clinical but also similar in device cost. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery.

Thank you in advance for your assistance,

Stanley M. Wilson, M.D.

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

Submitter : Dr. Brian Latham **Date:** 09/25/2006

Organization : St. Rita's Medical Center

Category : Hospital

Issue Areas/Comments

Medication Therapy Management Services

Medication Therapy Management Services

The suggested changes to the payment of pharmacist services is disheartening. Considereing there are several studies showing pharmacists in-depth involvement and review of medications leads to improved health and reduced costs. Lower overall healthcare costs by reducing the list of medications to what is needed, preventing duplications. Also pharmacist counseling on the medication so patients know what to expect and the importance of daily therapy---reduced readmissions to hospital. Ensuring the patient is on the correct dose and making adjustments to provide the optimal benefit. Pharmacists are not just couseling a patient, they are making changes for improving their therapy. They have the drug knowledge that other disciplines do not and unfortunately will not be able to make this impact to the patient if we are not paid. The decision needs to be made to provide medication reconciliation payments. Overall, the health of patients and, satisfaction of physician's and patients would increase while the cost of healthcare would decrease. Thank You. Brian Latham, Pharm.D.

Submitter : Archana Lucchesi **Date:** 09/25/2006

Organization : Archana Lucchesi

Category : Radiologist

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

The proposed cuts place payment below cost of service. We are already in an urban county getting rural payments. Any drop in PET payments will result in us unable to spend money to upgrade equipment, and if it costs us more to do the service than we are getting paid, we will curtail access.