Submitter :

Date: 10/02/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"
Cristina Lopez-Penalver, MD

CMS-1321-P-387-Attach-1.DOC

ADVANCED SURGICAL ASSOCIATES

September 27, 2006

Advanced Surgical Institute
Moises Jacobs, MD, F.A.C.S.
Cristina Lopez-Penalver, MD, F.A.C.S.
Eddie Gomez, MD, F.A.C.S.

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-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

Dear Administrator:

We appreciate the opportunity to provide comment on the CMS proposed Physician Rule #CMS-1321-P. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy. We would like to highlight the negative impact these proposed rates will have on breast conservation therapy since we currently recommend a 5-day radiation therapy treatment option (balloon brachytherapy) for clinically specific Medicare beneficiaries.

The RVUs are scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below. This is unacceptable. We find the patients are more compliant with 5-day breast brachytherapy versus the standard course of radiation treatments which can run from 6-8 weeks.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

This procedure takes place in the procedure room in our office. A patient must meet strict selection criteria before we surgically implant the balloon catheter that delivers the radiation; and because of the time involved in planning, catheter implantation and device cost, the proposed RVU reduction will result in this procedure no longer being available for Medicare women. The cost of the procedure will exceed the proposed reimbursement and every patient will be forced to have the procedure in the hospital – which is a significant waste of healthcare dollars. The office is the preferred site of service, and office placement should be the site of service used to reduce unnecessary Operating Room costs.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor equal to a 5% reduction and that this floor remain in effect during the time required for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC. This will help CMS prepare a more informed proposal in the readjustment of RVUs that pertain to breast brachytherapy.

Thank you in advance for your assistance,

Cristina Lopez-Penalver, M.D., F.A.C.S.

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: 10/02/2006

Organization : **Metrika, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1321-P-388-Attach-1.DOC

Michael Allen
Founder
Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, California 94085

October 2, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, Maryland 21244-8015

RE: CMS-1321-P, Provision L. Independent Diagnostic Testing Facility (IDTF) Issues, 4. Place of Service

This letter is in regard to the proposed revisions to Medicare's *Payment Policies Under the Physician Fee Schedule for Calendar Year 2007.* On page 236 of the proposal under 4. Place of Service, CMS requests "public comment regarding the types of [diagnostic testing services] that can be safely and appropriately used in a residential setting".

On behalf of Metrika, Inc., I would like to recommend that CMS include in this category those diagnostic tests approved by the FDA for home use. For example, Metrika's A1CNow+ device was cleared by the FDA in 2002 with the following indication for use:

> *The A1CNow™ test provides quantitative measurement of the percent of glycated hemoglobin (% HbA1C) levels in capillary (fingerstick) whole blood samples. The test is for* ***home use*** *by people with diabetes to monitor glycemic control.*

Tests approved by the FDA for use in the home have undergone clinical and non-clinical studies in order to evaluate certain performance characteristics such as device precision and specificity, and appropriate use by test subjects. These studies demonstrated the safety and effectiveness of the A1CNow test for its intended use in the home setting.

As part of the revisions to the 2007 Physician Fee Schedule, I recommend that CMS include hemoglobin A1C testing using a device cleared by the FDA for home use in its list of residential diagnostic tests.

Thank you for taking the time to consider these comments.

Sincerely,

Michael Allen

U.S. Food and Drug Administration

FDA Talk Paper

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

FDA CLEARS HOME GLYCATED HEMOGLOBIN TEST FOR DIABETICS

The Food and Drug Administration (FDA) has cleared the first over-the-counter test that measures glycated hemoglobin in people with diabetes to help monitor how well they are managing their disease (glycemic control).

The test, called Metrika A1c Now, is currently available by prescription only. Over-the-counter status means that the test can now be purchased without a prescription and used at home, with results on the spot, making it readily available to people with diabetes.

Diabetes is a chronic disease in which blood glucose (sugar) levels are too high. Abnormally high levels of glucose can damage the small and large blood vessels, leading to blindness, kidney disease, amputation of limbs, stroke, and heart disease.

Glycated hemoglobin is a unique substance created as a result of interaction between hemoglobin and glucose.

The level of glycated hemoglobin provides information on the average level of glucose in the body over a 90 to 120 day period of time.

The glycated hemoglobin test should be performed two to four times a year to monitor long-term control over blood glucose levels. Glycated hemoglobin tests provide information to complement that obtained from daily finger stick blood glucose tests that measure glucose at a single point in time.

To perform the Metrika A1c Now test, the patient takes a blood sample from his finger with a lancet and places it in a monitor. The monitor displays test results in eight minutes. Unlike some other products, there is no need to send the sample back to the physician to get results. The patient gets the results on the spot.

FDA cleared the test for non-prescription use based on a clinical study conducted by the manufacturer, Metrika, Inc., of Sunnyvale, Calif. The study compared test

results obtained by lay users of the device to test results obtained by medical professionals. In the study, 286 patients-271 diabetics and 15 nondiabetics-used the test without physician supervision.

The results were comparable to those obtained by medical professionals.

The Metrika A1c Now test has been certified by the National Glycohemoglobin Standardization Program, an independent certification body.

About 17 million Americans have diabetes. Many of them may find the new home glycated hemoglobin test helpful.

####

Submitter : Dr. Michael Krusch
Organization : Dr. Michael Krusch
Category : Physician
Date: 10/02/2006

Issue Areas/Comments

Background

Background

Please see detailed comments.

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

I am responding to the CMS proposal of 9/21/06 regarding the proposed changes in the physician fee schedule for 36478 and 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479 and find several issues of great concern:

1. RVUs have consistently been reduced from 2005 levels:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84

While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the, per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, Anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Michael P. Krusch, MD, FACPh
Greensboro, NC

Impact

Impact

In ability to provide service and loss of access to care by Medicare beneficiaries. Please see detailed comments.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Decrease in RVUs for cpt code 36478. Please see detailed comments.

Submitter : Dr. Neil Waravdekar

Organization : Frederick Medical & Pulmonary Associates

Category : Physician

Date: 10/03/2006

Issue Areas/Comments

Background

Background

The proposed rule would cut reimbursement for central DEXA scaning which is the gold standard for osteoporosis screening. Untreated osteoporosis can lead to fractures of the hips, arms, long bones and spine which cause significant morbidity and mortality for the elderly.

GENERAL

GENERAL

I am a Pulmonary and Critical Care Physician who screens and treats patients for osteoporosis. The proposed rule would limit the ablity to screen for osteoporosis by use of central DEXA scanning which is the best screening test for this. This would cut a basic preventive service to Medicare patients and is a drastic contrast to your commitment to disease prevention. The 'Welcome to Medicare' physical has been billed as an access point to up-to-date important screenings and central DEXA scans are one of these. In essence you would be offering screening then denying access to the screening test.

If the proposed cuts take effect, I will be unable to offer this important screening test in my office. This will ultimately affect the ability of Medicare patients to afford this necessary preventive screening.

Submitter : Dr. Anonymous **Date:** 10/03/2006

Organization : Dr. Anonymous

Category : Federal Government

Issue Areas/Comments

Background

Background

This is in regard to the IDTF proposal for comprehensive liability insurance. IT will be too burdensome to calculate the 20% of Medicare billings.

GENERAL

GENERAL

Often we don't know how much we are able to bill Medicare. It would be better to just have a flat number so that we can be covered without creating an undo burden.

Impact

Impact

THe proposed rule states that the insurance must be 300,00 dollars or 20% of the medicare billings, whichever is greater.

Submitter : **Mr. Steven Hopland** **Date: 10/03/2006**

Organization : **Medical Care, LLC**

Category : **Physician**

Issue Areas/Comments

Background

Background

The reduction in reimbersment will greatly reduce the used of DXA and screening of osteoperosis. This would prohibit future capital investment in new equipment and technology required to best treat our patients. Prevention and screening is MUCH cheaper that treatment and long term care.

Impact

Impact

Reimbersment should remain the same or a modest increase to keep the true level of reinbersment the same. All other costs of our physian office are increasing as reimbersment decrease.

Submitter : **Dr. john mauriello** **Date: 10/03/2006**

Organization : **Dr. john mauriello**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

We have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479

There are three issues of concern;

1. Values have been consistently reduced:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84
d. Practice expense consistently rises (salaries, utilities, etc.)

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable in terms of both capital acquisition cost ($37,900 for laser and $25,000 for RF) and per patient supply costs ($360 for laser and $750 for radiofrequency).

We are requesting that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5.

We are also requesting that the fully implemented facility practice expense RVU remain at the 2006 value of 2.54.

Submitter : Ms. Valerie Baldwin RN OCN **Date:** 10/03/2006

Organization : South Carolina Oncology Associates

Category : Nurse

Issue Areas/Comments

Background

Background

ASP issues: In reposnse to specific types of activities manufactureres would otherwise contract for or perform and the neccesity of those services. Oncology patients are the most complex patients to manage of any medical specialty. Once a drug has been purchased our Pharm-D must receive the drug, maintain an inventory,mix in appropriate diluents, avoid waste and dispense appropriately to patients with adequate blood counts and performance status for treatment, infusion times are correct,allergies or possible adverse events from drug reactions must be verified.Not only must IV medications be handled in this manner but oral chemotherapy drugs are equally important.IMPAC,our oncology specific EMR plays an important role in our ability to deliver quality patient care that is proactive, rather than reactive. Each diagnosis and stage are reviewed by physicians, using a variety of guidelines the most effacacious regimens for the appropriate settings are then entered in our EMR. Each regimen is then identified for known additional risk factors or toxicicities and appropriate supportive care is added to the regimen. For instance a level 5 emetogenic chemotherapy has the appropriate IV antiemetic added. Risks of febrile neutropenia are identified and evidenced based guidelines are followed.Drugs with risks of diarrhea are managed proctively in order to reduce risks of dehydration, hospitalization, ER visits and poor quality of life. Each patient meets with the physician, recommendations are made and shared decison making occurs.
In addition to these services each patient is scheduled for patient education. Our oncology certified educator instructs patients about their chemotherapy drugs, desired and possible side effects and measures they should take if they should experience these side effects.In addition prescriptions for medications for management, written instructions, a book, and a risk assessment are completed. The risk assessment facilitates individualized patient care by identifying additional known risk factors in addition to the known risks associated with the chemo regimen. We have e-tablets that patients are requested to complete prior to each visit. The patients are asked a series of questions and are asked to provide a measurement of the severity of a variety of toxicities. This tool assists us to better focus our visits on the areas the patient is having problems. It also provides a baseline and on going report so we are able to measure the efficacy of our interventions.The report also provides a T-score which a score>65 indicative of depression. Automatic e-mails are generated to our social workers who are able to make initial contact and assessment and then recommend appropriate intervention. Sometimes it is as easy as some financial assistance, assisstance navigating through the system, other times it is more severe and they may need to see a physician. Patients are scheduled with the same nurse each visit.facilitating individualized,efficient, familiar care. The nurse is also able to monitor compliance, report complications to the physician and receive constant feed back through the e-tablet report and patient during treatment. Each patient is assessed,information provided and managed.By documenting in the EMR, the majority of data is easily retreived.We also have 3 triage nurses who assists pts. NONE OF THESE SERVICES ARE REIMBURSED.We are then able to query the data base, receive reports, measure our performance, and improve.We have a continuous feed back loop.The NEJM March 2006 had a study reported anyone of us has a 55% chance of receiving proper healthcare, over 1.5 million errors occur in this country every year at a cost of billions of dollars. The majority related to omissions and adverse events.The drug manufacturers could play a huge role im improving patient care and reducing health care costs if we could devise a system that would allow community oncology to be reimbursed for the services we provide.

Impact

Impact

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Provisions of the Proposed Rule

Provisions of the Proposed Rule

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Submitter : Dr. RANDALL OREM **Date:** 10/03/2006

Organization : FAIRINGTON CARDIOVASCULAR AND WELLNESS CENTER

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

We have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479

There are three issues of concern;

1. Values have been consistently reduced:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84
d. Practice expense consistently rises (salaries, utilities, etc.)

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

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a. 2006: 51.5
b. 2007: 47.77
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Each of these technologies are comparable in term of both capital acquisition cost ($37,900 for laser and $25,000 for RF) and per patient supply costs ($360 for laser and $750 for radiofrequency).

We are requesting that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5.

We are also requesting that the fully implemented facility practice expense RVU remain at the 2006 value of 2.54.

Submitter : **Mrs. Catherine Morris** **Date: 10/03/2006**

Organization : **Diomed, Inc.**

Category : **Nurse**

Issue Areas/Comments

Background

Background

Reduction in RVU for office treatment

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

We have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479

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We are requesting that the fully implemented, non-facility practice expense RVU for 36478 remain at the 2006 rate for 36475 of 51.5.

We are also requesting that the fully implemented facility practice expense RVU remain at the 2006 value of 2.54.

Impact

Impact

Acquisition cost of technology exceeds proposed payment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Diminished access to care for medicare beneficiaries

Submitter : **Dr. Lloyd Halvorson** **Date: 10/03/2006**

Organization : **Frederick Medical & Pulmonary Associates**

Category : **Physician**

Issue Areas/Comments

Background

Background

I am writing this letter to express my concern regarding the proposed changes to Bone Mass Measurement (BMM) Tests.

I am a physician who specializes in Pulmonary and Critical Care Medicine. I treat many patients who are using steroids for Asthma. As you are aware, Steroidal use contributes to bone loss.

I am against these proposed changes because the proposed rule would cut central DXA which is the gold standard for osteoporosis screening. In addition these cuts will discourage preventative care, which we both know are necessary.

Submitter : **Dr. Robert Aki** **Date: 10/03/2006**

Organization : **Dr. Robert Aki**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-398-Attach-1.DOC

Attach
398

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-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

Once it is determined women are eligible for breast brachytherapy based on strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in some cases, in the physician's office in the procedure room. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some women and this option should be available for them.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to

provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Robert Aki. MD

Robert Aki, MD
605 W. Central Road, #201
Arlington Heights, IL 60005

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. David Charles** **Date: 10/03/2006**

Organization : **Alliance for Patient Access**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-399-Attach-1.RTF

THE ALLIANCE FOR PATIENT ACCESS

October 3, 2006

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking
Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Proposed Revisions to the Physician Fee Schedule for Calendar Year 2007
CMS-1321-P
Comments on Changes to Practice Expense Relative Values for codes 64612, 64613 and 64614

Dear Dr. McClellan:

As chairman of the Alliance for Patient Access (AfPA), an organization of physicians throughout the nation whose mission is to ensure and protect patient access to approved medical treatments in the U.S., and as a neurologist who has been practicing in an academic setting for 12 years, I am pleased to submit comments on the Proposed Rule for the 2007 Physician Fee Schedule. The Proposed Rule outlines changes to the work relative value units (RVUs), the practice expense RVUs and the conversion factor for services paid under the Physician Fee Schedule. If the changes are adopted as proposed, there will be substantial reductions in payments for many of the services provided by me and my fellow AfPA members, which may mean that we will no longer be able to offer these services to our Medicare patients.

In these comments, I focus specifically on changes in the practice expense RVUs for chemodenervation procedures (codes 64612, 64613 and 64614) because the proposed reductions in these procedures will have a particular impact on my practice and the practices of other AfPA members. These procedures are performed in the treatment of patients with serious movement disorders—many of which are rare diseases—for which chemodenervation offers a relatively noninvasive way to provide significant relief to these patients.

In the Proposed Rule, CMS is proposing to revise the practice expense RVUs for most procedures due to a change in the method CMS uses to determine these RVUs. As I understand it, these changes will result in drastic declines (35 to 54% drops) in the practice expense RVUs for codes 64612, 64613 and 64614 over the next 4 years.

I am not an expert in your methods, but it seems to me that reductions of this magnitude should be very carefully considered—including the potential impact on patient access—before these are implemented. Therefore, I would recommend that further analysis of these changes be conducted prior to implementation of the major changes to the current methodology that were announced in the Proposed Rule. If adjustments are determined to be warranted, the transition should be sufficiently long to minimize any impact on patient access. I would recommend that a floor of 95-percent be applied so that practice expense RVUs do not fall by more than 5-percent from year-to-year.

I would also like to express my support for recommendations made nearly universally by professional medical groups that CMS work with Congress to avoid implementation of a 5.1-percent reduction in the conversion factor. If the proposed change in the conversion factor is adopted, I am concerned that many Medicare beneficiaries may find their access to services reduced.

Thank you for your consideration of my comments.

Sincerely yours,

P. David Charles, M.D.
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Submitter : **Michael Sherman** **Date: 10/03/2006**

Organization : **Michael P. Sherman, MD, PhD., A Medical Corporatio**

Category : **Physician**

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

This is a rediculous recommendation with no substantial logical basis for it's recommendation. I strongly disagree with this proposal as it is based on some theoretical price, not actual marketplace pricing. I believe that the current ASP model, while not ideal, allows for the greatest amount of choices which, in turn, allows for the best patient care. Reimbursement has already changed dramatically in the past year and any further change in the ASP system using theoretical allocations could jeopardize the Oncology practices further. How can you base your price on what oncologists "might" order? No other drug is sold this way.

Submitter : **Dr. kenneth sacks** **Date: 10/03/2006**

Organization : **Medical Specialist of Fairfield**

Category : **Physician**

Issue Areas/Comments

Background

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I am commenting as the former managing partner of a rather large oncolgy practice. We always found the bundling arrangements that some pharmacutical firms employ to be so objectionable as to consider them equivalent to blackmail. Those practices which capitulate to these arrangements do so entirely to improve the drug's margin and have the consequence of increasing the cost of medical care for all stakeholders. The practice should be disallowed and ASP calculated on real costs. Thank you.

Submitter : Dr. Kenneth Hatch **Date:** 10/03/2006

Organization : The University of Arizona College of Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-402-Attach-1.PDF

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September 25, 2006

Mark B. McClellan, MD,PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

RE: ***Oncotech Extreme Drug Resistant Assay***

Dear Dr. McClellan.

At the Arizona Cancer Center we rely upon the Extreme Drug Resistant Assay to identify chemotherapy drugs to which the patient would be more likely to respond. This benefits the patient significantly since they are not subjected to drugs less likely to be of benefit. This also benefits Medicare because the patients may be spared the expense of ineffective chemotherapy.

We collect the tissue during either an inpatient or outpatient surgical procedure. It is then transported to California where the Oncotech Lab performs the EDR assay. By linking the surgical procedure to Medicare Part A procedure it would fall to the hospital to be responsible for the cost of the assay. Currently, Medical Part B is paying and Oncotech has graciously accepted the going Medicare rate despite the actual charges being higher.

We strongly urge you to consider leaving the Oncotech's EDR services in the Medicare Part B program. This will lead to better care for patients in a more cost-effective fashion.

Sincerely,

Kenneth Hatch, MD
Professor of OB/GYN

KDH:ral
(9/26/06)

Submitter : **Dr. Richard Neville** **Date: 10/03/2006**

Organization : **Richard Neville, M.D.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

We have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479

There are three issues of concern;

1. Values have been consistently reduced:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84
d. Practice expense consistently rises (salaries, utilities, etc.)

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable in term of both capital acquisition cost ($37,900 for laser and $25,000 for RF) and per patient supply costs ($360 for laser and $750 for radiofrequency).

We are requesting that the fully implemented, non-facility practice expense RVU for 36478 remain at the 2006 rate for 36475 of 51.5.

We are also requesting that the fully implemented facility practice expense RVU remain at the 2006 value of 2.54.