**Submitter :** Dr. Walter Nikesch **Date:** 10/05/2006

**Organization :** CyberKnife Center of Palm Beach

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

GENERAL

October 5, 2006

I am presently working at a freestanding CyberKnife Radiosurgery Center. We have been in operation for about 1 year. I have seen first hand what radiosurgery using this modality can do to improve patients lives. Most of our patients have cancer and no other treatment options. This is their only hope. We ve had many complete responses in cases which were considered hopeless. Funding and reimbursment for this type of procedure should not be cut.

Our number one treatment area is lung cancer in patients for one reason or another who cannot or will not undergo surgery. Radiosurgery is a painless procedure with low morbidity and is well tolorated by these patients. We are able to ablate their tumors in most cases. Improtantly . . . the cost of this procedure is much less than that of surgery and the post surgical care.

Several studies are presently under way to determine if radiosurgery is as good as surgery in tumor ablation. Preliminary results are good. Funding should not be cut for this procedure since in the long run it could reduce overall health care costs.

Thank you

Walter Nikesch, PhD, FACR, FAAPM
Director of Physics
CyberKnife Center of Palm Beach
Phone 561-799-2828
Fax 561-775-3788

**Submitter :** Mr. Greg Smith **Date:** 10/05/2006

**Organization :** Womble Carlyle Sandridge & Rice, PLLC

**Category :** Attorney/Law Firm

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-439-Attach-1.DOC

HHS-1321-P
439

WOMBLE CARLYLE SANDRIDGE & RICE

A PROFESSIONAL LIMITED LIABILITY COMPANY

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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: File Code CMS–1321–P**
**In Opposition to: Section I. Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests**

To Whom It May Concern:

The purpose of this letter is to comment formally in opposition to CMS' August 22, 2006 Proposed Rules that address changes to "Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests." Our firm represents a mobile imaging company that provides a diagnostic ultrasound service in five (5) states in the Southeast (the "Company"). The Company's service is provided with technologically advanced equipment and highly qualified and experienced technologists in many areas where the quality of diagnostic services is inferior and/or access is limited. Unlike CT and MRI imaging technologies, ultrasound is a much lower cost, portable technology that may be effectively and efficiently offered in the physician practice suite and supervised by the treating / ordering physician.

While not entirely clear, the Proposed Rules would seem to preclude the Company's (and that of other "on-site" or "in-office" suppliers of ultrasound services) ability to provide its services as it does currently. We believe strongly that the resulting impact of these Proposed Rules if adopted would be highly detrimental to Medicare Program Patients in terms of reduced access to and quality of valuable diagnostic imaging services.

The unintended effects of CMS' Proposed Rules, if adopted, are as follows:

**1. Reduced Access to Diagnostic Services**

In-office ultrasound suppliers like the Company provide services in physician practices, many of which are located in rural, non-metropolitan areas in which the quality and convenience of diagnostic ultrasound is not available or limited.

The Company provides ultrasound service in the physician's practice facility under the direction, control and supervision of the on-site physician and physician staff. For Medicare beneficiaries, the convenience of on-site service is very important in determining whether the patient ultimately receives the ultrasound imaging study. In certain markets, alternative service outlets (e.g. hospital outpatient imaging departments and fixed imaging centers) may entail drives beyond a twenty (20) mile radius for patient treatment. In other markets, service delays of 10-14 days for the scheduling of an exam are not uncommon. These lengthy drive times and scheduling delays do not exist with on-site, imaging services.

In-office ultrasound service is not only convenient, it is provided in a comfortable, familiar environment for Medicare patients who dislike the difficulty of accessing hospital-based imaging departments. From a patient convenience standpoint, patients are more likely to follow physician orders to have an imaging study if it is performed in the physician's office versus the hospital.

In-office ultrasound providers are also able to have direct communication and interaction with the treating physician in urgent healthcare situations (e.g. AAA, DVT, etc.) in which immediate action must be taken to insure the best treatment for the patient. As well, patients value the involvement of their trusted physician in diagnostic imaging services which is made possible by the on-site nature of our service.

**Conclusion: Proposed Rules, if adopted, will result in reduced access for Medicare patients to imaging services in rural and other market areas.**

**2. Reduced Quality of Services to Medicare Patients**

The Proposed Rules, if adopted, would limit the Company's (and other high quality ultrasound suppliers) ability to provide its high quality diagnostic ultrasound service to physicians. Physicians rely on the Company to discover and rule out patient pathology with clinical excellence that is unavailable locally. The Company's clinical personnel maintain the highest levels of credentials in the industry through the ARDMS®. The Company's current clinical staff comprises the top one (1) percent of clinicians nationally based on the number of credentials individually maintained through the ARDMS®, a nationally recognized organization that certifies the quality of ultrasound technologists. The Company will no longer be able to provide this clinical talent in the market place if the Proposed Rules are adopted.

In addition to the quality of the Company's service delivered through the technical component of the service, the Company also only contracts with board certified radiologists and cardiologists for the interpretation of ultrasound studies. In today's environment where radiologists and cardiologists are in high demand and limited in the rural healthcare environment, the Company facilitates an interpretation from a very experienced and trained medical professional that otherwise would be unavailable. The delivery of these high quality, professional services is made possible by significant Company investment in information technology.

The Company currently provides ultrasound service to smaller, rural hospitals in certain markets since these facilities are unable to recruit and maintain qualified medical technologists to provide ultrasound at their facilities. While the Proposed Rules would not directly affect the services provided to these facilities, the indirect impact of the Proposed Rules on physician customers would curtail the Company's provision of these rural hospital-based services.

Any discussion of the Proposed Rules would not be complete without addressing one possible alternative to on-site, IDTF providers, which is available to physician practices – direct physician ownership of equipment. Based on actual experience, we believe strongly for several reasons that lower quality ultrasound is more prevalent in practices where equipment is directly owned by the physician practice.

One, ultrasound technologists in these environments do not provide enough volume of ultrasound to hone adequately their skills or to grow experience levels.

Two, credentialing and experience requirements are not as strict or as easily monitored or enforced.

Three, internal training resources are non-existent or severely limited as compared to larger IDTF ultrasound providers who manage, train and develop teams of Sonographers with cross-training abilities and internal CME resources.

Four, in certain situations, physician practices may purchase sub-standard or old ultrasound technology due to limited exam volume that is not sufficient to cover the cost of premium technology. Of course, many small physician practices cannot afford imaging technology regardless of its cost. On-site providers must offer the most current, diagnostically sensitive equipment in order for the service to provide the highest quality of patient care to appeal to physician practices.

Lastly, the fact that the ultrasound service is "contracted" versus "owned" does not changed the basic need for a valid, medically necessary ultrasound exam order from the physician. In fact, external IDTF standards and requirements, together with internal physician policies, are likely to lead to increased compliance in this regard and better control over the appropriate ordering of imaging services.

**Conclusion: Proposed Rules, if adopted, will result in a reduction in the quality of imaging services available to Medicare patients in rural and other market areas.**

## Other Considerations

The Company recognizes that the practices of some providers of imaging services in the marketplace may concern CMS for the potential of overutilization. In the provision of its services, the Company has adopted the following safeguards to eliminate the potential for overutilization and to integrate appropriately the imaging service into the physician's practice:

1. The Company provides services under a written lease for a year or more (personnel and equipment) for a set amount of time rather than on per procedure basis. The physician practice is at risk for loss in providing the ultrasound service and the fixed lease payments do not vary with the volume or value of referrals.

2. Supervision of ultrasound technologist. The physician practice is required to supervise and is responsible for the on-site ultrasound technologist.

3. Ultrasound Utilization Review Program. The C ompany administers ( and physician practices agree to) a utilization review program, which addresses the medical necessity of ordered ultrasound studies on a semi-annual basis to identify potential misuse or overuse of ultrasound imaging by the practice.

**Conclusion**

The Company strongly opposes CMS' Proposed Rules in its application to providers of diagnostic imaging services. We believe that the proposed IDTF supplier compliance standards in Sections L.2, L.3 and L.4 of the August 22, 2006 Federal Register, combined with the requirement that imaging services be provided on-site in the ordering physician's practice suite, will address the overutilization concerns of CMS. The unnecessary breadth of the proposed regulations needlessly sacrifices the high quality, convenient, accessible patient care that can be provided directly at the offices of physician practices by on-site imaging suppliers. Any regulatory action by CMS should instead focus on arrangements where the potential for abuse is greater and the corresponding patient and program benefits are substantially less; i.e., diagnostic services not provided directly at the traditional physician practice site.

Sincerely,

**WOMBLE CARLYLE SANDRIDGE & RICE, PLLC**

Greg Smith, Member

**Submitter :** **Dr. Anonymous** **Date: 10/05/2006**

**Organization :** **Dr. Anonymous**

**Category :** **Federal Government**

**Issue Areas/Comments**

**Background**

Background

IDTFs

**GENERAL**

GENERAL

CMS should require IDTFs to provide a copy of lease (minimum 12 months) or proof of ownership for the property.

**Submitter :** Dr. Michael Hardacre **Date:** 10/05/2006

**Organization :** Central Indiana Cancer Centers

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

Purposed robotic radiosurgery changes for Jan. 2007 would significantly impact my ability as an oncologist to provided the lastest needed technologies in the war on cancer.

CMS-1321-P-441-Attach-1.DOC

Attach #
441

Michael C. Hardacre, M.D.
Director of Radiosurgery
Central Indiana Cancer Centers
1346 E. County Line Road, Indianapolis, IN, 46227
(317)841-5656

October 4, 2006

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

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request yo ur assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that "***any SRS code changes would be premature without cost data to support a code restructuring***". (CMS-1506-P, page 156).

[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

| | **# centers operating Jan 1st** | **New centers treating during year** | **% of centers in first year** |
|---|---|---|---|
| **2004** CY 2004 | 12 | 8 | 67% |
| **2005** CY 2005 | 20 | 15 | 43% |

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities w ith vastly differing resource r equirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

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

Sincerely,

Michael C. Hardacre, M.D.
Central Indiana Cancer Center
1346 E. County Line Road, Indianapolis, IN, 46227
(317)841-5656

**Submitter :** **Mr. Mohamed Ali** **Date: 10/05/2006**

**Organization :** **Mr. Mohamed Ali**

**Category :** **Other Practitioner**

**Issue Areas/Comments**

**GENERAL**

GENERAL

My comment is with regards to the reduction in payments for the CyberKnife treatments. If today I am told that I have brain tumor or one very close to my spinal cord I don't think I will hesitate a moment to ask for CyberKnife. This is the most modern, smart technology availabela and it needs to be supported by all concern.

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

**Organization :** **American Pharmacists Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-443-Attach-1.DOC

# American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

October 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
PO Box 8015
Baltimore, MD 21244-8015

Re: CMS-1321-P

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed revisions to the payment policies under the physician fee schedule for calendar year 2007. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The proposed rule contains a number of modifications to the payment methodology for products and services reimbursed under Medicare Part B. One issue addressed in the rule – payment for covered outpatient drugs and biologicals – is of significant interest to the Association and our pharmacist members. APhA appreciates the Centers for Medicare and Medicaid Services' (CMS) efforts to refine the payment system so that it accurately pays for the cost of the product and the costs associated with the administration and/or supply of the product, however, we have two concerns with the proposed rule. Specifically, APhA is concerned that the regulation fails to account for class of trade issues in the calculation of ASP and does not address pharmacy supplying fees or dispensing fees.

**Proposed Payment for Covered Outpatient Drugs and Biologicals**

***ASP Issues***

The proposed rule examines a number of issues related to the calculation and submission of manufacturers' Average Sales Price (ASP) data. These issues include the effect of price concessions and service fees paid by manufacturers on ASP data. According to the proposed rule, CMS intends to issue a separate rule to clarify how price concessions and fees must be treated for purposes of the ASP calculation.

APhA supports the Agency's efforts to refine the ASP calculation to more accurately reflect the cost to obtain a drug product. However, we must reiterate our concerns that the ASP calculation does not accurately determine the "average" price. Because the ASP is intended to represent the "average" rate

that Part B suppliers pay, the ASP calculation includes sales to hospitals and physicians, as well as pharmacies. The payment methodology fails to take into account the various classes of trade. Drug products are not uniformly priced across all purchasers – pharmaceutical pricing is based on various classes of trade. Because physicians prescribe – and in most instances pharmacists do not – manufacturers can encourage physician prescribing of certain drugs by offering a lower price to physician purchasers. Most pharmacies and pharmacists do no have access to this lower price.

Because not all purchasers have access to the same prices, APhA urges the Agency to further revise the ASP formula to take into account the various classes of trade. The Agency must also continually evaluate the ASP reimbursement rate to determine if purchasers – including pharmacists and pharmacies – can acquire Part B products as the ASP rate. If pharmacists and other suppliers are unable to provide Part B drugs at the ASP reimbursement rate, many suppliers may be required to discontinue providing these drug products to their patients and physicians. This could result in patients losing access to these valuable medications.

***Dispensing Fee***

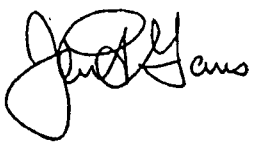
In 2005, CMS implemented a separate pharmacy supplying fee for immunosuppressive drugs, oral anti-cancer agents, and oral anti-emetics used as part of a chemotherapy regimen, and increased the existing dispensing fee for inhalation drugs. For 2006, the Agency made slight revisions to the supplying and dispensing fees for all refill prescriptions.

The proposed fee schedule for 2007, however, does not address the issue of pharmacy supplying or dispensing fees. The proposed rule contains no mention of either of these payments to pharmacies. APhA assumes that CMS chose not to address these fees in the proposed rule because the Agency intends to maintain the current supplying and dispensing fees established in 2006. We request that the Agency clarify in the final rule that it will continue to reimburse pharmacy providers at the 2006 supplying and dispensing rates.

In conclusion, APhA reiterates our request that CMS revise the ASP calculation formula to account for the various classes of trade. We also ask the Agency to address the issue of pharmacy supplying and dispensing fees in the final regulation. At a minimum, the Agency must clarify that it will continue to reimburse pharmacy providers at the 2006 supplying and dispensing fee rates.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Kristina E. Lunner, APhA's Acting Vice President of Policy and Communications at 202-429-7507 or klunner@aphanet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Kristina E. Lunner, Acting Vice President, Policy & Communications

**Submitter :** **Mr. Robert Knorr** **Date: 10/05/2006**

**Organization :** **Tapestry Medical**

**Category :** **Other Health Care Provider**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachments

**Impact**

Impact

SUMMARY: We believe that the proposed reductions of 40-50% for G-0248 and G-0249 are unreasonable and do not reflect the true cost of providing these atypical services. We are requesting that CMS increase the Direct PE RVUs for G-0248 by at least 1.57 and for G-0249 by at least 0.82 over current RVUs in order to more accurately reflect the actual cost of these services. We recommend the total Fully Implemented RUV for G-0248 be no less than 8.20 and for G0249 be no less than 4.79. These recommendations are based on our experience as one of the few providers of Home INR Monitoring services in the country.

We have provided additional data to support our recommendation

CMS-1321-P-444-Attach-1.PDF

CMS-1321-P-444-Attach-2.PDF

Hetchet
497

**TAPESTRY** MEDICAL

1404 Concannon Blvd., Livermore, CA 94550

October 6, 2006

Hon. Leslie Norwalk, ESQ.
Deputy 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: "Provisions 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**: We believe that the proposed reductions of 40-50% for G-0248 and G-0249 are unreasonable and do not reflect the true cost of providing these atypical services. We are requesting that CMS increase the Direct PE RVUs for G-0248 by at least 1.57 and for G-0249 by at least 0.82 over current RVUs in order to more accurately reflect the actual cost of these services. We recommend the total Fully Implemented RUV for G-0248 be no less than 8.20 and for G0249 be no less than 4.79. These recommendations are based on our experience as one of the few providers of Home INR Monitoring services in the country.

Dear Ms. Norwalk:

Tapestry Medical is pleased to provide this comment letter to the "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"). We wish to comment specifically on proposed § II.A.5.(k) as it relates to the Resource-Based Practice Expense (PE) RVU Proposals for CMS Billing Codes G-0248 and G-0249. Tapestry Medical is an approved Medicare provider focused exclusively on providing Home INR Monitoring services (G-0248 and G-0249). Several years, I was personally involved in the original estimation of resources requirements when the Home INR Monitoring Program was first implemented. At the time, we provided CMS with a comprehensive analysis of our good faith estimate of the resource requirements for these atypical services. Our comments today are based on the experience and data that we have collected while providing over 2,500 G-0249 services to hundreds of eligible beneficiaries over the past two years.

We are concerned that the substantial proposed reductions in PE RVUs for these two codes do not accurately reflect the true cost of providing these unique services. Based on our updated analysis and experience, we recommend that CMS increase the Direct PE RVUs:

1. for G-0248 by at least 1.57 over current levels resulting in a Fully Implemented PE RVU of no less than 8.20 and
2. for G-0249 by at least 0.82 over current levels resulting in a Fully Implemented PE RVU of no less than 4.79.

Typically, we would also ask for a corresponding increase in Indirect PE RVUs based on a typical ratio of direct to indirect expenses. However, we recognize that the significant general operating costs associated with our initial Medicare enrollment was atypical. However, we reserve the right to revisit this assumption if this level of indirect costs continues in the future.

Home INR Monitoring is a unique benefit that involves providing beneficiaries with dedicated capital equipment and ancillary supplies to enable self-testing. In addition, providers such as Tapestry Medical educate new users in the care and use the INR monitoring equipment and facilitate the documentation and transfer of patient-generated testing results to the beneficiary's treating physician. Non-physician providers such as Tapestry Medical play an important role in providing access to this unique service because treating physicians have expressed strong reluctance to provide either G-0248 or G-0249 themselves.[1,2] Considering physician's reluctance to provide G-0248 or G-0249 services, CMS should expect that access to Home INR Monitoring will be seriously compromised if the substantial proposed RVU reductions are implemented.

Companies such as Tapestry Medical underwrite the risk associated with purchasing expensive capital equipment by providing the INR monitor to the beneficiaries and ensuring that patients test in accordance with their physician's instructions. Equipment can be lost, stolen, misused or patients can discontinue using the equipment for any reason. Retrieving and recertifying unused equipment from beneficiaries can be extremely difficult, time-consuming and costly. Nonetheless, we undertake this risk based on the assumptions that:

1. the cost of the equipment will be recouped over time as G-0249 services are provided,
2. beneficiaries will require (on average) 8 units of G-0249 services per year[3], and
3. RVUs for G-0248 and G-0249 will be sufficient to cover the value of the equipment and inadvertent equipment and supply wastage/spoilage by the beneficiary.

I am very concerned that the Direct Practice Expense Values used to create Resource-Based Practice Expense Relative Value Units in the Proposed Rule have resulted in substantial

[1] See CMS-1321-P Public Comment (#92425) submitted by Dr. Jack Ansell – Chairman of Anticoagulation Forum on October 5, 2006.

[2] See also, the August 2002 of "CAP TODAY" (www.cap.org) which highlights concerns expressed by the American College of Cardiology and other stakeholders.

[3] One unit of service supports 4 self-tests over a maximum frequency of four tests every 28 days

proposed reductions in the Non-Facility PE RVUs for G-0248 and G-0249. If fully implemented, these proposed reductions would result in a 50% decrease in G-0248 RVUs and a 40% decrease in G-0249 RVUs. We believe that such reductions are unreasonable and are substantially less than the true cost of providing these services. Furthermore, such reductions do not adequately consider the substantial risk that providers such as Tapestry Medical have already borne with beneficiaries have who have been provided with one of our INR monitors.

Based on meetings that I with CMS several years ago, I suspect that the methodology being used by CMS to calculate the per unit cost of the INR monitor in the Proposed Rule may be contributing to the unreasonable RVUs reductions that are now being proposed. It should be remembered that each INR monitor is provided to beneficiaries for their exclusive use over the estimated useful life of the equipment. Given that beneficiaries perform (on average) 32 tests or 8 units of G-0249 services per year, we reasonably expect that they will perform 40 units of G-0249 services over the expected useful life of the equipment. Therefore, the $1,975 price of the INR monitor should be amortized over 40 units of service at a rate of ~$50 per G-0249. I recommend that CMS review its methodology to ensure that the final calculation used in the Fully Implemented PE RVUs support this amortization rate for the INR monitor.

I recommend that CMS implement the following changes to the NPRM Direct Practice Expense Inputs for G-0248 and G-0249. These recommended changes have been incorporated in the attached three separate worksheets in the excel workbook. These files follow the same format as CMS' NPRM Direct Practice Expense Inputs included in the Proposed Rule.

| **Direct Practice Expense Input** | **Applicable Code** | **Recommended Change** |
|---|---|---|
| Clinical Labor | | |
| | G-0248 | 1. RATE should change in future years to reflect increases in Social Security Cost of Living Allowance.<br>2. Increase G1_I from 50 to 120 minutes to reflect the minimum amount of time required for clinical staff to perform demonstrate and document use and care of INR monitor in accordance with protocol used by manufacturer to obtain FDA approval.<br>3. Decrease G1X_I from 20 to 10 minutes to reflect the minimum time required for clinical staff to confirm patient's ability to perform testing after initial demonstration.<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs over current levels for this item by** |

| | | |
|---|---|---|
| | | **approximately 0.59.** |
| | G-0249 | 1. DESC should change to reflect Medical/Technical Assistant used to provide testing supplies and report test results to treating physician.<br>2. RATE should decrease in 2007 from 0.37 to 0.26 to reflect the lower level clinical staff required.<br>3. RATE should change in future years to reflect increases in Social Security Cost of Living Allowance.<br>**4.** Increase GO_I from 13 to 40 minutes to reflect the actual time required for clinical staff to provide testing supplies on a monthly basis and collect, document and report 4 test results to treating physician. **[NOTE: This time of 40 minutes per 1 unit of service (i.e. 4 tests) is based on the actual time required to provide over 2,500 G-0249 services over the past two years.]**<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.15.** |
| Medical Equipment | | |
| | G-0248 | 1. PRICE should decrease from $2000 to $1975 to reflect the current price for the market-leading CoaguChek® PST Monitor manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>2. EQTI should be changed from 50 to 120 to be consistent with the above comment #2 related to Clinical Labor – G-0248.<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.52.** |
| | G-0249 | 1. LIFE should be changed from 5 to 3 to reflect the fact that beneficiaries require (on average) only 8 units of G-0249 services per year rather than the 13 unit maximum allowance. **[NOTE: It appears that CMS currently amortizes the full price of the monitor over 65 units of G-0249 (i.e. 5 year life times the 13 unit maximum allowed). Since our experience over the past two years is that (on average) patients only require 8 units of G-0249 per year (i.e. 40% less than the 13 unit maximum), we are recommending that the LIFE be reduced by 40% in order to adjust the amortization** |

| | | |
|---|---|---|
| | | **rate to a level that enables providers such as us to recover the full price of the equipment over the 40 G-0249 units that we expect to provide over a five year period.]**<br>2. PRICE should decrease from $2000 to $1975 to reflect the current price for the market-leading CoaguChek® PST Monitor manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>3. The following items which are dedicated to the collecting, documenting, and reporting of INR test data (and not part of our general overhread) should be added to the list of equipment required to provide G-0249 services.<br>• Customized INR Monitoring Computer System (ED011) at $75,000<br>• Computer Desktop (ED021) at $2,501<br>• Computer Server (ED022) at $22,567<br>• Laser Printer (ED032) at $1,199<br>4. The LIFE for this additional dedicated equipment should be 5 years.<br>5. The EQTI for these additional items should be 12 minutes. This time is based on a calculation of 10,000 minutes of monthly operating time divided by our expected average installed base of customers over the next 5 years (~800).<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.58.** |
| Supplies | | |
| | G-0248 | 1. PRICE of test strip INR (SJ055) should increase from $21 to $21.875 to reflect the current price for the market-leading CoaguChek® PST strip manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>2. The following items should be added to the list of supplies required to provide G-0248 services.<br>a. Video Tape (SK086) at $2.049<br>b. Device Shipping Cost (SK106) at $12.00<br><br>**We estimate that the above changes will increase the Non-Facility PE RVUs for this item by approximately 0.46.** |

| | | |
|---|---|---|
| | G-0249 | 1. PRICE of test strip INR (SJ055) should increase from $21 to $21.875 to reflect the current price for the market-leading CoaguChek® PST Monitor manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>2. The following item should be deleted from the list of items needed to provide testing supplies to patients when providing G-0249 services.<br>a. Swab-pad, alcohol (SJ053).<br><br>**We estimate that the above changes will increase the Non-Facility PE RVUs for this item by approximately 0.09.** |

**Summary:**
The above changes are based on our actual experience in providing over 2,500 G-0249 services over the past two years. We estimate that the aforementioned changes will increase the Direct PE RVUs for G-0248 by 1.57 over current levels and G-0249 by 0.82 over current levels and more accurately reflect the actual cost of providing these services. As one of the few providers in the country providing Home INR Monitoring services, we believe that these changes are the minimum required for us to continue servicing beneficiaries in the future.

On behalf of the hundreds of beneficiaries and physicians that we service, I sincerely appreciate the opportunity to provide these comments.

Sincerely,

Robert J. Knorr
Chief Executive Officer

| | | PROCCODE | SOURCE | CPEP | CATEGORY_07 | Supply_Code_07 | DESCRIPTION | QTY_07 | UNIT_07 | PRICE | QTY_NF | QTY_FAC | in_cost | out_cost | GLOBAL | Post_Op_Visits | Source_for_Xwalk | PEAC_mtg | PEAC_Tab | Estimated DIRECT PE RVU |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **G-0248** | | | | | | | | | | | | | | | | | | | | |
| | 2007 NPRM | | | | | | | | | | | | | | | | | | | |
| | | G0248 | CMS | CMS | Hypodermic, IV | SC021 | lancet | 1 item | | 0.038 | 4 | | 0.152 | | XXX | | | | | |
| | | G0248 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | 1 item | | 0.013 | 4 | | 0.052 | | XXX | | | | | |
| | | G0248 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | 1 item | | 21 | 4 | | 84 | | XXX | | | | | |
| | | G0248 | CMS | CMS | Office Supply, Grocery | SK011 | battery, AAA | 1 item | | 0.485 | 3 | | 1.455 | | XXX | | | | | |
| | | G0248 | CMS | CMS | Office Supply, Grocery | SK062 | patient education booklet | 1 item | | 1.55 | 1 | | 1.55 | | XXX | | | | | 0.00 |
| | Recommendation | | | | | | | | | | | | | | | | | | | |
| | No change | G0248 | CMS | CMS | Hypodermic, IV | SC021 | lancet | 1 item | | 0.038 | 4 | | 0.152 | | XXX | | | | | 0.00 |
| | No change | G0248 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | 1 item | | 0.013 | 4 | | 0.052 | | XXX | | | | | 0.00 |
| | Change price | G0248 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | 1 item | | 21.875 | 4 | | 87.50 | | XXX | | | | | 2.31 |
| | No change | G0248 | CMS | CMS | Office Supply, Grocery | SK011 | battery, AAA | 1 item | | 0.485 | 3 | | 1.455 | | XXX | | | | | 0.04 |
| | No change | G0248 | CMS | CMS | Office Supply, Grocery | SK062 | patient education booklet | 1 item | | 1.55 | 1 | | 1.55 | | XXX | | | | | 0.04 |
| | Add | G0248 | CMS | CMS | Office Supply, Grocery | SK088 | video tape, VHS | 1 item | | 2.048 | 1 | 0 | 2.048 | 0.000 | | | | | | 0.05 |
| | Add | G0248 | CMS | CMS | Office Supply, Grocery | SK106 | device shipping cost | 1 item | | 12 | 1 | | 12 | | XXX | | | | | 0.32 |
| | | | | | | | Estimated Impact of Changes on Direct RVUs | | | 0.46 | | | | | | | | | | 2.76 |
| **G-0249** | | | | | | | | | | | | | | | | | | | | |
| | 2007 NPRM | | | | | | | | | | | | | | | | | | | |
| | | G0249 | CMS | CMS | Hypodermic, IV | SC021 | lancet | 1 item | | 0.038 | 4 | | 0.152 | | XXX | | | | | |
| | | G0249 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | 1 item | | 0.013 | 4 | | 0.052 | | XXX | | | | | |
| | | G0249 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | 1 item | | 21 | 4 | | 84 | | XXX | | | | | |
| | Recommendation | | | | | | | | | | | | | | | | | | | |
| | No change | G0249 | CMS | CMS | Hypodermic, IV | SC021 | lancet | 1 item | | 0.038 | 4 | | 0.152 | | XXX | | | | | 0.00 |
| | Delete | G0249 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | 0 item | | 0 | 0 | | 0 | | XXX | | | | | 0.00 |
| | Change price | G0249 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | 1 item | | 21.875 | 4 | | 87.50 | | XXX | | | | | 2.31 |
| | | | | | | | Estimated Impact of Changes on Direct RVUs | | | 0.09 | | | | | | | | | | 2.31 |

**Submitter :** Mr. Robert Knorr **Date:** 10/05/2006

**Organization :** Tapestry Medical

**Category :** Other Health Care Provider

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment. Which should have been attached to my previous submission related to Section II.A.5.(k).

CMS-1321-P-445-Attach-1.PDF

**CLINICAL LABOR**

| | PROC CODE | SOURCE | CPEP | STAFFCODE | DESC | RATE | g0_I | g1_I | g1x_I | g0_o | g1_o | g1x_o | IN | OUT | SOURCECD | GLOB | PEAC_MTG | PEAC_TAB | Estimated DIRECT PE RVU |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **G-0248** | | | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | | | |
| | G0248 | CMS | CMS | L037D | RN/LPN/MTA | | 0.37 | 5 | 50 | 20 | 0 | 0 | 0 Y | N | | XXX | | | |
| Recommendation | | | | | | | | | | | | | | | | | | | |
| Changes | G0248 | CMS | CMS | L037D | RN/LPN/MTA | | 0.37 | 5 | 120 | 10 | 0 | 0 | 0 Y | N | | XXX | | | 1.32 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | | | | | | | | | | | **1.32** |
| **G-0249** | | | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | | | |
| | G0249 | CMS | CMS | L037D | RN/LPN/MTA | | 0.37 | 0 | 13 | 0 | 0 | 0 | 0 Y | N | | XXX | | | |
| Recommendation | | | | | | | | | | | | | | | | | | | |
| Changes | G0249 | CMS | CMS | L028A | Medical Technical Assistz | | 0.26 | 0 | 40 | 0 | 0 | 0 | 0 Y | N | | XXX | | | 0.27 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | | | | | | | | | | | **0.27** |

**EQUIPMENT**

| | PROCCODE | SOURCE | CPEP | Equip_Category_07 | Equip_Code_07 | Description | LIFE | PRICE | EQTI | EQTO | Value d_NF | Valued _FAC | SOURC ECD | GLOB | PEAC_mtg | PEAC 2007_ _tab | code | Estimated DIRECT PE RVU |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **G-0248** | | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | | |
| | G0248 | CMS | CMS | OTHER EQUIPMENT | EQ031 | INR monitor, home | 5 | 2000 | 50 | 0 | Y | Y | | XXX | | | | |
| Recommendation | | | | | | | | | | | | | | | | | | |
| Change | G0248 | CMS | CMS | OTHER EQUIPMENT | EQ031 | INR monitor, home | 3 | 1975 | 120 | 0 | Y | Y | | XXX | | | | 7.82 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | **6.52** | | | | | | | | | **7.82** |
| **G-0249** | | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | | |
| | G0249 | CMS | CMS | OTHER EQUIPMENT | EQ031 | INR monitor, home | 5 | 2000 | 20 | 0 | Y | Y | | XXX | | | | |
| Recommendation | | | | | | | | | | | | | | | | | | |
| Change | G0249 | CMS | CMS | OTHER EQUIPMENT | EQ031 | INR monitor, home | 3 | 1975 | 20 | 0 | Y | Y | | XXX | | | | 1.30 |
| Add | G0249 | CMS | CMS | DOCUMENTATION | ED011 | computer system, record and verify | 5 | 75000 | 12 | 0 | Y | Y | | XXX | | | | 1.50 |
| Add | G0249 | CMS | CMS | DOCUMENTATION | ED021 | computer, desktop, w-monitor | 5 | 2501 | 12 | 0 | Y | Y | | XXX | | | | 0.05 |
| Add | G0249 | CMS | CMS | DOCUMENTATION | ED022 | computer, server | 5 | 22567 | 12 | 0 | Y | Y | | XXX | | | | 0.45 |
| Add | G0249 | CMS | CMS | DOCUMENTATION | ED032 | printer, laser, paper | 5 | 1199 | 12 | 0 | Y | Y | | 000 | | | | 0.02 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | **6.99** | | | | | | | | | **3.33** |

**SUPPLIES**

| | PROCCODE | SOURCE | CPEP | CATEGORY_07 | Supply_Code_07 | DESCRIPTION | QTY_07 | UNIT_07 | PRICE | QTY_I | QTY_Fin_cost | out_cost | GLOBAL | Post_Op_Source_for_3 | PEAC | PEAC_Tab | Estimated DIRECT PE RVU |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **G-0248** | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | |
| | G0248 | CMS | CMS | Hypodermic, IV | SC021 | lancet | | 1 item | 0.038 | 4 | 0.152 | | XXX | | | | |
| | G0248 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | | 1 item | 0.013 | 4 | 0.052 | | XXX | | | | |
| | G0248 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | | 1 item | 21 | 4 | 84 | | XXX | | | | |
| | G0248 | CMS | CMS | Office Supply, Grocery | SK011 | battery, AAA | | 1 item | 0.485 | 3 | 1.455 | | XXX | | | | 0.00 |
| | G0248 | CMS | CMS | Office Supply, Grocery | SK062 | patient education booklet | | 1 item | 1.55 | 1 | 1.55 | | XXX | | | | |
| Recommendation | | | | | | | | | | | | | | | | | |
| No | G0248 | CMS | CMS | Hypodermic, IV | SC021 | lancet | | 1 item | 0.038 | 4 | 0.152 | | XXX | | | | 0.00 |
| No | G0248 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | | 1 item | 0.013 | 4 | 0.052 | | XXX | | | | 0.00 |
| Cha | G0248 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | | 1 item | 21.875 | 4 | 87.50 | | XXX | | | | 2.31 |
| No | G0248 | CMS | CMS | Office Supply, Grocery | SK011 | battery, AAA | | 1 item | 0.485 | 3 | 1.455 | | XXX | | | | 0.04 |
| No | G0248 | CMS | CMS | Office Supply, Grocery | SK062 | patient education booklet | | 1 item | 1.55 | 1 | 1.55 | | XXX | | | | 0.04 |
| Add | G0248 | CMS | CMS | Office Supply, Grocery | SK086 | video tape, VHS | | 1 item | 2.049 | 1 | 0 2.049 | 0.000 | | | | | 0.05 |
| Add | G0248 | CMS | CMS | Office Supply, Grocery | SK105 | device shipping cost | | 1 item | 12 | 1 | 12 | | XXX | | | | 0.32 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | **6.68** | | | | | | | | **2.76** |
| **G-0249** | | | | | | | | | | | | | | | | | |
| 2007 NPRM | | | | | | | | | | | | | | | | | |
| | G0249 | CMS | CMS | Hypodermic, IV | SC021 | lancet | | 1 item | 0.038 | 4 | 0.152 | | XXX | | | | |
| | G0249 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | | 1 item | 0.013 | 4 | 0.052 | | XXX | | | | |
| | G0249 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | | 1 item | 21 | 4 | 84 | | XXX | | | | |
| Recommendation | | | | | | | | | | | | | | | | | |
| No | G0249 | CMS | CMS | Hypodermic, IV | SC021 | lancet | | 1 item | 0.038 | 4 | 0.152 | | XXX | | | | 0.00 |
| Del | G0249 | CMS | CMS | Pharmacy, NonRx | SJ053 | swab-pad, alcohol | | 0 item | 0 | 0 | 0 | | XXX | | | | 0.00 |
| Cha | G0249 | CMS | CMS | Pharmacy, NonRx | SJ055 | test strip, INR | | 1 item | 21.875 | 4 | 87.50 | | XXX | | | | 2.31 |
| | **Estimated Impact of Changes on Direct RVUs** | | | | | | | | **6.99** | | | | | | | | **2.31** |

**Submitter :** **Dr. Glen Coulomb** **Date: 10/05/2006**

**Organization :** **Dr. Glen Coulomb**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Responding to CMS proposed change in physician fee schedule for 36478 and 36479- Endovenous Laser Ablation-office based. I have several concerns over the '07 (PE) RVUs-
A. RVUs are continually falling from '05 levels- Practice expenses are constantly rising, especially salaries for Reg. Vascular Techs whose services are necessary for the imaging of diseased veins under the skin- these cuts will prevent physicians from being able to offer this necessary procedure and reduce access of Medicare beneficiaries to the non-surgical approach(with resulting better outcomes and reduced morbidities) of their symptomatic vein disease.
B. The conversion factor for '07 is also reduced- further lowering reimbursement.
C. Values for radiofrequency ablation have been consistently higher than those for laser ablation. The initial capital outlay for the laser is higher, and the per procedure costs for the physician are about the same. Therefore , the overall cost to deliver this service to our patients is higher, and several studies demonstrate a higher post-procedure risk of DVTs for radiofrequency procedures.

I would recommend that the non-facility practice expense RVU for 36475 remain at the '06 level of 51.5 and the RVU for 36478 be raised to the same.
I would be glad to discuss this with any interested committee member.
Thank you in advance,
Glen Coulomb, M.D.
Member, American College of Phlebology

**Submitter :** **Dr. Gary Cunningham** **Date: 10/05/2006**

**Organization :** **Dr. Gary Cunningham**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-447-Attach-1.RTF

Gary K. Cunningham, D.O.
Phlebology/Sclerotherapy
6901 S Yorktown Ave
Tulsa, OK 74136

**10/04/2006**

**RE: CMS 1321-P - Proposal dated September 21, 2006**

The above referenced proposal contains substantial reductions in the physician fee schedule for CPT 36478 (and CPT 36479) when this service (Endovenous Laser Ablation) is performed in a non-facility (e.g., office-based) setting.

This proposal continues a dangerous downward trend in reimbursement for these procedures as noted by the following for CPT 36478:

2006: RVU 46.91
2007: RVU 43.53
2008: RVU 40.84

While reimbursement for this service continuously declines, practice expenses incurred to perform these medically necessary services relentlessly increase, placing an increasingly unsustainable financial burden on the physician treating Medicare patients in need of this care.

Reimbursement must be adequate to cover pro-rata general overhead expenses of operating a clinic, including administrative, clerical, and medical personnel, security, sterilization services, office equipment and supplies, office rent, janitorial services, medical waste disposal, OSHA compliance, liability and other insurance, laboratory costs, repairs, utilities, etc., etc. In addition, there are substantial direct costs associated with these particular procedures. Acquisition and maintenance costs for the laser equipment are typically between approximately $40,000 and $80,000 for the laser generator which has a useful life of perhaps 7 to 10 years plus approximately $4,000 to $8,000 per annum in basic maintenance exclusive of occasional unplanned repair expense which can be extraordinary. (Our laser requires more than $7,000 in routine annual maintenance and required in excess of $35,000 in repairs in a single year.) Acquisition of venous duplex ultrasound equipment requires approximately $30,000 to $120,000 to which ongoing maintenance costs must be added. Fiberoptic laser catheters, percutaneous micropuncture access sets, vascular dilators and introducer catheters and guidewires are consumed with each procedure in addition to anesthesia supplies, anesthesia monitoring equipment and personnel, intravenous medication supplies, antiseptics, surgical instruments, sterile drapes, syringes, needles, gauze, tray covers, gloves, gowns, masks, eye protection, bandaging supplies, compression stockings, and sundry other procedural supplies. Finally, maintaining a registered vascular technologist on staff or using per diem or per procedure outside contract personnel can add enormously to procedure costs.

Even the *current* rate of reimbursement is only marginal in terms of compensation for physician services after subtracting practice expenses. We expect at least a 3% increase in expenses over the next year, which will translate into a decrease in physician compensation after expenses of between 4% and 21% (depending on individual practice overhead) *before any decrease in Medicare reimbursement is factored in*. Considering that we are already very near the point where it is becoming not worthwhile to provide this service under Medicare reimbursement, the planned reductions in Medicare allowables will surely compromise the availability of care for these patients.

Furthermore, under the proposal, reimbursement for CPT 36475 / 36476 (Radiofrequency Vein Ablation) continues

Gary K. Cunningham, D.O.
Phlebology/Sclerotherapy
6901 S Yorktown Ave
Tulsa, OK 74136

to be consistently higher than that for laser ablation as noted below:

| Year | RVU's 36475 - Radiofrequency | RVU's 36478 - Laser |
|---|---|---|
| 2006 | 51.50 | 46.91 |
| 2007 | 47.77 | 45.53 |
| 2008 | 44.42 | 40.84 |

The ostensible rational for this discrepancy is that the radiofrequency treatment catheter is more expensive than the laser treatment catheter. However, our facility owns both types of equipment and, in truth, each of these technologies are comparable in overall practice expense when all factors are considered including the higher initial capital acquisition cost, higher ongoing maintenance, and specialized safety training and personnel precautions that must be taken when using laser equipment.

**In summary, Medicare reimbursement for 36478 is already poor and there is no room for further reductions. Such decreases will certainly dissuade many practitioners from providing this service to Medicare beneficiaries, thus limiting their access to this medically necessary treatment. RVU's for 36478 are not reasonably balanced with those for 36475 and should be increased from 46.91 to 51.50 and maintained at or above that level now and for the foreseeable future. Similar action should be taken for the respective RVU's for 36479 relative to 36476.**

Thank you for your time and consideration in reviewing this important information. Please feel free to contact me if you have any questions.

Sincerely,

Gary K. Cunningham, D.O
GKC/sc

**Submitter :** Mr. Stuart Born **Date:** 10/05/2006

**Organization :** Rocky Mountain CyberKnife

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

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

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

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

**Organization :** ELMORE MEDICAL VEIN & LASER TREATMENT CENTER

**Category :** Physician

**Issue Areas/Comments**

**Background**

Background

AQUISITION COSTS OF TECHNOLOGY EXCEEDS PROPOSED PAYMENT

**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 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

DIMINISHED ACSESSED TO CARE FOR MEDICARE BENEFICIARIES

**Submitter :** **Mr. James Giger** **Date: 10/05/2006**

**Organization :** **Systematic Management Systems**

**Category :** **Other Health Care Professional**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-450-Attach-1.DOC

Reference File Code CMS-1321-P
Section (N) Public Consultation for Medicare Payment for
New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

## BACKGROUND

As identified by the House, Ways and Means Committee Report and finalized by the Conference Committee Report (copies attached) Section 4554 of the Balanced Budget Act of 1997 (BBA-1997) the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests (Committee) was formed to develop National Policies for the Medicare Part B Clinical Laboratory Tests Benefit.

Congress' statutorily mandated establishment of the Negotiated Rulemaking Committee, in essence, preempted the field of payment and coverage for the Medicare Part B laboratory benefits. The Committee's National Coverage Determinations and Administrative Policies became binding on the Secretary (HHS) in accordance with Section 4554(b) of the BBA-1997 no later than January 1, 1999.

As published in the Federal Register on November 23, 2001 pursuant to Section 4554(b) of the BBA-1997 and subject to a Final Agreement of the Committee dated August 31, 1999 (copy attached), 23 national policies were developed by the Negotiating Committee. These national policies were designed to promote uniformity and integrity through universal simplified administrative requirements to be followed for all laboratory covered services without any differentiation/distinction as to where the services were provided. (See attached synopsis of Committee's key applicable Final Administrative Policies for Clinical Diagnostic Laboratory Tests)

One of the Negotiated Rulemaking Committee's 23 National Policies (commonly referred to as a National Coverage Determination or NCD) addressed Blood Glucose Testing. This often utilized laboratory service is universally accepted as needed to be performed (up to several times a day) for a Medicare Part B beneficiary who is afflicted with **diabetes** or similar illness/medical condition. (Copy of the final NCD for Blood Glucose Testing is attached)

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
## AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
## BLOOD GLUCOSE MONITORING IN SNFs

CMS states that the purpose of its publication contained in the Federal Register dated August 22, 2006 is to take an opportunity to restate its long standing policy on coverage of blood glucose monitoring services and proposes to codify physician certification requirements for blood glucose monitoring in SNFs.

Prior to the issuance of Program Memorandums AB-00-099 (August 24, 2000) and AB-00-108 (December 1, 2000) CMS published that it had no national policy for blood glucose testing (monitoring). The issuance of these two instructions were the initial publications issued by CMS to its Medicare contractors.

The above instructions were issued despite CMS' (HHS) confirmed concurrence with the proposed rule provision published by the Committee (Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests) in the Federal Register dated March 10, 2000. The Committee's unanimous agreement precluded any participant from taking any action to inhibit the proposed regulation as final and published by the Department of Health and Human Services (HHS) through the Health Care Financing Administration (currently known as CMS).

In PM AB-00-108, CMS, addressing laboratory services, restates Section 1862(a)(1)(A) of the Social Security Act requirement that the service needs to be reasonable for the diagnosis and treatment of an illness in order to be covered by Medicare. CMS cites 42 CFR 410.32 and 411.15 for the proposition that the physician must order the test/service and use the result in the management of the beneficiary's specific medical problem. However, CMS went further to include the following additional requirement: **"Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician order for another laboratory service."** Clearly by their own terms, CMS confesses that the statute or regulations do not require such criteria in order for a SNF to perform a treating physician ordered subsequent laboratory test.

We are submitting the comment below as part of our objection to the proposed rule by CMS which is based on previous publications that are in conflict with or unsupported under the Congressionally binding Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' NCD and Administrative Policies.

## COMMENT

In the proposed rule section which is identified and entitled *Blood Glucose Monitoring in SNFs* a reference is made to the CMS On-Line Manual Pub 100-04 Chapter 7 (Section 90.1) which inappropriately and incorrectly states that "routine glucose monitoring of diabetic as never covered in a SNF". This completely ambiguous and severe misstatement must be eliminated and/or qualified to define routine as not being related to a physician ordered Medicare Part B laboratory service for blood glucose testing. Coverage for blood glucose testing for a Medicare Part B beneficiary (regardless of the place of service including a SNF) is mandated by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' National Coverage Determination (NCD) for Blood Glucose Testing. This NCD is expansive as it is to apply to all testing of blood samples where glucose levels are determined. Previously on at least two occasions, CMS has clearly instructed its Medicare Contractors that blood glucose testing performed by a Medicare (SNF) provider pursuant to a physician order under Medicare Part B can **never be considered or denied as being routine**.

Submitted by:
James J. Giger

October 5, 2006

**Submitter :** Mr. James Giger

**Date:** 10/05/2006

**Organization :** Systematic Management Systems

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-451-Attach-1.DOC

Reference File Code CMS-1321-P
Section (N) Public Consultation for Medicare Payment for
New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

## BACKGROUND

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## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
## AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
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CMS states that the purpose of its publication contained in the Federal Register dated August 22, 2006 is to take an opportunity to restate its long standing policy on coverage of blood glucose monitoring services and proposes to codify physician certification requirements for blood glucose monitoring in SNFs.

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We are submitting the comment below as part of our objection to the proposed rule by CMS which is based on previous publications that are in conflict with or unsupported under the Congressionally binding Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' NCD and Administrative Policies.

## COMMENT

CMS' proposed rule identified and entitled *Blood Glucose Monitoring in SNFs* includes a revision to 42 CFR 424.24(f) requiring individual certification of a blood glucose test ordered by the Treating Physician. Because of the required Treating Physician's certification of the need for such test(ing) in accordance with an individual SNF resident's care plan, this new certification requirement appears to be a clearly unnecessary and duplicative of this administrative certification requirement. Any additional certification requirement is clearly contrary to the stated purpose and documentation requirements contained in the Negotiated Rulemaking Committee's Administrative Policies (as contained in the Final Rule published in the Federal Register dated November 23, 2001, starting at page 58787).

Submitted by:
James J. Giger

October 5, 2006

**Submitter :** **Dr. Paul Cheatum** **Date: 10/05/2006**

**Organization :** **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

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,

Paul Cheatum, MD

**Submitter :** **Dr. Satish Vayuvegula** **Date: 10/05/2006**

**Organization :** **Dr. Satish Vayuvegula**

**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,

Satish Vayuvegula, MD