Submitter : Dr. Gregory Fischer **Date:** 10/03/2006

Organization : Laboratory Accreditation Board of ABRET

Category : Physician

Issue Areas/Comments

Background

Background

The Laboratory Accreditation Board of the American Board of Registration of Electroencephalographic and Evoked Potential Technologists (LAB of ABRET) has in place, a process for assessing quality of data produced by EEG laboratories. LAB of ABRET also reviews a limited set of EEG laboratory policies and procedures -- primarily those necessary for the generation of high quality and readily interpretable electroencephalographic recordings.

GENERAL

GENERAL

See Attachment

CMS-1321-P-404-Attach-1.DOC

HHS
4/34

October 3, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, Maryland
Electronic address: http://www.cms.hhs.gov/eRulemaking

Re: CMS-1321-P
IDTF issues

Dear Sirs:

In your notice of proposed rulemaking, you asked for public comments about proposed performance standards for Independent Diagnostic Testing Facilities (IDTFs). You asked about any organizations that have current established standards for diagnostic testing.

With the goal of improving the quality of diagnostic electroencephalographic (EEG) testing throughout the United States, the Laboratory Accreditation Board of the American Board of Electroencephalographic and Evoked Potentials Technologists, Inc. (LAB of ABRET) has been accrediting EEG laboratories since early 2005. Standards for assessing the adequacy of EEG laboratory procedures and data, are based on current Guidelines published by the American Clinical Neurophysiology Society (ACNS).

ACNS has published Guidelines for neurophysiologic testing since 1970, and is a major national organization representing specialists in Clinical Neurophysiology. Since 1947, the ACNS (formerly known as the American EEG Society) has represented and facilitated the educational and scientific needs of Clinical Neurophysiology community. The eighteen hundred members of ACNS include the leaders in this field at most medical centers and medical schools and also includes, as members, many community practitioners across the US.

The LAB of ABRET laboratory process is officially endorsed by ACNS.

The testing procedures assessed and reviewed by LAB of ABRET pertain to electroencephalography. Such procedures use, for example, the following CPT codes 95812 95813 95816 95819 95822 95824 and 95827.

Our laboratory accreditation process is available for review at:

http://www.abret.org/lacc/intro.php

The ACNS Guideslines we follow are available at:
http://www.acns.org/

If the Laboratory Accreditation Board of ABRET can be of assistance to you in helping assure quality EEG diagnostic testing, please feel free to contact me, or our executive director, Janice Walbert.

Respectfully,

Gregory G. Fischer M.D.
President, Laboratory Accreditation Board of ABRET
Gundersen Clinic
1836 South Avenue
La Crosse WI 54601
608-775-2060
fax: 608-775-6358

Janice Walbert
ABRET Executive Office
1904 Croydon Drive
Springfield IL 62703
217-553-3758
fax: 217-585-6663

Submitter : **Eddy Luh** **Date: 10/03/2006**

Organization : **Eddy H Luh MD PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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;

Values have been consistently reduced:
2006: 46.91
2007: 43.53
2008: 40.84
Practice expense consistently rises (salaries, utilities, etc.)
The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.
Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
2006: 51.5
2007: 47.77
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.

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

Organization : **National Osteoporosis Foundation**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - Provisions of the Proposed Rule

CMS-1321-P-406-Attach-1.PDF

Hrng IF
406

NATIONAL OSTEOPOROSIS FOUNDATION

Standing Tall For You®

October 4, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: 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; Proposed Rule

Dear Administrator McClellan:

Introduction
On behalf of the National Osteoporosis Foundation (NOF), thank you for the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B and the Proposed Rule. This letter's comments address "BONE MASS MEASUREMENT TESTS."

NOF is the nation's leading voluntary health organization solely dedicated to osteoporosis and bone health. Its mission is to prevent osteoporosis, promote lifelong bone health and help improve the lives of those affected by osteoporosis and related fractures and find a cure. NOF achieves its mission through programs of awareness, advocacy, public and health professional education and research. NOF is a leading authority for anyone seeking up-to-date, medically sound information and educational material on the causes, prevention, detection and treatment of osteoporosis.

In the United States, osteoporosis is a public health threat for 44 million Americans, 55 percent of the people 50 years of age and older. Ten million Americans are estimated to already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis. Of the ten million Americans with osteoporosis, eight million are women and two million are men.

1232 22nd Street, N.W. • Washington, D.C. 20037-1202 • 202.223.2226 • Fax 202.223.2237 • www.nof.org

Osteoporosis often is called a "silent disease" because bone loss occurs without symptoms. People may not know that they have osteoporosis until their bones become so weak that a sudden movement causes a fracture or a vertebra to collapse. Collapsed vertebrae initially may be felt or seen in the form of severe back pain, loss of height, or spinal deformities such as stooped posture.

BONE MASS MEASUREMENT TESTS

NOF is pleased that Medicare is updating and finalizing the "Medicare Coverage of and Payment for Bone Mass Measurements" interim final rule it published June 24, 1998 because it is vital that Medicare coverage keep up-to-date with the scientific evidence on the prevention, assessment, and diagnosis of osteoporosis, a pervasive disease that often can have severe consequences. From its inception, NOF has advocated for appropriate Medicare coverage of bone mass measurement (BMM).

Definition
NOF agrees with CMS on the new definition of BMM and its reasoning that newer techniques of dual energy x-ray absorptiometry (DXA) are superior to single photon absorptiometry (SPA).

Conditions for coverage
NOF agrees with the newly proposed conditions for coverage as they incorporate current scientific evidence on using central DXA as the preferred measurement of bone mass density (BMD) in diagnosing and monitoring the effects of therapy and allow for future evidence to be incorporated, too.

Standards on frequency of coverage
NOF generally agrees with the proposed standards on frequency of coverage, but it has one area that it would like to clarify. One of the categories for beneficiaries who can be covered is an individual with primary hyperparathyroidism. According to the US Surgeon General's Report, this disease is relatively common in older people, especially postmenopausal women. "Typically cortical bone (for example, in the distal forearm) is affected to a greater extent than trabecular bone (for example, in the spine) in primary hyperparathyroidism (Silverberg et al. 1989). It is presumed that the reduction in bone mass is associated with the increased risk of fracture seen in these patients (Khosla and Melton 2002)."[i] A recent study in 2006 states: "Indeed, the distal part of the limbs are the most affected areas in PHPT (primary hyperparathyroidism) whatever the amount of cortical or trabecular bone."[ii]

Therefore, NOF proposes adding an exception under standards for frequency of coverage 410.31 (c) (2). This exception would describe an individual with primary hyperparathyroidism being covered when tested initially with DXA at the axial skeleton (hip and spine) under HCPCS 76075 (Healthcare Common Procedure Coding System) and at the appendicular skeleton (peripheral) (for

example, radius, wrist, and heel), under HCPCS 76075, to diagnose whether he or she has osteoporosis. Because there is a preferential loss of cortical bone in hyperparathyroidism, the results of testing bone density at one peripheral bone site (e.g. forearm) in addition to the hip and spine at the time provides a better picture of certain patients' actual medical condition. Therefore, we suggest that the following be included:

> (iii) initial testing for osteoporosis in patients with hyperparathyroidism by DXA on the axial and appendicular skeleton

Beneficiaries who may be covered
NOF agrees with the proposed change to beneficiaries who can be covered because glucocorticoid-induced bone loss develops quickly, leads to an increased risk of fractures, and fewer than 25 percent of patients prescribed oral glucocorticoids receive treatment to prevent or treat osteoporosis.[iii]

Use of national coverage determination process
NOF understands the rationale for proposing that the national coverage determination (NCD) process be used to identify additional BMM systems for purposes of 410.31(b)(2) and (b)(3). NOF agrees with this rationale providing that currently stated CMS policies are followed. These policies state that when there is a complete formal request for a new coverage determination, CMS will publicly track the process, allowing it to be transparent; provide an understandable decision memorandum prior to a NCD based on scientific and clinical evidence; offer adequate notice and opportunity to comment; be timely; and offer a reasonable mechanism for reconsideration.

Conclusion
Although NOF believes that Medicare coverage of bone mass measurement needs to be expanded so that the legal definition of qualified individuals keeps pace with additional current scientific and clinical evidence, it is aware that this change necessitates the passage of new legislation.

Thank you again for the opportunity to comment on the proposed final rule, and if we can assist you in any way, including implementation of the rule, please do not hesitate to contact Roberta Biegel, senior director of public policy and government relations, at 202-721-6364 or roberta@nof.org.

Sincerely,

Thomas Einhorn MD

Thomas A. Einhorn, MD
Co-chair, Advocacy Committee

Conrad Johnston MD

C. Conrad Johnston, Jr., MD
Co-chair, Advocacy Committee

CC: Bill Larson

Citations:

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[i] U.S. Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, 2004: 49.

[ii] Chappard C, et al. Bone status in primary hyperparathyroidism assessed by regional bone mineral density from the whole body scan and QUS imaging at calcaneus. Joint Bone Spine 2006 Jan; 73(1): 86-94.

[iii] McIlwain HH. Glucocorticoid-induced osteoporosis: pathogenesis, diagnosis, and management. Preventive Medicine 2003 Feb; 36(2): 243-9.

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

Organization : **Western Rockingham Family Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am very alarmed and frustrated at the recent proposed regulations by the CMS regarding reimbursement for the performance of BMM tests. I am a family physician in a rural area of North Carolina and perform BMM tests on many patients who would not otherwise have received one. Over 80% of our patients who had BMM tests had osteopenia or osteoporosis. Much time is often involved in evaluating BMM test results and recommending the proper treatment for osteopenia and osteoporosis. Patients must be educated about their future risks related to these disease states to ensure compliance with therapy. Treatment recommendations often include dietary therapy and over the counter therapy to ensure appropriate calcium and Vitamin D intake. Also, additional lifestyle modifications are prescribed such as weight bearing exercise, physical therapy and fall prevention. Presciption medication used to treat osteopenia and osteoporosis also requires extensive evaluation of patient fracture risk and benefits of medication therapy vs. possible side effects. In our clinic we educate patients about the medications available and assist them in choosing drug therapy that is right for them. Again, this ensures compliance with medication therapy. Education on proper administration is very important with bisphosphonates and Forteo injections, two types of medications used to decrease the incidence of fractures in patients with osteoporosis. On average, registration and testing alone requires 30 minutes face to face with the patient just for the testing with an additional 30 minutes per episode for follow up to testing with review of results and treatment management. I do agree that the glucocorticoid therapy should be changed for individuals from 7.5 mg per day to 5.0 mg per day. Early diagnosis with aggresive management has resulted in reducing fracture risk and improving the quality of life for many of our patients. The downside of not performing BMM tests will be rising death rates and rising costs to the government to manage the convalescence of patients due to the increased rates of spine and hip fractures. When reimbursement rates are cut, this test will become unavailable to many in our senior population because physicians will no longer be able to afford to provide BMM tests for their patients. The goverment will ultimately pay much more for making such an unsavory decision. Please intervene and stop the reduction to the conversion factor. Please support patients and physicians by acting on this before your October adjournment. Thank you for your time and consideration.

Submitter : Dr. Jerry Ninia **Date:** 10/04/2006

Organization : Varicose Vein Center

Category : Physician

Issue Areas/Comments

Background

Background

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 - office based.

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 employ 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. It will be 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,

Jerry G. Ninia, MD

Submitter : **Dr. Janice Hong Messier** **Date: 10/04/2006**

Organization : **Raleigh Vein and Laser Center**

Category : **Physician**

Issue Areas/Comments

Background

Background

I have reviewed the proposed 2007 fully implemented, non-facility practice expense RVUs ofr codes 36478 and 36479 and find of most concern the issue of reduced levels for next year and years to follow. While my practice expenses continue to rise it will be increasingly difficult for me to provide these services in the office. This will necessitate my utilizing more hospital in-patient services to cover the costs ie using hospital salaried employees (RVTs and RNs) to assist and therefore drive the actual cost higher.

GENERAL

GENERAL

see above for my comment

Impact

Impact

While the 2007 medicare physician fee schedule is already scheduled for a 5.1% across the board cut in reimbursement, along with proposed cuts for non-invasive vascular imaging, the physician will be unable to perform this extremely important procedure in an office setting. Ultimately, there will also be a loss of access to care for Medicare beneficiaries if the proposed cuts continue. ALready, my referring primary care physicians are not accepting any new medicare patients.

Submitter : **Dr. Jeffrey Gibson** **Date: 10/04/2006**

Organization : **Wisconsin Phlebology Grp - Vein Clinics of America**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

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

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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.

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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.

Respectfully submitted,

Jeffrey S. Gibson, MD

Submitter : **Dr. nick morrison** **Date: 10/04/2006**

Organization : **Dr. nick morrison**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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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,

Nick Morrison, MD, FACS, FACPh
Member, Board of Directors, American College of Phlebology

Submitter : **Dr. Helane Fronek** **Date: 10/04/2006**

Organization : **Dr. Helane Fronek**

Category : **Physician**

Issue Areas/Comments

Background

Background

CMS 1321-P

Policy and Recommendation: Comment

Physician Fee Schedule Practice Expense

Proposal dated September 21, 2006

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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.

Further, Endovenous Laser Therapy represents the biggest advance in the treatment of varicose veins, which are an extremely common cause of morbidity and disability. Compared with vein stripping, an Endovenous Laser Treatment is significantly more efficacious and cost-effective, resulting in charges that are a fraction of the cost of vein stripping. I believe that insurance companies should be focusing their efforts on encouraging this more effective and less costly method. This will have the intended effect of reducing the cost of caring for this large group of patients. If reimbursement for this procedure continues to be reduced, this will give physicians no incentive to switch from the more traditional hospital-based vein stripping procedure, which is less effective and more expensive. It doesn't take a genius to understand this. Please think about it.

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

Respectfully submitted,

Helane Fronek, MD, FACP, FACPh
Past-President, American College of Phlebology

Submitter : **Dr. Mark Featherston** **Date: 10/04/2006**

Organization : **Dr. Mark Featherston**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

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

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

Respectfully submitted,

Mark W. Featherston, MD

Submitter : **Dr. Jack Ansell** **Date: 10/04/2006**

Organization : **Anticoagulation Forum**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-414-Attach-1.DOC

Attachment
414

October 4, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

COMMENT TO: "IDTF Issues"

File Code CMS-1321-P: Comments Related to Proposed Rulemaking re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

SUMMARY: I am requesting that CMS ensures that Section L.4. of the Final Rule confirm that G0248 and G0249 services can be provided to eligible Medicare beneficiaries by either IDTFs or physicians from a single centrally-located office regardless of where the patients happens to be located. Doing so will ensure that CMS' initial policy objectives for this important benefit are met in the most efficient manner.

Dear Dr. McClellan,

I wish to address this comment to 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 (Proposed Rule) as it relates to the provision of Home INR Monitoring services (G-0248 and G-0249) provided by Independent Diagnostic Testing Facilities (IDTFs). I am writing to offer my opinion about this Proposed Rule as both a practicing Hematologist at the Boston University School of Medicine and as Founder and Chair of the Anticoagulation Forum (AC Forum).

The AC Forum is a national network of anticoagulation clinics providers with a membership of over 3,000 health care professionals. These providers represent over 1,000 anticoagulation clinics, which care for over 250,000 individuals on oral anticoagulation therapy, including many Medicare beneficiaries.

Over the past seven years I have written several letters to CMS - initially to recommend coverage of the INR home testing service for selected patients and later to suggest policies to ensure efficient implementation of this service. Given the discretionary limitations available to CMS, the AC Forum joined several other medical organizations in supporting the use of IDTFs as an efficient provider of the technical component of these services (G0248 and G0249), and, as a more likely provider than physicians (who

must provide G0250). It is possible that more physicians would be willing to provide these services directly (rather than using IDTFs) if the cost of the monitor was paid for as Durable Medical Equipment or Medicare transferred the amortized cost of the monitor in G-0249 to a one-time upfront cost included in G0248.

CMS approved national coverage of Home INR Monitoring based on studies showing home INR monitoring significantly improves management and clinical outcomes of selected patients on anticoagulation therapy. By incorporating Home INR Monitoring products into a diagnostic service benefit, CMS has empowered a form of chronic disease management. This specialized management will improve beneficiary health outcomes.

IDTFs that offer G-0248 and G-249 services provide a longitudinal multifaceted INR data set (e.g. INR results, Target Ranges, Alert Values and other factors from the patient's history) which, I believe, is critically needed to support proper anticoagulant prescribing. Accurate prescribing is necessary in order to prevent morbidity and mortality commonly associated with anticoagulant underdose or overdose. In some cases the anticoagulant dose must be adjusted frequently, sometimes on an urgent basis, and when the on-call physician is not in the office to review the patient's medical record.

I am concerned that Section L.4. of the Proposed Rule could undermine this benefit by adding administrative complexities that would make it impractical for these services to be provided by IDTFs. Specifically it is possible that the "place of service" for G-0248 and G-2049 could be interpreted to mean that these services would be provided in the patient's beneficiary's residence. If this were to occur, I understand that it would require IDTFs that provide these services to patients on a national basis from a single, central office to become registered in every Medicare jurisdiction in the United States. If the Final Rule is interpreted in this manner it will have a profound effect on the ability of IDTF to provide this service at all. In the past, a number of physicians have indicated to CMS that furnishing equipment and supplies to patient's for their home-use is not a business most physicians would be prepared to do. Therefore, ensuring that IDTFs are able to provide G-0248 and G-0249 services in the most efficient manner is of vitale importance to me and others interested in this benefit.

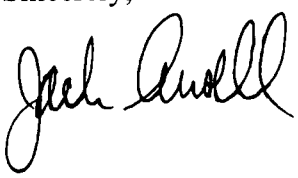
As an individual physician and as the AC Forum Chair I want to express my concern that CMS should allow IDTFs to provide G-0248 and G0249 services to beneficiaries on a national basis from a central office. Limiting the service to beneficiaries who reside in the same carrier jurisdiction as the IDTF is registered would disrupt service for an individual patient as each travels from state to state. Beneficiaries would have to change IDTF providers, IDTF providers would have to connect with new physicians, and both connections would have to be made before a weekly INR result is reported. By changing IDTF providers, the INR result information may be lost or delayed.

IDTFs play an important role in CMS's diagnostic service structure. In addition to underwriting the risk of expensive monitoring equipment, IDTFs are able to seamlessly provide test supplies to a beneficiary wherever each happens to be. These same IDTFs have developed systems for collecting Home INR test data and making it available to

physicians electronically. Continuous access to a patient's recent INR information and current anticoagulant dose enables physicians to provide consistent care throughout the year regardless of where the patient or physician is located.

On behalf of all current and future Home INR Monitoring patients, I am requesting that CMS ensures that the IDTFs that provide the INR benefit (G0248 and G0249) be allowed to service eligible Medicare beneficiaries from a single centrally-located office regardless of where the patients happens to be located. Doing so will ensure that CMS' initial policy objectives are met in the most efficient manner, with the greatest potential to improve the health outcomes of the beneficiaries we all serve.

Sincerely,



Jack E. Ansell, M.D.

Submitter : **Mr. Jerry Stringham** **Date: 10/04/2006**

Organization : **Medical Technology Partners, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-1321-P-415-Attach-1.PDF

Attachment
4/5

MEDICAL TECHNOLOGY PARTNERS

October 3, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1321–P
P.O. Box 8015
Baltimore, MD 21244–8015

Re: CMS–1321–P (Four-Year Transition)

Dear CMS:

I am commenting on the proposed payment for CPT code 36566.

After commenting in 2005 that the practice expense RVU was incorrect for this newly established code and that the payment level was inaccurate, this code was sent to the RUC for review. Our earlier comment stated that the established practice expense RVU contained a clerical error. This was confirmed when RUC received input from the professional societies and re-established the rate for this code. The process resulted in a r ecalculation of t he nec essary s upplies t o perform this procedure, and t he R UC revalued CPT 36566 in the spring of 2006.

While CPT 36566 is not a new code for 2007, which would make it automatically eligible under the proposed methodology to be paid at the fully transitioned rate, this unique situation of an error when initially establishing practice expense RVUs warrants exceptional consideration. It is essentially a new code (created in 2003) that is just being properly priced in the non-facility setting for the first time.

A gradual phase-in of this code will make it impossible for physicians to perform this procedure in the physician office setting for Medicare beneficiaries. Therefore, we request that CPT 36566 fall under the new code criteria for establishing non-facility rate setting and be fully transitioned in 2007.

If you have any questions, please do not hesitate to contact me at 301-296-4334.

Sincerely,

Jerry Stringham
President

15200 Shady Grove Road, Suite 350, Rockville, Maryland 20850 • 301-296-4334 • (f) 443-583-2476

Submitter : **Dr. Chainarong Limvarapuss** **Date: 10/04/2006**

Organization : **Solano Hematology Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

THe proposed new ASP pricing would have a detremintal effect on my ability to offer best therapies to my patients. This proposed pricing would would not reflect the actual available price in the marketplace, but would be based on a theoretical price that in reality, is not available. It is vital to the treatment of my patients, that I be able to purchase best medicines availble at a realistic price that is also reimbursable at a price that does not incur a loss for my prctice. Changing the ASP to this new proposed pricing would force me, and other physicians like me, to choose medicines based on lowest available cost instead of most effective avialable. I urgue you, for the health and welfare of the american people, to reconsider this proposed change. Thank you.

Impact

Impact

My comments deal with ASP Issues.

Submitter : Dr. Mark Kasari **Date:** 10/04/2006

Organization : Carolina Kidney Care Procedure Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Carolina Kidney Care is an extension of an office practice and had been established two years ago. The center is supporting a large dialysis population. We have seen an improvement in fistulas, but maintaining access patency remains a problem. Procedural reimbursement covers the Nursing staff, equipment-angioplasty balloons, wires and catheters, a radiology technician, and other personnel. A reduction in reimbursement will adversely effect our patients and may increase inpatient procedures and hospitalizations. I support the position as outlined by the American Society of Diagnostic and interventional Nephrology (ASDIN). Thank you

Submitter : **Laura Lewis** **Date: 10/04/2006**

Organization : **Carolina Kiy Care Procedure Center**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : Carolina Kidney Care Procedure Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : **Miss. Daniela Gibbs** **Date: 10/04/2006**

Organization : **Carolina Kidney Care**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Mr. Richard Nee **Date:** 10/04/2006

Organization : RMS Lifeline Inc.

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See Comment

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.