

225

**LA CHEIM ADULT BEHAVIORAL HEALTH SERVICES**

5263 Claremont Avenue  
Oakland, CA 94618-1032  
Ph: (510) 596-8125 Fax: (510) 596-8352  
Email: ps@lacheim.org

13 September 2005

PHP

Kane  
Hart  
Sanao  
Bazell  
Asplen

Centers for Medicare and Medicaid Services  
Department of Health & Human Services  
attn: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Ladies/Gentlemen:

You propose to reduce the base rate for partial hospitalization service by 14% for the next calendar year. I have not read that you simultaneously propose to reduce the stipulated quantity and quality of services (e.g. number of program hours/week, frequency of physician visits, intensity of treatment planning and updating, frequency of individual therapy, etc.). As a psychologist with decades of clinical experience, I do not recommend reduction of present CMS quality standards which would very seriously compromise the effectiveness of Partial Hospitalization Programs.

I understand that your proposed rate cut is founded on reduced costs shown from 2005 cost reports filed by some CMHC. I know of no CMHC nor hospital in California, that has been able to close its books for FY 2005 in 1-2 months to provide you such base data. I suggest that your sample may therefore be totally unrepresentative of the national CMHC and hospital populations that provide partial hospitalization services.

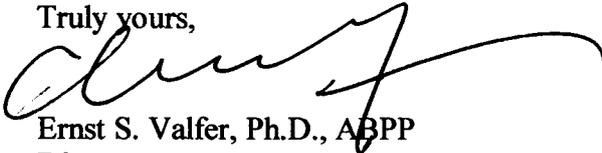
We are a relatively small non-profit CMHC providing Partial Hospitalization and other mental health services to Medicare and other insurance covered adult patients for 12 years. All of our patients have chronic and serious mental disorders with a history of repeated in-patient hospitalizations. Most of them are indigent.

We pride ourselves in the quality of the therapeutic services and care we provide. Our patients repeatedly tell us that ours is the first program of many they have attended in the past where their mental health has very significantly improved by the time they are discharged. Many patients remain out of hospitals and are able to return to normal life. Not surprisingly our costs are relatively high so that we struggle to break even at the end of each year, and sometimes we do not make it. Even during the past fiscal year we have had to cut staff compensation between 5-20% and reduce our overhead to a bare minimum. Additionally many of our staff volunteer many hours of work time. It is not possible to cut costs further unless we seriously reduce our quality of service and compromise meeting the intend and letter of the federal laws.

A 14% cut in the daily Medicare rate for partial hospitalization would therefore force us to close our clinic and not provide PHP services to Medicare patients. With the continuously decreasing number of psychiatrists in this area who accept Medicare patients, most of the patients we serve would either have to be hospitalized at very much higher cost or remain without any intensive, medically supervised mental health services.

We therefore urge CMS to retain the present rate structure for PHP with an appropriate cost of living increment.

Truly yours,

A handwritten signature in black ink, appearing to read 'Ernst S. Valfer', written in a cursive style.

Ernst S. Valfer, Ph.D., ABPP  
Director

226

## ARKANSAS HYPERBARIC ASSOCIATES

#2 ST. VINCENT CIRCLE, LITTLE ROCK, ARKANSAS 72205

September 2, 2005

SCOD/A/D

Kane  
Hart  
Sanow  
Bazell  
Ahmed

Mr. Herb Kuhn  
Director, Center for Medicare Management  
Centers for Medicare and Medicaid Services  
200 Independence Ave., SW  
Washington DC 20201

Attention: File Code CMS-1501-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates – Drugs, Biologicals and Radiopharmaceuticals Non Pass-throughs.

Dear Mr. Kuhn:

It has recently come to the attention of our wound center that proposed rule CMS-1501-P contains apparent errors which could seriously affect wound care in our clinic as well as in Wound Care Centers all across the country. These errors relate to the reimbursement rates for the bioengineered skin substitutes, Apligraf and Dermagraft. These are the only 2 such products currently available in the wound care market. Their development has, to some extent, revolutionized some aspects of wound care in this country.

Having used both products many times in our wound care center, I can truthfully say that I have been amazed in their effectiveness in accelerating the healing of problem wounds. I can also say that I have seen numerous cases where the rapid healing promoted by these products has prevented multiple hospitalizations, amputations and even deaths (from recurrent infections) as well as relief from pain suffering and prolonged disability. When these factors are considered, one can see that in the long run these therapies are cost effective.

To date, these products have been paid in the hospital prospective payment system as specified covered outpatient drugs. We think they should continue to be paid in this manner in 2006. Patient access to these products will be seriously jeopardized by the proposed payment changes. The proposed changes drop the reimbursement for these products to 30% below their selling price. This may make it impossible for us to offer these incredibly effective therapies to our patients and have an over all negative impact on wound care in this country.

September 8, 2005

Page 2

This letter is being written to petition CMS to correct what we see as an error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug at average sale price plus 8%, thereby assuring that we, and our patients, continue to have access to these new technologies which have greatly improved wound care in this country.

Thank you, for your consideration in this matter.

Sincerely,

A handwritten signature in black ink that reads "Gary Villines MD". The signature is written in a cursive style with a small triangle at the end of the "D".

Gary Villines, MD  
Medical Director  
St. Vincent Wound Care Center

Little Rock, Arkansas 72205

227

† CATHOLIC HEALTH  
INITIATIVES

# St. Vincent Wound Care Center

In Partnership with Physicians of Arkansas Hyperbaric Associates

August 30, 2005

William Lagaly, D.O.

Leslie Sessions, M.D.

Gary Villines, M.D.

Lloyd Warford, M.D.

Mr. Herb Kuhn  
Director, Center for Medicare Management  
Centers for Medicare and Medicaid Services  
200 Independence Ave., SW  
Washington DC 20201

SCOD/A/D

Kane  
Hart  
Sanow  
Bazul  
Ahmed

ATTENTION: FILE CODE CMS-1501-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates-Drugs, Biologicals and Radiopharmaceuticals Non Pass-throughs

Dear Mr. Kuhn:

It has come to our attention that proposed rule CMS-1501-P as described above contains errors which would seriously impact and undermine wound care in our clinic and the United States. These errors relate to the payment rates for the wound healing products Apligraf and Dermagraft.

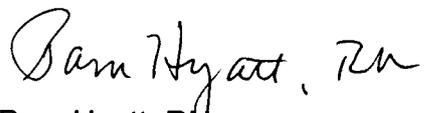
To date these products have been paid in the *hospital outpatient* prospective payment system as specified covered outpatient drugs. We think they should continue to be paid in this manner in 2006. Patient access to these products will be seriously jeopardized by the payment rates in the proposed rule.

Apligraf and Dermagraft are important elements of advanced wound care and have been shown to speed rates of healing and have preserved and improved the quality of life for many people. Many people would likely have required limb amputations without the benefit of these products.

It is our understanding that in the proposed rule, both Dermagraft and Apligraf would be incorrectly paid based on rates from claims data instead of the current method of payment based on average sales price plus 8%. With the proposed method of payment, both products will experience a significant decrease in reimbursement. The proposed reimbursement is actually 30% below the selling price of the products. This may make it impossible for us to offer these very effective therapies to our patients and will have a very negative impact on the quality of care.

This letter is actually to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug at average sale price plus 8%.

Thank you for your attention to this matter.

A handwritten signature in black ink that reads "Pam Hyatt, RN". The signature is written in a cursive, flowing style.

Pam Hyatt, RN  
Nurse Manager  
St. Vincent Wound Care Center

228

† CATHOLIC HEALTH INITIATIVES

# St. Vincent Wound Care Center

In Partnership with Physicians of Arkansas Hyperbaric Associates

William Lagaly, D.O. Leslie Sessions, M.D.  
Gary Villalpando, M.D. 2005 Lloyd Warford, M.D.

SCOD/AD Kane  
Hart  
Sanaou  
Bazeel  
Ahmed

Mr. Herb Kuhn  
Director, Center for Medicare Management  
Centers for Medicare and Medicaid Services  
200 Independence Ave., SW  
Washington DC 20201

ATTENTION: FILE CODE CMS-1501-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates-Drugs, Biologicals and Radiopharmaceuticals Non Pass-throughs

Dear Mr. Kuhn:

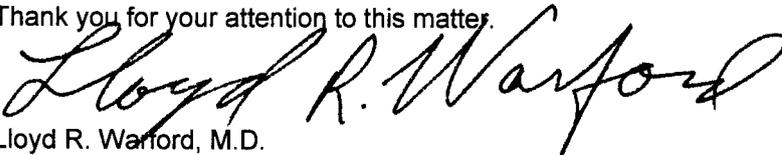
It has come to the attention of our wound center that proposed rule CMS-1501-P, as described above, contains apparent errors which would seriously impact and undermine wound care in our clinic and the United States. These errors relate to the payment rates for the wound healing products Apligraf and Dermagraft.

We often use both of these products in our clinic and we have found that most patients achieve more rapid healing as a result. This often will prevent multiple hospitalizations, amputations and serious illness due to infection. Our patients report relief of pain and an improvement in their quality of life. With these factors in mind, I am sure that you can realize the cost effectiveness of the use of these products.

To date these products have been paid in the *hospital outpatient* prospective payment system as specified covered outpatient drugs. We think they should continue to be paid in this manner in 2006. Patient access to these products will be seriously jeopardized by the payment rates in the proposed rule. The proposed changes will drop reimbursement to below the cost of the graft skins. This will make it impossible to offer these very effective therapies to our patients.

This letter is to petition CMS to correct what we see as an error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug at average sale price plus 8%. This will assure that our patient will continue to have access to these new technologies which have revolutionized wound care in this country.

Thank you for your attention to this matter.



Lloyd R. Warford, M.D.  
St. Vincent Wound Care Center  
Little Rock, AR

229

# JOHN R. DEXTER, M.D., FAAPM&R

*Neurologic and Orthopedic Rehabilitation  
Wound Care*

*Board Certified PM & R*

13Sep2005

*SCOD/A/D*

*Kare  
Hart  
Sarnow  
Bazeel  
Ahmed*

Mark McClellan, M.D., PhD  
Administrator  
Centers for Medicare and Medicaid Services  
United States Department of Health and Human Services  
Attention: CMS – 1505 – P  
Post Office Box 8016  
7500 Security Boulevard  
Baltimore, Maryland 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS – 1505 – P  
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Dr. McClellan:

I am the medical director at the Tennessee Christian Medical Center Wound Center in Madison, Tennessee, and am writing to comment on the 2006 Medicare payment Proposal for Hospital Outpatient facilities.

As a part of my practice, I care for patients with chronic wounds and as such am extremely concerned with the proposed 2006 Medicare Hospital Outpatient payment rates for advanced wound products – Dermagraft [C 9201] and Apligraf [C 1305]. Therefore, I am commenting on the Centers for Medicare and Medicaid Services [CMS] Proposed Rule published in the July 25, 2005, *Federal Register* titled, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule."

Dermagraft and Apligraf have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

**824 Wren Road, P O Box 569, Goodlettsville, Tennessee 37070-0569**  
**Telephone: (615) 859-2884 Facsimile: (615) 859-2807**

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft.

In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product.

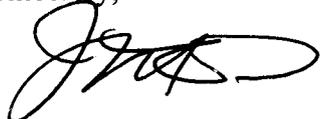
However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and Dermagraft -- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32

There may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively.

I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Sincerely,



John R. Dexter MD, FAAPMR

cc: Herb Kuhn - Director, Center for Medicare Management  
Mary Hayter - Smith & Nephew



230-0  
(3)

Cryo

Kane  
Samard  
Hart  
Bazell  
Huygster

September 14, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1501-P  
PO Box 8016  
Baltimore, MD 21244-8018

1818 Carew Street, Suite 210  
Fort Wayne, IN 46805

7910 W Jefferson Blvd, Suite 212  
Fort Wayne, IN 46804

2512 East Dupont Road, Suite 210  
Fort Wayne, IN 46825

**RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate**

To Whom It May Concern:

260.482.8681  
Fax: 260.373.4699

I am a surgeon who performs cryosurgery, as a matter of fact I will doing one shortly today. In July there was a federal registered statement that contained outpatient payment rates as prospective for 2006. The proposed payment rate for prostate cryoablation was \$5,659. That basically will not be able to cover the cost of the hospital for probes, patient time and operative time. Presently it costs our hospital between \$8,500 and \$9,500 to perform this procedure.

The procedure is beneficial to gentleman who has radiation failure, who have nodular disease who are too ill to undergo radical prostatectomy and is of dramatic benefit to them. Their side effects profile is also dramatically improved.

Unfortunately, if we can't cover the cost of the procedure it is going to be difficult to continue to perform procedures with this machine for the folks.

I would ask for your attention and appreciate your time.

Sincerely,

Rhys A. Rudolph M.D.

RAR/mcz

Dictated/not read

cc: James L. Hart, CMS  
7500 Security Blvd  
Mail Stop C4-07-07  
Baltimore, MD 21244

231

PHP

(8)

Signatures

Kane  
Hart  
Sarnow  
Bazell  
Asplen

September 8, 2005

We the members of the Ambulatory Association for Behavioral Healthcare of Northern California (AABH-NC) which include membership of twenty seven hospitals and free standing CMHC's, have been informed of CMS's intention to decrease the partial hospitalization rate of reimbursement by 14% in January, '06. We are strongly opposed to this change in reimbursement and feel that the cost analysis completed by CMS reflected a small sampling of cases from the fiscal perspective and did not take into consideration the clinical issues that may have contributed to this decreased cost base.

As you may or may not know, the cost of living is extremely high in the Bay Area of Northern California. Rent, utilities, salaries are the highest in the country and such a suggested decrease would essentially close many of our programs and reduce the availability and quality of programs that CMS requires. This decrease in rate would eliminate an essential level of the continuum of care that would likely result in higher utilization of inpatient psychiatric services.

Currently people with severe and persistent mental illness are underserved in all of our communities in part due to a decrease in reimbursement to physicians and private agencies who have decided that they cannot adequately provide for this population. Programs like ours will likely follow the same course of action if this recommendation is passed and the patients who need care the most will not have any alternatives to mental health care.

Respectfully,

AABH-NC membership

Tiel Giles, RN, MFT  
Seton Medical Center

Judy MFT  
Alameda County Medical Center

Marlene Stephens, MFT  
Mt Diablo Medical Pavilion

Mona V. Letchandani  
Alta Bates Summit Medical Center

Joey Sikand, Psy.D.  
President, The Hume Center

Heidi Assaf  
PSYD, MFT Lacheim Inc.

Chunfer PhD  
La Chem Adult Behavioral Health Services

Lynn Wallac  
Director of Marketing  
& Business Development

Patty Esperid, MFT  
DIRECTOR-EDEN MEDICAL CENTER  
PSYCHIATRIC SERVICES

Hanna Striba-Ham  
Alta Bates Summit Med' Ctr.

15018

CMS-1502-P-2

232

Submitter : Dr. Mingxiong Huang  
Organization : Univ of California San Deigo/San Diego VA Hospital  
Category : Other Health Care Professional

Date: 08/03/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-P-2-Attach-1.DOC

Imaging  
MEG

Kane  
SANDW  
HART  
BAZELL  
Hunter  
Burley



UCSD Medical Center  
HILLCREST

August 3, 2005

Shirl Ackerman-Ross, DFO, CMS, DOC  
Attention: CMS-1501-P  
Mail Stop C4-05-17  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244-1850

**Ref: CMS MEG Reimbursement**

Dear Ms. Ackerman-Ross:

I am very surprised to know from the government website for MEDICARE, indicating that the new APC values for all 3 MEG codes will be changed to \$620 from about \$5200 previously for an epilepsy MEG scan. As an MEG scientist for more than ten years, I strongly encourage CMS to re-evaluate this decision.

When making the decision about the CMS MEG reimbursement, the following crucial factors should be considered: 1) The cost of MEG system (MEG sensor unit plus the magnetic shielded room) is in the order \$2M ~ \$3M, and siting cost can easily be \$0.5M ~\$1M; 2) The cost for operating an MEG system includes the service contract costs of \$60,000 ~ \$120,000/year plus the liquid helium cost of ~\$40,000/year; 3) The MEG scanning time for each epilepsy case is about 4 hours (in two sessions), much longer than the scanning times for other imaging methods such as MRI; 4) The cost of manpower -- In general, it takes a PhD level MEG scientist about 20 hours to identify and localize spikes in one patient. Considering all these costs, it is clear that the previous rate at about \$5200/scan is more reasonable than the new rate at \$620/scan.

As a large number of publications have demonstrated that MEG's high temporal resolution and high spatial resolution and localization accuracy is unique for non-invasively localizing epileptic foci, **the new APC codes at approximately \$ 620 per scan may drive many MEG clinical programs out of business and lead to a major lost to our epileptic patients.**

I sincerely hope that CMS can re-evaluate new MEG Reimbursement rate. If you have any questions about this letter, please feel free to contact me. Thank you very much for your time and consideration.

Sincerely,

Mingxiong Huang, Ph.D.  
Associate Adjunct Professor, Associate Director of MEG  
Department of Radiology Service, University of California San Diego/  
VA San Diego Healthcare System  
3350 La Jolla Village Drive  
San Diego, CA 92161  
Tel: 858-552-8585 ext 2947  
Fax: 858-552-7404 or 858-642-3836  
Email: mxhuang@ucsd.edu

150\$-P  
↑  
CMS-1502-P-606

SCUD A+D

Date: 09/06/2005

234

KANE  
SANDW  
HART

BAZELL  
AHMED

Submitter : Dr. Eric Foreman, DPM  
Organization : Arnold S. Gross, DPM PC  
Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

W use Apligraf. The error in reimbursement figuring for 2006 would effect patient care and patient health in my practice.

~~CMS-1502-P-795~~

SCOD/A/D

235



101-P

Date: 09/09/2005

Kane  
SANDY  
HART  
BAZEL  
AHMED

Submitter : Dr. CARLOS VALLADARES  
Organization : WSSPC  
Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

PLEASE CORRECT AND REVIEW YOUR PROPOSED POLICY RE: APLIGRAF AND DERMAGRAFT AS BOTH OF THESE PRODUCTS ARE ESSENTIAL TO OUR WOUND HEALING.

~~CMS-1502-P-796~~

SCOD A/D

236



Date: 09/09/2005

1301-P

Submitter : carla stefan  
Organization : WSSPC  
Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

KANE  
SNOW  
HART  
BAZELL  
AHMED

PLEASE CORRECT AND REVIEW YOUR PROPOSED POLICY RE: APLIGRAF AND DERMAGRAFT AS BOTH OF THESE PRODUCTS ARE ESSENTIAL TO OUR WOUND HEALING.

CMS-1501P

SEARCH

237

CMS-1502-P-1040

Submitter : Dr. Edward Coleman  
Organization : Academy of Molecular Imaging  
Category : Physician

Date: 09/16/2005

Imaging

Karne  
SNOW  
HART  
BAZELL  
Hunder  
Burley

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1502-P-1040-Attach-1.DOC



# ACADEMY OF MOLECULAR IMAGING

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CTT Molecular Imaging, Inc.

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Medicine at UCLA

Richard M. Bergman, M.D.  
University of Michigan

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Young University, and U.S. Coast  
Guard Hospital, San Diego, CA

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Lawrence Berkeley  
National Laboratory

Walter J. Dixon, Ph.D.  
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at San Francisco

Richard D. Gelber, Ph.D.  
David Geffen School of  
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Council Chair  
for Nuclear Imaging  
Richard A. Foy, Ph.D.  
University of California  
at San Francisco

Institute for Clinical PET  
Robert Hawkins, M.D., Ph.D.  
U.S. Coast Guard Hospital

Institute for Molecular  
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Tom Nuyt, Ph.D.  
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Institute for Molecular  
Imaging in Drug Development  
Timothy J. McCarthy, Ph.D.  
Texas Global Research  
and Development

Henry Van Brocklin, Ph.D.  
Lawrence Berkeley  
National Laboratory

William E. Barlow, Ph.D.  
University of Michigan

September 15, 2005

The Honorable Mark McClellan  
Administrator  
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-1501-P**

**Re: Medicare Program; Changes to the Hospital Outpatient  
Prospective Payment System and Calendar Year 2006  
Payment Rates**

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1501-P, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, published in the Federal Register on July 25, 2005. The AMI is comprised of academicians, researchers and nuclear medicine physicians utilizing Positron Emission Tomography (PET) technology, and serves as the focal point for PET education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI also speaks for thousands of physicians, scientists and patients with regard to this lifesaving technology. The AMI greatly appreciates the time and attention that you and your staff have devoted to making PET and PET/CT technology accessible to Medicare beneficiaries.

### Summary

PET/CT is one of the leading imaging technologies used for the management of cancer patients. This new imaging technology was first introduced in 2000, and thus had limited hospital utilization in 2001 and 2002. PET/CT is now more widely used in hospitals, and because it provides to physicians numerous clinical benefits beyond conventional PET, and provides to patients more precise treatment planning, it will eventually replace the use of PET-only scanners in the United States.

Hospitals incur more capital and maintenance costs with a PET/CT scanner than with a conventional PET scanner.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to assign the PET/CT New Technology classification payment rate to New Technology APC 1514 (\$1250). This payment rate is far below the true cost of PET/CT, and it significantly underpays hospitals. This rate also does not recognize the additional diagnostic benefits provided by PET/CT over traditional diagnostic PET and computed tomography (CT) scans.

AMI recommends that in the final hospital outpatient rule, CMS reimburse PET/CT in a New Technology Ambulatory Payment Classification (APC) and, because there is no available claims data for PET/CT, that it base the payment rate on external data. For the reasons set forth below, we respectfully recommend that CMS assign CPT codes 78814<sup>1</sup>, 78815<sup>2</sup>, and 78816<sup>3</sup> to APC 1519, with a payment rate of \$1,750.

This recommendation is consistent with the New Technology payment policy for new products where no claims data exist, and will make PET/CT available to Medicare beneficiaries in hospitals. This payment rate also reflects the clinical and cost differences between PET and PET/CT.

### **Clinical Differences Between PET and PET/CT**

PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. PET employs two scans to accurately identify the location of this signal. The first detects the metabolic signal; the second detects a radioactive source circulating throughout the body, and is used to correct the metabolic scan for radioactivity that is absorbed or attenuated by the body. The PET scan provides accurate metabolic information, but it does not determine the exact anatomic location of the signal in the body.

The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities, such as CT and MRI, do not. Certain diseases cause abnormalities of blood flow or metabolism before anatomic changes become apparent. These abnormalities can be detected by PET at a stage when the anatomic imaging scans appear normal. Moreover, whereas anatomic imaging depends on the size and growth rate of lesions to determine the likelihood of malignancy, PET physicians can determine the presence or absence of malignancy through the evaluation of tissue metabolism.

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<sup>1</sup> CPT code 78814 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g. chest, head/neck).

<sup>2</sup> CPT code 78815 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh.

<sup>3</sup> CPT code 78816 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body.

CT is a standard imaging method that provides high-resolution anatomic information by detecting differences in the density of various tissues. The combination of PET and CT into a single device, known as a PET/CT, is a breakthrough in imaging because the images from a PET scan and a CT scan can be seamlessly merged into an image that more accurately identifies and localizes tumors in the body.

When the results of the scans are fused together, they provide the most complete non-invasive information available on cancer location and metabolism. In addition, PET/CT allows both tests to be performed without moving the patient, and the resulting images leave less room for error in interpretation due to the more accurate picture of the cancer provided by the scan.

The benefits to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy.** A PET/CT image separates malignant from benign processes and reveals tumors that may otherwise be obscured by the scars and swelling that result from therapies such as surgery, radiation, and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor.

#### **Background on FY 2005 and FY 2006 Hospital Outpatient Payment for PET/CT**

During the 2005 rulemaking process for the Hospital Outpatient Prospective Payment System (HOPPS), PET/CT was a new technology with no identifiable Medicare claims data. Because PET/CT did not yet have an established CPT code when HOPPS rates were set, CMS did not set a payment rate for PET/CT when it published the final hospital outpatient rule on November 15, 2004.

The American Medical Association (AMA) granted three new CPT codes (78814, 78815, and 78816), which were implemented in January 2005, to describe PET with concurrent CT when CT is used solely for attenuation correction and anatomical localization (rather than for diagnostic purposes).

In March 2005, with no discussion and without soliciting public comment, CMS assigned these three new codes to New Technology APC 1514, in the Hospital Outpatient Quarterly Update Transmittal 514. CMS established the payment rate of \$1,250, which is \$100 higher than the payment rate for PET scans in APC 1513. CMS correctly assigned PET/CT to a different APC from PET. This is consistent with the Food and Drug Administration's (FDA) conclusion in both its premarket approvals and regulations that PET/CT is a different medical device from PET. For example, PET/CT devices are specifically cleared by the FDA for marketing under the 510(k) process on the basis of marketed (or predicate) PET/CT devices, not PET devices.

However, it is unclear how CMS arrived at the payment rate established in the Quarterly Update. CMS provided no rationale for the rate, and because no code for PET/CT then existed (codes for

PET/CT were first implemented in January 2005), there was no identifiable claims data for PET/CT.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to continue its assignment of PET/CT codes to New Technology APC 1514 with a payment rate of \$1,250.<sup>4</sup> Although AMI agrees with CMS that PET/CT should remain in the New Technology classification for 2006, we believe the current and proposed payment rates are too low and, due to the lack of claims data, should be modified on the basis of external data.

### **Recommendation for the Final Hospital Outpatient Rule for PET/CT**

AMI greatly appreciates the hard work and careful consideration CMS put into developing the proposed rule. We are concerned, however, that the proposed payment rate for PET/CT does not adequately cover hospitals' costs for providing PET/CT services. The costs and resource use involved in a PET/CT scan are more substantial than those involved in a PET-only scan. For example, hospitals incur more capital and maintenance costs with PET/CT than with conventional PET. A new PET/CT scanner costs approximately \$1.8 million dollars, compared to \$1.2 million for a conventional PET scanner. Further, a PET/CT scanner carries twice the operating cost of a conventional PET scanner, with an annual maintenance contract of approximately \$240,000, compared to \$120,000 for a PET-only scanner.

AMI is also concerned that the proposed payment rate for PET/CT does not reflect that the CT scan performed during a PET/CT is not limited to one part of the body but includes the entire area imaged by the PET scan. When a physician orders a PET/CT and a diagnostic CT the nuclear medicine physician can in some cases perform both a CT scan for attenuation correction and a diagnostic CT scan with contrast with a single PET/CT scan. For example, CPT code 78815 could include a CT scan from the skull base to the mid-thigh, which is equivalent in area to a CT scan of the neck, chest, abdomen, pelvis, and part of the lower extremity. The CT portion of a PET/CT may be equivalent to multiple diagnostic CT scans and is performed with or without contrast. This is more efficient than performing one PET scan plus several separate CT scans for different regions of the body. An individual regional CT scan with contrasts is reimbursed by Medicare at approximately \$300.

In some instances a nuclear medicine physician needs to order both a PET/CT and a diagnostic CT scan. For example, the clinical protocol for diagnosing a small lung nodule calls for the patient to hold their breath during the scan. Because PET/CT requires a longer period of time for image acquisition, it is not possible to perform the PET/CT scan and diagnostic CT scan simultaneously. In that case, the physician must perform a separate diagnostic CT scan.

Because the PET/CT CPT codes and payment rate were first implemented in April 2005, there is no available Medicare claims data for PET/CT. Therefore, for the final hospital outpatient rule

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<sup>4</sup> We appreciate that CMS corrected its technical error with respect to the PET/CT rate, published in the proposed rule as \$1150.

for FY 2006, CMS should base the New Technology payment rate for PET/CT on external data and economic analysis. The attached paper shows the hospital cost of providing a PET/CT scan, based on the extrapolation of a published economic cost model. According to its authors, the model is based on average national utilization rates in the hospital outpatient department, and is adjusted for PET/CT equipment and operational requirements. Based on this economic analysis, the costs for a PET/CT scan are approximately \$1,717. The present PET/CT payment rate is therefore far below the true costs of providing the service in hospital outpatient departments. CMS should use this published economic model cost analysis to set the New Technology rate for 2006.

Based on this external analysis, we recommend that CMS assign CPT codes 78814, 78815, and 78816 to APC 1519 with a payment rate of \$1,750. This recommendation is consistent with the attached data, with the clinical use of PET/CT, and with the greater relative resource use associated with PET/CT than with conventional PET.

#### **AMI Supports the Proposed Payment Classification for PET Scans**

We strongly support the proposal in the rule to maintain covered FDG PET procedures in New Technology APC 1513. This decision reflects the fact that the hospital outpatient claims data used to set the 2006 proposed payment rates do not accurately reflect the costs of providing these services. Adequate payment for these services is essential to ensure patient access to this important technology. AMI will continue to work with CMS and providers on issues relating to PET claims data.

#### **Payment for Radiopharmaceutical Fluorodeoxyglucose (FDG)**

The proposed rule makes significant changes to hospital outpatient payments for radiopharmaceuticals in 2006 and subsequent years. The rule proposes to pay for FDG and other radiopharmaceuticals based on hospital charges reduced to costs by the hospital cost to charge ratio (CCR). AMI supports this proposal but has concerns about its implementation. AMI is committed to working with CMS and other stakeholders on payment issues for nuclear medicine therapies and isotopes, including how to implement CMS's proposed payment methodology appropriately in FY 2006.

AMI recommends that the hospital-wide CCR be used, as this is the appropriate hospital cost center for FDG. Hospitals have a wide variety of mark-up policies for drugs and radionuclides. It will be critical that hospitals charge appropriately and that CMS and contractors apply the correct CCR. AMI will work with providers to educate them regarding the proposed new payment methodology for FDG.

AMI is interested in working with CMS on establishing appropriate payments for FDG and other radiopharmaceuticals in subsequent years. In the proposed rule CMS asks for comments on whether radiopharmaceuticals should be paid based on average sales price (ASP) starting in 2007. Due to the difficulties with reporting ASP for FDG and other radiopharmaceuticals, AMI believes that CMS should study this issue further in the context of a public process that allows

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September 15, 2005  
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for significant stakeholder input. AMI stands ready to work with CMS and other stakeholders on payment for FDG in 2007 and subsequent years.

AMI appreciates the opportunity to submit these comments, and looks forward to an ongoing dialogue with CMS on these important issues.

Sincerely,

*R. Edward Coleman*

Dr. R. Edward Coleman  
Immediate Past President  
Academy of Molecular Imaging

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CMS-1502-P-583

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Submitter : Mrs. Carol Benton  
Organization : William Beaumont Hospital Wound Care  
Category : Nurse

Date: 09/06/2005

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Sanow  
HAT  
BAZEL  
AHMED

Issue Areas/Comments

GENERAL

GENERAL

We use the product Apligraf for patients having difficulty healing both diabetic and venous ulcers. I understand that the reimbursement for 2006 has been significantly affected by an administrative error. This would prevent us from using the product and directly impact patient care in our department. Please consider correcting the error of reimbursement for this product.