**Submitter :** **Mr. Matthew Matushek** **Date: 10/08/2006**

**Organization :** **Community Healthcare System**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-574-Attach-1.PDF

HHCW #
574

*Community Healthcare System*

# Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 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 your 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,

[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.

fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 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

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

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).

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.

2. 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. Our institution did begin CyberKnife operation until May 2005.

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

3. 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.

4. 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 with vastly differing resource requirements. 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,

Matt Matushek, Regional Director Radiation Oncology
Community Healthcare System
901 MacArthur Blvd., Munster, IN 46321
219.836.6390 / mmatushek@comhs.org

**Submitter :** **Ms. Janet Hieshetter** **Date: 10/08/2006**

**Organization :** **Dystonia Medical Research Foundation**

**Category :** **Consumer Group**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-575-Attach-1.RTF

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. Eddy Lucas** **Date: 10/08/2006**

**Organization :** **Dr. Eddy Lucas**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Making these revisions will increase patient quality of care.

**GENERAL**

GENERAL

CMS 1321-P
Medicare Program; Revisions to payment policies under the physician fee schedule for 2007.
Proposal date August 8, 2006

I am responding to the CMS proposal of 8/8/6 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I fully agree that there needs to be a reduction of the fee schedule at least to the level and probably greater than that which is proposed.

Because of the high reimbursement and the very little training to do this procedure many physicians are doing this procedure resulting in poor care to the patient.

At the American College of Physicians meeting there are the physicians from vascular surgery and interventional radiology who could be easily trained to provide comprehensive vein care. However, there are also GPs, neurologist, Ob/Gyns, general radiologists, FPs, internal medicine, plastic surgeons, dermatolgist, and many other specialities which have no training in ultrasound, percutaneous techniques, or venous anatomy and physiology. The most serious danger of this is the large reimbursements that attracts this wide range of practioners. This results in the ablation of the greater saphenous being performed which is not needed in 30% of cases. If this is ablated than the vein cannot be used ig the patient ever needs a bypass procedure in the future. Futhermore, many of the physicians only do this procedure when the patient needs additional care. The patient is therefore incompletely treated and told that this is all that can be done. If the patient is then able to find a physician that can adequately treat his problems there has often been adverse eventsto the patient and because of the cosmetic nature of these is not reimbursed.

There are instances where the patient has had deep venous disease with resultant ablation of the saphenous vein requiring amputation.

I therefore believe that the best way to provide comprehensive care for venous disease is to limit reimbursement for this procedure so that unqualified physicians are not doing this procedure.

Sincerely,

Eddy Lucas MD
1011 N Preserve
Wichita, KS 67206

**Impact**

Impact

See General Comment Below

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comment Below

**Submitter :** **Dr. Laura Keating** **Date: 10/08/2006**

**Organization :** **Dr. Laura Keating**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Making these revisions as proposed will negatively impact the Medicare populations access to quality health care. As the cost to provide high quality, specialized care for venous insufficiency continues to rise, the reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

**GENERAL**

GENERAL

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
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physieian fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT eodes 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 (malpractice insurance,salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand, commanding extremely high salaries in excess of $70,000 per year plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries. Further, overall cost of care for the venous insufficiency population will likely rise, considering such things as the need for ehronic wound care for non-healing ulcer patients, recurrent thrombophlebitis, bleeding from varicosities which in most cases requires at least an ER visit and sometimes transfusions, and increased risk for DVT. Also consider that endovenous ablation procedures already offer high quality lower cost care for saphenous vein insufficiency as compared to traditional venous stripping. In addition, consider that we are treating an aging population, many of whom are poor surgical candidates.

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 (upwards of $37,900 for laser and rising with improving technology which minimizes patient pain and bruising 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.

Thank you for your time and reconsideration of these proposed cuts in reimbursement.

Respectfully submitted,

Laura Graybeal Keating, M.D.
Beckley, West Virginia
lauriekeating@hotmail.com

**Submitter :** **Dr. Samuel Shelanski** **Date: 10/08/2006**

**Organization :** **Loveland Hematology/Oncology Assoc.**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

The potential impact of changing rules concerning ASP reimbursement for bundled mediations is significant. Currently, I have the ability to choose which medications are most appropriate for each of my patients depending upon their disease, distance they travel to my office, home situation etc. If changes are made that affect the cost of a drug such as Aranesp, and I can only afford to use it if I also prescribe Neulasts, then I am in fact limited in my choices. There may often be ties when I would choose to use only one drug out of a bundle, but if the reimbursement is calculated upon a bundled price, then I am deprived of the choice of using that drug.

**Impact**

Impact

Refer to General Comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

Refer to General Comment below.

CMS-1321-P-579

**Submitter :** **Mr. Douglas Cunningham** **Date: 10/08/2006**

**Organization :** **TwinCrest Group**

**Category :** **Laboratory Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-579-Attach-1.DOC

HH[illegible] 519

TwinCrest Group

"Bringing specialty physicians together with pathologists for financial opportunities"

DATE: October 10, 2006

TO: Centers for Medicare & Medicaid Services

FROM: Doug Cunningham, Co-Founder, TwinCrest Group

SUBJECT: Comments to File Code CMS-1321-P
"REASSIGNMENT AND PHYSICIAN SELF REFERRAL"

My objective in commenting on the subject proposed rules is to assure that in-office pathology laboratories owned and operated by specialty practices for their patients are not disadvantaged relative to pathology laboratories owned and operated by pathologists. I am not requesting any special considerations for in-office pathology laboratories other than continuation of fair and equal treatment which I believe exists today.

I support many of the proposals to restrict "pod" or "condo" laboratories and a variety of technical / professional fee ("TC / PC") schemes because they are not the intent or spirit of CMS' regulations. These also happen to be issues dear to the pathologist community, although that community's agenda is one of protectionism.

In any revisions to CMS' regulations, I want to be certain that in-office pathology laboratories found in specialty group practices such as dermatology, urology and gastroenterology do not suffer any harm. Some pathologists are not particularly happy about in-office laboratories because they are draining testing volume from the laboratories owned by these pathologists. If that isn't enough of self-interest, the battle cry from these pathologists is now shifting from pod/condo laboratories, in which they feel they have won, to the in-office specialty group practice pathology laboratories. T hat bat tle c ry inc ludes c laims o f o ver-utilization, p oor q uality o f pathology diagnosis and high pricing. Nothing could be further from the truth.

Allow me to explain TwinCrest Group's approach to in-office pathology laboratories so you can have a balanced view in which to gauge the anticipated comments to this File Code from pathology organizations that are working themselves into a heated frenzy to ban in-office pathology laboratories. I have these points to make:

- An in-office pathology laboratory provides better patient service. For example, patient specimens do not leave the practice. There are no lost specimens due to shipment to an off-site reference laboratory. Turnaround time to obtain a test result is far better. There is no searching for reports sent by a reference laboratory. Instead, results are entered directly into the practice's records. And, best of all, the patient can meet with the practice's pathologist to review any adverse test results. In the manner pathology is practiced today, it is a rarity for a pathologist to meet with a patient.

- Pricing in any laboratory is a non-issue. Today it does not matter what a specialty physician or a pathologist wishes to charge because virtually all payers, including Medicare, have a fee schedule they use to reimburse for pathology services. In a number of cases, the fees paid by many carriers are substantially less than fees paid by Medicare.

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Offices in:
Chicago, Cleveland, Detroit,
Los Angeles and New Jersey

- Over-utilization is an over-used excuse. It appears that most pathologists have never heard of the National Comprehensive Cancer Network (NCCN) and the standards they publish for the treatment of an extensive list of virtually all known cancers. That is not the case with specialty practice physicians who pay close attention to these standards. For example, NCCN's Clinical Practice Guidelines in Oncology has a 33 page document titled "Prostate Cancer Early Detection" (version1.2006 issued on 5/17/06) which states on page MS-9: "The panel recommends an ex tended-pattern 12- core bio psy." T winCrest s upports al l o f NCCN's standards and encourages specialty practices with in-office pathology laboratories to do the same. The reason for following the standards is two-fold. First, doing less than the standard, unless there is a clear documented medical reason for doing so, subjects the specialty physician to a lawsuit if something goes wrong because the patient was not provided standard of care treatment. Second, doing more than the standard, unless there is a clear documented medical reason for doing so, may cause an unpleasant OIG audit.

- Quality of diagnosis by a pathologist in an in-office pathology laboratory is a non-issue. In most cases, the pathologist who is diagnosing the patient's tissue at the in-office pathology laboratory is generally the same pathologist who would have been diagnosing that same tissue in his/her own pathology laboratory or in a hospital laboratory prior to the existence of the in-office laboratory. Because the pathologist is from a local pathology group, he or she also has access to others in the group to assist in difficult cases. TwinCrest does not recruit, nor does it subscribe to retaining sub-standard pathologists. The pathology organizations who are strongly against in-office laboratories like to use the story of retired pathologists being hired into in-office laboratories with the implication these pathologists do not have the skills to provided quality diagnosis. TwinCrest avoids that argument by assuring the specialty practice only retains pathologists with sub-specialty training in the cases they are to diagnosis.

Also, allow me to explain what TwinCrest Group is and what it does. TwinCrest was formed by three individuals with extensive experience in the laboratory industry. I am one of those individuals. TwinCrest assists specialty practices in providing the full gamut of pathology services to their patients. Here are important points regarding TwinCrest:

- TwinCrest is directly compensated for the services it offers. It does not have any ownership in any in-office laboratory, it does not lease equipment to the specialty practice or its in-office laboratory and it does not lease employees to the specialty practice or its in-office laboratory. In short, there is a contractual relationship with the specialty practice that is clearly arms-length. There are no joint ventures or other questionable arrangements that might infringe on OIG's "safe harbors."

- Laboratory construction is contracted directly by the specialty practice with a contractor selected by TwinCrest.

- Laboratory equipment is selected by TwinCrest but purchased directly by the specialty practice from a very large national distributor.

- TwinCrest recruits histotechnicians candidates for the in-office laboratory and the specialty practice selects the final candidate(s), determines compensation and directly hires the individual(s).

- TwinCrest recruits pathology groups for the in-office laboratory through a formal Request for Proposal (RFP) process and the specialty practice selects the pathology group and negotiates compensation.

- Pathology billing services are contracted directly by the specialty practice with a contractor selected by TwinCrest.

- In the end, the specialty practice owns the built and fully equipped in-office laboratory, has one or more histotechnician employees, has a contract with a local pathology group and an outside pathology billing company. TwinCrest provides consulting services for a period determined by the specialty practice and is paid by the specialty practice for those services.

- TwinCrest provides operating guidelines to the specialty practice in that the in-office specialty practice pathology laboratory must be located within the practice, can only serve the patients of the practice, all pathology professional services must be provided at the in-office laboratory and the laboratory must be inspected and accredited by COLA.

The bottom line is there is a proper way to operate an in-office pathology laboratory for the benefit of patients. TwinCrest is very attentive to CMS' rules and regulations for physician office laboratories (POLs). There are over 106,000 POLs today that are CLIA-registered. And, TwinCrest will abide by any future new or revised rules and regulations promulgated by CMS regarding POLs.

Again, all I ask of CMS on behalf of TwinCrest is that in-office pathology laboratories be treated the same as pathology laboratories owned and operated by pathologists. I ask for no advantage against pathologist-owned laboratories nor is it fair to disadvantage in-office pathology laboratories as some pathologists and pathology organizations wish might occur via a CMS rules and regulations route.

Thank you for accepting these comments. Please contact me if you have any questions regarding TwinCrest Group.

**Submitter :** Dr. THOMAS ESKEW **Date:** 10/08/2006

**Organization :** WILMINGTON SURGICAL ASSOCIATES

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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 Proposal dated August 8, 2006 I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation. I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several issues of great concern: 1. RVUs have consistently been reduced from 2005 levels: a. 2006: 46.91 b. 2007: 43.53 c. 2008: 40.84 While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop! As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries. 2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment. 3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation: a. 2006: 51.5 b. 2007: 47.77 c. 2008: 44.52 Each of these technologics 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, Thomas D. Eskew, Jr., M.D., FACS, FACP

**Submitter :** **Dr. Michael Greenhawt** **Date: 10/08/2006**

**Organization :** **South Florida Oncology - Hematology**

**Category :** **Physician**

**Issue Areas/Comments**

**Impact**

Impact

October 8, 2006

Re: ASP issues

Dear Sirs:

I am writing to express my concerns regarding proposed changes in Medicare reimbursement for Part B covered drugs and biologicals in 2007.

Specifically, in regard to contract pricing, my contracts with pharmaceutical companies do not dictate the amount of drug that my practice purchases, but rather afford me the choice to purchase as much or as little of a particular drug as is necessary for the practice. I certainly appreciate the value offered by the contracts that I have, especially the Amgen Portfolio Contract.

Please be aware that my choice of therapies reflects the clinical needs of my patients, and my personal preferences, and is not driven by the terms of any contract. For example, the physicians in my practice have chosen to use the red cell growth factor Aranesp, instead of the similar product Procrit, due to greater dosing flexibility with Aranesp, and the potential to give treatment of equal efficacy with fewer injections. Similarly, the white cell growth factor Neulasta has major advantages over the similar product Neulasta, in that only one injection and trip to the office are needed for each course of chemotherapy, rather than multiple daily visits. In both cases, preference for one drug over another is driven by patient comfort and convenience. Of course, if a particular patient s circumstances make either Procrit or Neupogen the more appropriate drug, I and the other physicians in my practice may and do administer that drug.

The Amgen Portfolio Contract gives my practice the freedom to access discounts and rebates on whichever of the Amgen products we choose to utilize. The practice earns additional discounts for all products if we choose to purchase them, which helps us afford to continue providing growth factor therapy in the office setting. My acquisition cost, before rebates, for these products far exceeds ASP +6%. Without the Amgen contract and the flexibility that it provides, all of the practice s Medicare patients, and most if not all patients with other insurance coverage, would have to go elsewhere to receive these medications. I am sure you are aware that these medications have been shown to improve results of cancer treatments and to positively influence length and quality of life for these patients.

Also as you are undoubtedly aware, current ASP calculations are based on prices and discounts actually available in the market. I am concerned that proposed changes to the ASP system that would use theoretic allocation of discounts, rather than actual market prices, to set reimbursement would worsen the difference between my acquisition cost and Medicare reimbursement. This would reduce my choices of which drugs to prescribe, and access to these important drugs for my Medicare (and other) patients.

**Submitter :** **Dr. Charles Dietzek** **Date: 10/08/2006**

**Organization :** **Vein & Vascular Institute**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments. Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. It will also negatively affect physician practices and their ability to function.

**GENERAL**

GENERAL

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
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36475 and CPT 36476 Endovenous Radiofrequency Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36475 and 36476 and find several issues of great concern:
How is it possible that a procedure that was just given a new code in 2004, (CPT 36475,36476, Radiofrequency Endovenous Ablation) has its practice expense devalued 2 years later and in subsequent years when the costs of performing this procedure is now higher. Values for codes 36475 and 36476, radiofrequency vein ablation are reduced as listed:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52
There is no govermental control against rising overhead in physician or hospital practices. The costs of the equipment has not been reduced. How is it then that there can be a reduction.
This is wholesale manipulation of the numbers, just to lower expenditures and therefore costs to the federal goverment and not based on the reality of what it takes to deliver this service to patients.
How are physicians suppose to provide these services and purchase equipment based on projected revenues, which I did in 2005, and then have the goverment decide to lower payment and put my practice at financial risk and my patients at risk of not obtaining this service.

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 myself and other physicians to perform these procedures and ultimately result in a loss of access to care for Medicare beneficiaries.
In addition, while the goverment reduces payment, it does nothing to help physicians bargain collectively with insurance companies who stand behind antitrust laws that allow them to follow in-suit with CMS's reduction in payment to physicians and allow them to enjoy greater revenues. You must appreciate that third party payors already pay a lower percentage of medicare rates. Why are these insurance companies not regulated in their profits as well but rather allowed to florish under the umbrella of good business practice.
I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Charles Dietzek, D.O.,FACOS
Vein and Vascular Institute
1000 White horse Rd. Suite 703
Voorhees, N.J. 08043
cdietzek@comcast.net

**Impact**

Impact

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
Pracitice expense RVU values for codes 36475 and 36476, radiofrequency vein ablation have been reduced in following years.
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

**Provisions of the Proposed Rule**

**Submitter :** **Mr. Bernard Ness** **Date: 10/08/2006**

**Organization :** **B. J. Ness Consulting Group, LLC**

**Category :** **Laboratory Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See attachment"

CMS-1321-P-583-Attach-1.PDF

cases, the fees paid by many insurance carriers are substantially less than fees paid by Medicare.

- Over-utilization is a greatly over-used excuse. Most pathologists have never heard of the National Comprehensive Cancer Network (NCCN) and the standards they publish for the treatment of an extensive list of virtually all known cancers. That is not the case with specialty practice physicians who pay close attention to these standards. For example, NCCN's Clinical Practice Guidelines in Oncology has a 33 page document titled "Prostate Cancer Early Detection" (version1.2006 issued on 5/17/06) which states on page MS-9: "The panel recommends an extended-pattern 12-core biopsy." We support all of NCCN's standards and encourage specialty practices with in-office pathology laboratories to do the same. The reason for following the standards is two-fold. First, doing less than the standard, unless there is a clear documented medical reason, subjects the specialty physician to a lawsuit should anything go wrong because the patient was not provided standard of care treatment. Second, doing more than the standard, unless there is a clear documented medical reason for doing so, may cause an unpleasant OIG audit. These standards are utilized to maximize the detection of cancer for the specialists for better clinical outcomes.

- The quality of diagnoses by a pathologist in an in-office pathology laboratory is another non-issue. In most cases, the pathologist diagnosing the patient's tissue at the in-office pathology laboratory is likely the same pathologist who would have been diagnosing that same tissue in his/her own pathology laboratory or in a hospital laboratory prior to the existence of the in-office laboratory. Since the pathologist is from a local pathology group, he/she also has access to others in the pathology group to assist in difficult cases. The pathology organizations who are strongly against in-office laboratories like to use the story of retired pathologists being hired into in-office laboratories with the implication these pathologists do not have the skills to provided quality diagnosis. Many times if retired pathologists are utilized they bring with them decades of experience in diagnosing cancer and other diseases. What is wrong with that?

The bottom line here is that there is a proper way to operate an in-office pathology laboratory for the benefit of patient care. There are over 106,000 POLs today that are CLIA-registered. Unfortunately, we have seen far too many instances where local pathologists or histotechnologists have tried to implement in office pathology laboratories that are suspect at best or out right illegal by current CMS and OIG standards.

Again, all we ask of CMS is that in-office pathology laboratories be treated the same as pathology laboratories owned and operated by pathologists. We ask for no advantage against pathologist-owned laboratories nor is it fair to disadvantage in-office pathology laboratories as some pathologists and pathology organizations wish might occur via a CMS rules and regulations route.

Thank you for accepting these comments. Please contact me if you have any questions.

5035 Cartagena Drive, Suite B100, Toledo, OH 43623 419.843.6400 bjness@BEX.net

**Submitter :** **Dr. Aksel Nordestgaard** **Date: 10/08/2006**

**Organization :** **Northwest Vein Center**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

**GENERAL**

GENERAL

CMS 1321 P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calender Year 2007 and other Changes Under part B
Proposal dated August 8, 2006.

I am responding to the CMS proposal of 8/8/6 regarding the proposed changes in the Physician schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

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

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

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

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

2. The proposed conversion factor for 2207 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:
   d. 2006: 51.5
   e. 2007: 47.77
   f. 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,
Aksel G. Nordestgaard, MD
Gig Harbor, WA 98335
a.nordy@comcast.net

**Impact**

Impact

Se General Comment below

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

Se General Comment below

**Submitter :** **Dr. Melvin Rosenblatt** **Date: 10/08/2006**

**Organization :** **Connecticut Image Guided Surgery**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

The reduction of the 36478, and 36479 codes will have a negative impact on the medicare patient population. Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments

**GENERAL**

GENERAL

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
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT 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. 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.
I am fearful that a reduction in reimbursement will create a scenario where those physicians who are expert at these treatments will not participate in Medicare. Other physicians, who are not as experienced will offer these services but will cut procedure costs at the cost of patient care. As for myself, I pride myself on patient care. If I can t provides these services at a high level of quality and cover my costs then I will be forced into not providing these services.

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,

Melvin Rosenblatt, M.D.
Fairfield CT.
mel@cigsurg.com

**Impact**

Impact

See General Comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comment below.

**Submitter :** **Dr. William Belsom** **Date: 10/08/2006**

**Organization :** **The Woman's Clinic**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

The proposed legisation will negatively impact access of the medicare population to varicose vein treatment.

**GENERAL**

GENERAL

CMS-1321-P
This legislation intends to lower the reimbursement of laser ablation of varicose veins to the medicare population. Varicose veins are a particularly insidious disease. It affects 30 per cent of women and 15 per cent of men. If untreated it leads to unhealed ulcers of the lower legs. Age is directly associated with severity of the problem. By treating the veins now, the government will save immediately and later in costs of wound care. Approximately 1.5 per cent of medicare reimbursement is for venous ulcer care.

The cost of our nursing, technical staff and utilities are going up. If this legislation passes this modality will be less available to those most in need of its benefit.

If you require more information about this technique and its benefits to the medicare patient, do not hesitate to contact me.

Sincerely,

William B. Belsom M.D.

**Impact**

Impact

See comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See comment below.

**Submitter :** **Ms. Terri McDonald** **Date: 10/08/2006**

**Organization :** **University of Tennessee Medical Center**

**Category :** **Nurse**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Extracranial stereotactic radiosurgery is far and above more difficult and time consuming to plan and treat than any intracranial treatment we have encountered and I'm sure by other SRS systems as well. It cannot be stressed enough, for this reason as well as others, the consideration that needs to be given to this matter. Please give consideration to the attached letter. Thank you.

CMS-1321-P-587-Attach-1.DOC

Attachment
551

October 6, 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

As a representative of the University of Tennessee Medical Center, I wish 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.

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 and G0340 resulting in a reduction in payment for the delivery of image-guided robotic stereotactic radiosurgery (SRS). This proposed reduction in reimbursement will have a significant financial impact for CyberKnife Centers in the U.S. Many of these centers, such as ours, have made a significant investment in a Cyberknife program in only the last two years to bring this state- of –the-art treatment option to patients in our region. We would recommend that CMS reconsider the proposed changes to reimbursement for G0339 and G0340 based on the following:

- 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. 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 robotic SRS procedures.

- 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. 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 c ollected for r eview a nd de termination o f f inal r ate s etting. T he p roposed AP C 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).

We believe strongly in the power of this technology based on the outcomes, some remarkable, that we have seen and experienced with the patients treated at our Center. As a regional referral hospital with Centers of Excellence in cancer, brain and spine, we are committed to be a provider for emerging technologies that will impact the mortality and morbidity of our patients. The proposed reimbursement cuts for image-guided robotic stereotactic radiosurgery will undoubtedly create financially difficulty maintaining this resource intensive and relatively new program.

We request assistance from CMS in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology. Our recommendations are:

▶ 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 cost data and reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Terri McDonald, RN
University Of Tennessee Medical Center
1924 Alcoa Hwy., Knoxville, TN 37920
865-544-6889/tmcdonal@mc.utmck.edu

**Submitter :** **Dr. Edmund MacLaughlin** **Date: 10/08/2006**

**Organization :** **Dr. Edmund MacLaughlin**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Comment regarding Coverage of Bone Mass Measurement (BMM) tests:
Please consider my comments very carefully. I am a rheumatologist in private practice in a medically underserved area (Dorchester County, MD.) The proposal to reduce reimbursement of DXA (CPT code 76075) from approximately $140. down to approximately $40. will make it impossible to perform quality DXA. The key central point is this: There is much poor quality DXA work being done throughout the United States. For those of us who do DXA properly, we cannot do it for $40.00. I invite you to send a representative to my office. I will show you study after study of improperly performed DXA. If you allow me to obtain the data bases of several Maryland hospitals, I can probbly show you thousands of improperly done studies. Typically, these studies are done by physicians who simply rubber-stamp the reports generated by the computers of the DXA machines. That type of DXA reporting is quick and easy, and the results are often wrong. Please send a representative to my office for half a day, and I will show you exactly why cutting reimbursement will ultimately result in excess morbidity and mortality of vulnerable seniors because they will have received improper treatment based upon worthless DXA studies that can be done for $40.00

**Submitter :** **Dr. John Chan** **Date: 10/09/2006**

**Organization :** **Stanford University**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

This will clearly influence the manner in which we are able to guide treatment in the care of women with ovarian cancer. In a situtation where there is no standard treatment, assay guided therapy has significantly impacted the manner in which we care for these unfortunate patients. please reconsider.

**Submitter :** **Dr. David MacMillan** **Date: 10/09/2006**

**Organization :** **Cosmetic Vein Centers of Virginia**

**Category :** **Ambulatory Surgical Center**

**Issue Areas/Comments**

**Background**

Background

Making these revisions as proposed will impact negatively on the Medicare population s access to quality, affordable health care, and undoubtedly these changes will be mirrored by other healthcare payors, magnifying the negative effect these changes will bring about. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments, by limiting the ability of physicians to perform the procedures in the most cost-effective manner office based, or ambulatory, surgery centers.

**GENERAL**

GENERAL

See Attachment

**Impact**

Impact

See general comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See general comment below.

CMS-1321-P-590-Attach-1.DOC

#590

Cosmetic Vein Centers of Virginia

October 9, 2006

Mark McClellan, MD, 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

**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**
**Proposal dated August 8, 2006.**

Impact of practice expense (PE) methodology changes on physician payment and the DRA reduction for Endovenous Surgical Procedure 36475 & 36476 done in the non-facility setting.

I am responding to CMS proposal of 8/8/06 regarding the overall proposed changes to the physician fee schedule, in particular, CPT 36475 and CPT 36476 for the Endovenous Radiofrequency Ablation procedure.

I have reviewed the proposed fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36475, 36475, 36478, and 36479. With the 2007 Medicare Physician Fee Schedule scheduled for a 5.1% reduction across the board cut in reimbursement and the impact of the additional reduction in PE changes it will have a significant affect for my specialty - Phlebology.

For 2007, it will be an overall reduction of **11%**, and this does not include the additional PE expense reductions that CMS has proposed to phase- in over the 2008-2010 time periods. These cuts will have an adverse impact on reimbursement and do not truly reflect the cost associated in doing these procedures.

These cuts in reimbursement have not been demonstrated to be justified, either based on actual reductions in the costs of performing the procedures in an outpatient (read: "cost-efficient") practice setting, nor by any demonstration of error in the original RVU computation. The proposed changes will negatively impact the ability of physicians to perform this extremely safe and clinically effective procedure and ultimately result in a loss of access to care for Medicare and other beneficiaries in the outpatient setting.

I urge CMS to take steps to ensure that patients continue to have access to the treatments and technologies that improve their quality of life and to preserve Medicare patients' access to surgical care in the office setting.

*1901 South Main St., Suite 2*
*Blacksburg, VA 24060*
*Phone 540-552-VEIN (8346)*
*Fax540-951-VEIN (8346)*
*www.veinrx.com*

Cosmetic Vein Centers of Virginia

My practice expenses are consistently rising, not decreasing. In addition, it has become increasingly difficult to provide these necessary services, given general inflationary trends in the healthcare industry as a whole, and regulatory changes in particular. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

**Recommendation:**

**PE RVU Methodology for 36475 and 36476**- I strongly recommends that CMS eliminate the proposed reductions in PE RVUs for endovenous procedures described by CPT codes 36475, 36476, 36478, and 36479. These recently established CPT codes were reviewed and evaluated with the appropriate cost data late in 2004 and were implemented in early 2005. Therefore the current 2006 values more closely reflect accurate PE expenses then the proposed PE calculations.

I urge CMS to maintain the current 2006 Non-facility –office based PE values for 2007.

| CPT | Description | 2006 Non- Facility PE RVUs |
|---|---|---|
| **36475(8)** | Endovenous RF(laser)A, 1st vein treated | **51.54** |
| **36476(9)** | Endovenous RF(laser)A, vein add-on | **7.9** |

Sincerely Yours,

David T MacMillan, MD, FACS
Cosmetic Vein Centers of Virginia

*1901 South Main St., Suite 2*
*Blacksburg, VA 24060*
*Phone 540-552-VEIN (8346)*
*Fax540-951-VEIN (8346)*
*www.veinrx.com*

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"see attachment" Boynton Beach Cancer Center

CMS-1321-P-591-Attach-1.DOC

Provisions of the Proposed Rule

see comments below

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.

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.

<u>Historical Precedent – Gamma Knife New Technology Codes</u>

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 with vastly differing resource requirements. 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,

Cole A. Giller, M.D., Ph.D., F.A.C. S.
Medical Director
Baylor Radiosurgery Center
Baylor University Medical Center
Dallas, Texas 75246
(214) 820-4673

**Submitter :** **Dr. Herbert Ladley** **Date: 10/09/2006**

**Organization :** **Cardiovascular Associates**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-1321-P-595-Attach-1.PDF

#595

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October 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of Cardiovascular Associates, P.C. we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that

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David C. Beckner, MD, FACC
John F. Berry, MD, FACC
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Christopher J. Kennedy, MD, FACC
R. Keith Kramer, MD, FACC
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James J. Merrill, MD, FACC
D. Christopher Metzger, MD, FACC
Cary H. Meyers, MD, FACC, FACS
Richard E. Michalik, MD, FACC
Gregory H. Miller, MD, FACC
Daniel M. O'Roark, DO, FACC
Arun Rao, MD, FACC
Harrison D. Turner, MD, FACC
Sarfraz A. Zaidi, MD, PhD, FRCPI

addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 18, 2006, and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost

structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Herbert D. Ladley, MD, FACC, FSCAI
President

#591

# Boynton Beach Cancer Center

October 3, 2006

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

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

Dear CMS Administrator:

I really appreciate the opportunity to provide comments on the CMS proposed Physician Rule # CMS-1321-P. I am very concerned about the impact these proposed rates will have on breast conservation therapy.

CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below:

| CPT Code | Description | Units | 2006 RVU | 2006 Average Rate | 2010 RVU | Variance 2010 to 2006 | Variance 2010 to 2006 |
|---|---|---|---|---|---|---|---|
| 99245 | office consult, comprehensive | 1 | 5.91 | $224 | 6.25 | $1 | 0% |
| 77263 | physician treatment planning, complex | 1 | 4.41 | $167 | 4.16 | ($18) | -10% |
| 77470 | special treatment procedure | 1 | 14.64 | $555 | 4.55 | ($391) | -71% |
| 76370 | CT for planning | 1 | 4.29 | $163 | 5.48 | $35 | 21% |
| 77370 | special medical physics consult | 1 | 3.68 | $139 | 2.51 | ($49) | -35% |
| 77290 | simulation, complex (contour volumes) | 1 | 9.02 | $342 | 15.22 | $206 | 60% |
| 77326 | Brachytherapy isodose plan | 1 | 3.78 | $143 | 3.89 | ($3) | -2% |
| 77300 | dose calc | 10 | 2.26 | $856 | 1.80 | ($209) | -24% |
| 77336 | weekly medical physics consult | 1 | 3.15 | $119 | 1.08 | ($81) | -67% |
| 77280 | simulation, simple | 5 | 4.62 | $875 | 5.27 | $72 | 8% |
| 77781 | Afterloading HDR brachy (1-4 source positions) | 10 | 23.69 | $8,978 | 6.58 | ($6,611) | -74% |
| | | | | | | ***($7,049)*** | ***-56%*** |

*NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees*

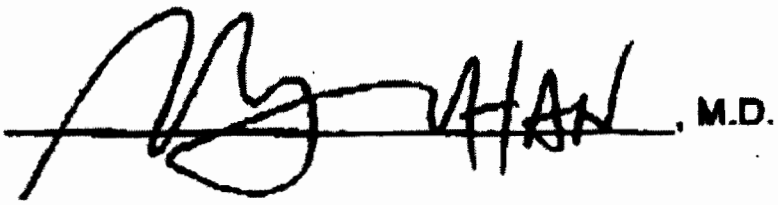
These rates are unacceptable and will prevent for Medicare breast cancer patients from having a five-day partial breast irradiation therapy treatment option. The alternative radiation treatment is Whole Beam External Radiation Therapy (WBXTR) where women must endure 6-8 weeks of radiation therapy.

HDR breast brachytherapy does require more time for the radiation oncologist to plan, calculate and treat than standard radiation therapy. These proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in the limiting access to this radiation treatment for women who are Medicare beneficiaries.

In closing, there are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, HDR breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to HDR breast brachytherapy.

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

**Regards,**



, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

**Submitter :** **Dr. Ole Peloso** **Date: 10/09/2006**

**Organization :** **Vein Center of New Mexico**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

These revisions (if enacted) as proposed will impact negatively on the Medicare populations' access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

**GENERAL**

GENERAL

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
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Ole A Peloso
Albuquerque, New Mexico
opeloso@comcast.net

**Impact**

Impact

See comments below

**Provisions of the Proposed Rule**

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHEMENT SCOTT STEINBERG MD

CMS-1321-P-596-Attach-1.DOC

#596

# SURGICAL ASSOCIATES, LLC

October 2, 2006

October 4, 2006

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

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

Dear Administrator:

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

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

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

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

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

Thank you in advance for your assistance,

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Scott Steinberg, M.D.

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

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHED MICHAEL QUINONES MD

CMS-1321-P-597-Attach-1.DOC

#597

# SURGICAL ASSOCIATES, LLC

October 2, 2006

October 4, 2006

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

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

Dear Administrator:

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

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

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Michael Quinones, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT SIDNEY STAPLETON JR MD

CMS-1321-P-598-Attach-1.DOC

#598

# SURGICAL ASSOCIATES, LLC

October 2, 2006

October 4, 2006

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

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Sidney L. Stapleton Jr.

Sidney Stapleton, Jr., M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT EUGENE HARRISON MD

CMS-1321-P-599-Attach-1.DOC

#599

# SURGICAL ASSOCIATES, LLC

October 2, 2006

October 4, 2006

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

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Eugene Harrison M.D.

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cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHEMENT SURAJ MENACHERY MD

CMS-1321-P-600-Attach-1.DOC

#600

# SURGICAL ASSOCIATES, LLC

October 2, 2006

October 4, 2006

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

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Suraj Menachery, M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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**Submitter :** **Mr. Milton Triana** **Date: 10/09/2006**

**Organization :** **St. Mary Medical Center**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-601-Attach-1.DOC

#601

*Community Healthcare System*

# Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 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 your 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,

[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.

fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 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

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

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

//signed//

Paul B. Moore, M.D., F.A.C.C.
President

**Submitter :** **Dr. Juan Reyna** **Date: 10/09/2006**

**Organization :** **Urology San Antonio PA**

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

**Issue Areas/Comments**

**Background**

Background

Will deminish the ability to provide quality pathology interepretation and less cost to Medicare.

**GENERAL**

GENERAL

See Attachment

**Impact**

Impact

CMS rules change proposal regarding pathology services particularly as they apply to "pod" labs

CMS-1321-P-608-Attach-1.TXT

#608

Dear Sirs,

This letter is in reference to your attempts to either delete or in any way diminish the current pathology services that are provided by "pod labs". We have had a wonderful service provided for us and our patients by Uropath and would be greatly disappointed if this could not continue. There are several reasons I can site for continuing this service.

1) Increased quality of interpretations, 2) Improved overall patient care, 3) Not added cost to Medicare but rather reduced it do to fewer biopsies with atypia reads and 4) those complaining about labs like UroPath are merely reacting to competition and loss of business. Lastly UroPath is entirely within the law as it stands. I would appreciate any help you could give us in this regard.

Sincerely,

Juan A. Reyna MD
President and CEO of Urology
7909 Fredricksberg Rd. #110
San Antonio, Texas 78229

**Submitter :** **Mrs. Lynn Sawyer** **Date: 10/09/2006**

**Organization :** **Hema/Onc Cons**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am concerned that the proposed changes to the reimbursement rules could keep physicians from being able to choose the best therapeutic agent to treat our patients. In regards to the ASP calculation changes for growth factor drugs I wish to share a few comments. First, we make clinical and patient access decisions on how to treat our patients. We choose Aranesp over procrit in most cases due to patient response, less frequent visits needed to the office which is better for the patient and a busy practice like ours that have no space to process patients anymore than necessary. It keeps all costs down when a patient comes to the office for less visits. We use Neulasta in most cases for the same reason less visits and more convenient for the patients and cost efficient for everyone. But we use both procrit and neupogen when clinically necessary for the patient. The Amgen APC contract is simply there for a practice to benefit from if you met the requirements and you are not penaltized if you don't met it. There are levels available for all sizes of practices to receive discounts. The discounts are available on individual products as well as a whole product line. ASP needs to continue to be calculated on actual prices that are available in the market not some possible made-up figure. The competition that the Amgen growth factor products brought to the market was a good thing and pricing on all growth factor products have decreased since there is not just one single drug available. It has improved patient care, pricing and patient access to drug. Amgen's programs for patient assistance are outstanding and help us care for our indigent and under-insured patients. Please consider my comments when reviewing this issue. Sincerely, Lynn Sawyer, Administrator for Hematology and Oncology Consultants, PA in Orlando,Florida. 407-898-5452

**Submitter :** **Dr. Raj Guptan** **Date: 10/09/2006**

**Organization :** **Venous Research Foundation**

**Category :** **Consumer Group**

**Issue Areas/Comments**

**Background**

Background

The revisions in payment policy of CMS adversely affects out of pocket expences for millions of americans

**GENERAL**

GENERAL

The revisions in payment policy of CMS adversely affects out of pocket expences for millions of americans

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

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 for primary treatmemt of a a common disorders effecting millions of elderly Americans

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

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,

Milton Triana, Administrator
St. Mary Medical Center
1500 S. Lake Park Avenue
Hobart, IN 46342
219/947-6000
mtriana@comhs.org

**Submitter :** **Date: 10/09/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHED KEN MCARTHUR MD

CMS-1321-P-602-Attach-1.DOC

#602


**SHACHNER & ZARAGOZA, M.D., P.A.**

GENERAL & LAPAROSCOPIC SURGERY • SURGICAL ONCOLOGY

DIPLOMATES AMERICAN BOARD OF SURGERY

MARK S. SHACHNER, M.D., F.A.C.S. | ALAN S. BASSIN, M.D., F.A.C.S | MELVIN E. PANN, M.D., F.A.C.S.

BERNARD J. ZARAGOZA, M.D., F.A.C.S. | KENDRICK D. MCARTHUR, D.O. | JOCELYN C. GRENIER, PA-C, MMS


October 4, 2006

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

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

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

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

Thank you in advance for your assistance,

**Thank you in advance for your assistance,**

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

**Submitter :** **Mr. Steven Pinkert** **Date: 10/09/2006**

**Organization :** **Cyberknife Center of Miami**

**Category :** **Attorney/Law Firm**

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am rsponding on behalf of the Cyberknife Center of Miami.

**Submitter :** **Mr. Steven Pinkert** **Date: 10/09/2006**

**Organization :** **Cyberknife Center of Palm Beach**

**Category :** **Attorney/Law Firm**

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am rsponding on behalf of the Cyberknife Center of Miami.

**Submitter :** **Dr. Richard Brenner** **Date: 10/09/2006**

**Organization :** **American Clinical Neurophysiology Society**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

**Submitter :** **Ms. Valerie Baldwin** **Date: 10/09/2006**

**Organization :** **South Carolina Oncology Associates**

**Category :** **Nurse**

**Issue Areas/Comments**

**Impact**

Impact

ASP-bona fide services:
Community oncology provides over 80% of oncology care. It is by far the most efficient setting for the provision of oncology care.We serve the patient, manufacturers and payors.

Services we provide our patients on behalf of manufacturers include:

1-Disease management: Diagnosis, staging, evidenced based treatment adhering to guidelines.Follow up and screening exams at appropriate intervals.Early diagnosis resulting in significant reduction in health care costs related to costs of intervention.The current standards of E/M coding 'face to face' are inadequate for use in oncology.

2- Risk management: Individual risk assessment, identify patients at high risk for developing complications related to neutropenia, anemia,constipation,diarrhea,nausea,vomiting,nutritional deficits, neuropathy, anxiety and,or depression. The current guidelines are generalized.The provision of this care facilitates more individualized care which optimizes outcomes and quality of life. It allows us to implement evidenced based intervention proactively. Reducc healthcare costs by reducing costly ER visits and hospitalizations. We also provide 24 hour call service, monitor compliance and follow up.

3-Medication therapy services and management: IV and oral medications. Patient education, desired and possible side effects and measures that should be taken should they experience them. Compliance monitoring in collaboration with our on site oncology specialty pharmacists.Manage complexities of comorbitities, side effects, reduce adverse events, all resulting in reducing health care costs.

4-Participate in clinical trials; feasability, screening, accrual, data management,reporting. Academic centers do not have the patient base to facilitate adequate accrual.Fragmented care results in poorly accessible, accurate, consistenet data.

5- Data mangement: Invest in tools that facilitate the collection of data in timely fashion as a by product of providing quality care. Electronic Medical Records,software, hardware, e-tablet technology that promotes the accumulation of accurate data. Patient self reported measurement of toxcicities and severity. Removes the clinicians perspective which may be biased. Laboratory and Radiology equipment. Information available in timely fashion resulting in reduction of medical errors related to omissions. Reduction of duplicate tests ordering resulting in reduced health care costs.
Ability to extract and report data in a timely, efficient manner reducing the time and costs of performing clinical trials.Ability continuously measure and improve outcomes.

5-Assist patients navigating the system. Answer questions, referals, financial services related to medications, housing, transportation comorbitity management, medical social workers, family counselors.

6- End of life issues management- Open discussions with patient related to advance directives. Facilitate identifying and honoring patient's wishes. The majority related to unknown patient wishes and family members who are unable to honor patient wishes because they are unaware of what their wishes were.The result of this is both a tragedy for the patient who ends up in the ICU on a ventilator for weeks when it was not their desire. Family members also suffer as a result of their inability to intervene, spend weeks waiting in the ICU and have memories of a loved one suffering in their last weeks of life. When this service is provided appropraitely there is not only a significant reduction in health care costs as a majority of health care dollars are spent in the last few weeks of life, there is also a significant improvement in patient and family quality of life because of the ability to honor patient wishes.

Staff that provide these necessary services that are not currently reimbursed:

Patient education nurses
On site oncology specialty pharmacists
Triage nurses
Research nurses
Nurse data managers
Medical Social Workers

**Submitter :** **Mr. Arturo Villamil** **Date: 10/09/2006**

**Organization :** **Fresenius Medical Care North America**

**Category :** **End-Stage Renal Disease Facility**

**Issue Areas/Comments**

**Background**

Background

ESRD Provisions

**GENERAL**

GENERAL

See attachment.

CMS-1321-P-611-Attach-1.DOC

#611

# Fresenius Medical Care

October 6, 2006

**BY HAND DELIVERY**
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

***Re: Federal Register Vol. 71, No. 162/August 22, 2006/Proposed Rules ESRD Provisions***

Dear Sir or Madam:

The Puerto Rico Operations Division of Fresenius Medical Care North America appreciates the opportunity to comment upon certain aspects of the above-referenced proposed rule which directly impact reimbursement rates for dialysis care furnished in Puerto Rico. If the proposed update is implemented, the effect of changes in the wage index calculation will be a -1.7%. The overall effect, once the reimbursement changes for medications are factored, is a -1.1%. Medicare is the primary source of coverage for over 85% of the approximately 3,700 dialysis patients receiving dialysis care in Puerto Rico. Therefore, these negative updates have an increased effect upon providers based in Puerto Rico.

The proposed rule seeks to reduce the wage index floor for calculating the ESRD composite rate to .80, from a current .90. CMS intends to continue reassessing and adjusting the floor on a calendar year basis, although the drafters recognize that an immediate elimination of the floor could adversely affect ESRD beneficiary access to care. This continuous reduction in the floor, however, negatively updates reimbursement in Puerto Rico because wage index values have not been realistically updated in quite some time, thus negatively impacting reimbursement on a yearly basis. We do not agree with the agency's proposed continuous reductions, and are amenable to engaging in a dialogue in search of other alternatives that do not imply further negative reimbursement updates.

Such negative updates adversely impact what is already a difficult climate from a reimbursement perspective. A number of recent changes, in sequence, have impacted the ability of providers, such as Fresenius Medical Care, to maintain their revenue stream and continue to provide state-of-the-art quality care. The case-mix adjusted payment system, which included case-mix adjustments to the composite rate for age, low body mass index and body surface area negatively impacted reimbursement in Puerto Rico, because of the genetic composition (shorter and narrower body frame) of the average dialysis patient. Further, there have been a number of increases in local operational costs, such as mandated nurse wage increases, and steep water and electric bill rate increases. Although justifiably deserved, the mandated nurse wage increases alone will total $2.5M over a period of three years, starting in July of 2005.[1] Simultaneously, the utilities rate increases have

[1] Fresenius Medical Care employs over 400 Registered Nurses in Puerto Rico, since only Registered Nurses can provide dialysis care. The vast majority of nurses qualified for the mandated wage increase. The average hourly wage will increase from $8.65 to $13.11 over the three year period starting in July 2005.

**Fresenius Medical Care North America**
**Puerto Rico Regional Office: Antillas Warehouse & Office Park, 461 Francia St., Suite 401, San Juan, PR 00917**
**Tel.: (787) 764-3172 Fax: (787) 756-6932**

increased operational costs by 2-3%, or approximately $1M per year. Water costs alone have risen by anywhere from 166% to 387% over the last two years and electricity costs have risen approximately 24% between calendar year 2005 and 2006.[2] Transportation costs into Puerto Rico are estimated at approximately 15% higher than in the US. All equipment and supplies used for dialysis services have to be imported since there is no local manufacturing. Additionally, the Commonwealth will impose a 7% sales tax effective November 15, 2006. Together, these elements add up to a significantly higher cost of delivering services than what may be contemplated by the drafters of the proposed rule.

Puerto Rico has a high incidence of ESRD for a number of historical and socio-economic factors, which deserve a detailed and studied analysis that is beyond the scope of these comments. However, the cost factors detailed above, combined with the fact that dialysis providers do not receive full reimbursement for the totality of the services provided to the dual-eligible population in Puerto Rico (this group comprises approximately 70% of the ESRD patient census in Puerto Rico), have severely constrained investment in new facilities and availability of care (long waiting lists are common) on an outpatient basis throughout the island.

Fresenius Medical Care has been a proactive voice and its representatives have been in communication with Commonwealth and federal authorities regarding the totality of the circumstances surrounding the incidence of ESRD and the quality and access to care for this segment of the Medicare population. However, in the face of proposed additional reimbursement cuts, combined with the operational cost increases detailed above, providers are being faced with a number of challenges, which ultimately may jeopardize and compromise the quality and frequency of attention that ESRD Medicare beneficiaries receive in Puerto Rico.

Therefore, we believe that the proposed wage index floor reduction should be suspended for calendar year 2007 and that the impact of any further floor reductions be considered thoroughly before implementation.

Additionally, we would like to suggest an update to the chart on page 49075. It states that there are 27 dialysis facilities performing 400,000 treatments a year. However, as of today there are 31 outpatient facilities performing approximately 550,000 in-center treatments per year.

We are available to discuss these comments in further detail. My telephone number is 787 764 3172 and my electronic mail address is arturo.villamil@fmc-na.com.

Sincerely,

Arturo Villamil
Vice President, Operations
Puerto Rico Region

Cc: James Kerr, CMS Regional Administrator, Region II
Delia Lasanta, Director, CMS Puerto Rico/USVI District Office
Hon. Luis Fortuño, Resident Commissioner

[2] As an example, the average kilowatt hour in Puerto Rico for the year 2003 was 12.61 cents, while the same kilowatt hour in the US cost an average of 7.42 cents.

**Submitter :** **Dr. Todd Greer** **Date: 10/09/2006**

**Organization :** **Vein Clinics Of America**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Adversely affects provision of medical care to patients with venous insufficiency. Further reductions will mean more providers getting out of venous disease treatment. Less patients being treated and controlled will result in more costly complications from a chronic progressive disease.

**GENERAL**

GENERAL

See attachment

**Impact**

Impact

To further reduce reimbursement to doctors trying to provide quality comprehensive medical care at low rates now. Thwy need ot be increased and not decreased.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

Progressive cuts to an already low profit margin for reating patients.

CMS-1321-P-612-Attach-1.DOC

#612 -1

*October 9, 2006*

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
Proposal dated August 8, 2006

Dear sirs, I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation. I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several issues of great concern to me as a practicing physician. :

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

   While my practice expenses, salaries, utilities, malpractice insurance and other costs consistently rise, it has become increasingly difficult to maintain the practice and to continue to provide these necessary services. As a full time phlebologist, I provide specialty treatment to those patients with vein disease not available even by most vascular surgeons. People face complications daily form phlebitis, bleeding, blood clots, and chronic leg ulcers, which have led to amputation. These are all manageable with proper knowledge and specialty treatment and phlebologists are the specialist trained to handle this chronic disease and complications.

   In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT), not actually necessary to provide high quality treatment, 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. A regular ultrasound tech with specialty training can provide this service at reduced cost if regulations were amended. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

   As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries. I understand that some insurance companies are trying to follow Medicare, cut their fees, and even require that only vascular surgeons and interventional radiologists be covered to treat vein disease. This is outrageous as Phlebology is now an AMA approved specialty and we are the only providers that specialize in vein disease. The other specialists focus on other areas of medicine and treat very little, if any, vein disease at all on a part time basis. Such a trend will lower the quality of healthcare for Americans.

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

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, tubing, etc.). 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 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,

Todd B. Greer, MD
Vein Clinics Of America
3440 Preston Ridge Rd., Suite 410
Alpharetta, GA 30005

#612-2

*October 9, 2006*

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
Proposal dated August 8, 2006

Dear sirs, I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation. I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several issues of great concern to me as a practicing physician. :

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    b. 2007: 43.53
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    While my practice expenses, salaries, utilities, malpractice insurance and other costs consistently rise, it has become increasingly difficult to maintain the practice and to continue to provide these necessary services. As a full time phlebologist, I provide specialty treatment to those patients with vein disease not available even by most vascular surgeons. People face complications daily form phlebitis, bleeding, blood clots, and chronic leg ulcers, which have led to amputation. These are all manageable with proper knowledge and specialty treatment and phlebologists are the specialist trained to handle this chronic disease and complications.

    In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT), not actually necessary to provide high quality treatment, 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. A regular ultrasound tech with specialty training can provide this service at reduced cost if regulations were amended. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

    As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries. I understand that some insurance companies are trying to follow Medicare, cut their fees, and even require that only vascular surgeons and interventional radiologists be covered to treat vein disease. This is outrageous as Phlebology is now an AMA approved specialty and we are the only providers that specialize in vein disease. The other specialists focus on other areas of medicine and treat very little, if any, vein disease at all on a part time basis. Such a trend will lower the quality of healthcare for Americans.

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

#609

The premier education and advocacy organization for the oncology team

Association of Community Cancer Centers


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**EXECUTIVE DIRECTOR:**
Christian G. Downs, JD, MHA


October 9, 2006

*BY ELECTRONIC FILING*

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 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)**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers ("ACCC"), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding revisions to payment policies under the Medicare physician fee schedule,


EXECUTIVE OFFICE: 11600 Nebel Street • Suite 201 • Rockville, MD 20852-2557 • 301.984.9496 • Fax: 301.770.1949
www.accc-cancer.org

physician payments at levels adequate to protect beneficiary access to care and work with the physician community to develop appropriate quality measures linked to payment incentives.

- Not implement the significant reductions in payment for drug administration services, as would occur under the proposed changes to the practice expense methodology, at least until the effect of these changes can be considered in conjunction with the expected reduction in the conversion factor and other changes mandated under the MMA and DRA and a determination can be made that beneficiary access to cancer care won't be compromised.

- Ensure continued beneficiary access to essential IVIG services by continuing to pay physicians for preadministration-related services for standard and specialty IVIG. If CMS believes there is a basis for discontinuing payment for these services, the reasons must be articulated and interested parties must have an opportunity to comment.

- Not impose any further reduction in payment for second and subsequent imaging services in the same session and continue to study the resources used in combinations of imaging services and assess the interaction of the existing multiple imaging procedure policy with the imaging payment reductions also required by the DRA;

- In order to ensure the accuracy and validity of the data used, and to protect beneficiary access to care, assure that adequate procedural and substantive safeguards are in place before using the widely available market price (WAMP) or average manufacturer price (AMP) for drugs instead of payment based on average sales price (ASP);

- Ensure that when compounded drugs are prescribed and provided, the costs associated with such compounding are included in the pricing, and instruct contractors accordingly in order to promote standardization in policies and pricing related to compounded drugs.

We discuss these recommendations below.

## I. Background

### A. Sustainable Growth Rate

Under the existing formula for calculating the physician fee schedule updates, physicians have been threatened with payment reductions for several years. Only through "eleventh hour" congressional action have the payment rates

instead been frozen. Once again, CMS anticipates a 5.1 reduction in the conversion factor for 2007 and further negative updates in later years. ACCC is very concerned about the effects of these cuts, and continued freezes, in payment rates on beneficiary access to cancer care and supportive services. A payment system that does not reflect the reality of health economics cannot be sustained, and physicians cannot continue to be held hostage each year under the specter of significant reductions in reimbursement. We urge CMS to work with physician groups and Congress to identify actions the agency can take to stabilize physician payments at appropriate levels permanently to protect beneficiary access to care. We strongly recommend that CMS implement any changes necessary to prevent the expected payment cuts.

CMS repeatedly has expressed its intention to promote improved quality of care while also ensuring adequate physician payments. ACCC continues to share CMS' interest in developing incentives to promote improved quality of care, and we urge CMS to continue to work with the physician community on developing quality measures and incentives. By linking consensus-based quality measures to payment incentives, Medicare could ensure that reimbursement remains adequate to protect beneficiary access to care while also encouraging physicians to improve the quality of care they provide.

**B. Practice Expense Issues and Drug Administration**

As set forth in more detail in ACCC's comments on CMS' proposed changes regarding the work relative value units ("RVUs") under the physician fee schedule and proposed changes to the practice expense ("PE") methodology, published in the Federal Register on June 29th, 2006, we have serious concerns about these proposed changes and their effect on beneficiary access to cancer care, particularly when they are considered in conjunction with other payment reductions set forth in this Proposed Rule.[4] As proposed, these PE RVU changes would result in 0.5 to 8.4 percent cuts in many drug administration codes in the first year, and once fully phased in, the payments for these codes would be reduced by 0.5 to 25 percent, before any changes in the conversion factor are applied.

ACCC urges CMS to carefully consider our previously submitted comments on the proposed changes to the PE RVUs and not to implement these reductions in drug administration payments before complete claims data for 2006 are available, and CMS has the opportunity to study the effect of these and other

---

4 Letter from Christian Downs, Executive Director of ACCC, to Mark McClellan, Administrator, CMS (August 21, 2006), available at http://www.accc-cancer.org/PUBPOL/pubpol_physissues.asp

payment changes required by the MMA and DRA and assure that beneficiary access to care won't be adversely affected.

### C. Preadministration-Related Services for Standard and Specialty IVIG

ACCC was pleased that in last year's physician fee schedule final rule CMS established a code (G0332) to allow billing for preadministration-related services for IVIG, and we are very concerned that this code is now listed in the Proposed Rule for 2007 as "deleted" even though there is no discussion of it in the preamble to the rule. As CMS noted in establishing the code last year, physicians incur additional costs related to obtaining standard and specialty IVIG, scheduling administration for specific patients, and ensuring that patients receive the most appropriate IVIG available at the time, taking into consideration the patient's condition and medical history. The circumstances that led CMS to establish this code have not changed, and CMS has not articulated any basis for changing the policy established last year. Therefore, the cost of these preadministration services must be continued.

If CMS intends to discontinue payment for preadministration related services for standard and specialty IVIG, the basis for this significant policy changes must be articulated and interested parties should have an opportunity to have their comments heard by CMS. Unless this dialogue occurs before implementation of the 2007 fee schedule, CMS should continue to pay physician for preadministration-related services for standard and specialty IVIG, to ensure patient access and patient safety.

### D. Radiation Oncology

As also noted in our previous comments, we urge CMS to finalize the work RVUs for the nine radiation oncology codes submitted by ACCC to the AMA/Specialty Society Relative Value Scale Committee (RUC) for review.[5] We also want to reiterate our concern that CMS' proposed practice RVUs for medical physics services are too low. Payment for these services that are essential to the provision of safe and effective radiation therapy would be reduced dramatically, even as demand for trained medical physicists has increased significantly. We urge CMS to review the direct practice expense inputs for these codes and ensure that accurate salary and time data are developed for the codes for 2008.

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5 Id. The codes at issue are 77263, 77280, 77290, 77300, 77315, 77331, 77334, and 77470.

ACCC also encourages CMS to continue the ongoing oncology demonstration project with any necessary adjustments. This demonstration provides data on quality issues and is an important additional source of reimbursement for physicians providing care to cancer patients.

## II. Miscellaneous Coding Issues – Global Period for Remote After-loading High Intensity Brachytherapy Procedures

We are pleased to see that CMS is proposing to eliminate the global period for remote after-loading high intensity brachytherapy procedures and permit separate payment each time the services are provided. This is consistent with the way care is actually provided to patients and is a more rationale payment approach. We would be interested in working with the AMA's Relative Value Update Committee (RUC) in considering any necessary revaluation of the work and practice expense values.

## III. DRA Proposals – Payment for Imaging Services

ACCC continues to be concerned about the effect of the current 25 percent reduction in payment for certain multiple imaging procedures performed on contiguous body parts, but we appreciate that CMS is proposing to maintain the cut at 25 percent rather than phasing in a 50 percent reduction, as originally proposed. We particularly urge CMS to make no further reductions until actual use of resources associated with multiple imaging procedures can be assessed in more detail, and the effects of the imaging provisions of the DRA can be considered. As we have noted previously, many of the costs associated with imaging procedures, such as equipment and supply costs, are the same for each scan, no matter how many scans are performed in a single session, and the technician often must readjust the patient's body position for each scan, even if the subsequent scan is of a contiguous body part. Therefore, we urge CMS to continue to seek the input of the American College of Radiology and other interested groups to assess the resources actually required to perform various combinations of imaging services and to determine the appropriate adjustment for multiple procedures.

In addition to the reduction in payment for multiple imaging procedures, CMS is proposing, pursuant to section 5102(b)(1) of the DRA, to reduce the payment for the technical component of imaging services under the physician fee schedule if the payment for the service under the outpatient prospective payment system (OPPS) is lower. Under such circumstances, payment under the physician fee schedule will be capped at the hospital outpatient department payment amount. We urge CMS to carefully assess the effect this payment cap has on the provision of the limited number of procedures for which physician fee

schedule rates are higher than the corresponding outpatient department rates and also to ensure that the cap is applied only to imaging services and not to codes that are integral to the provision of therapy, even if an imaging technology is a necessary component of the therapeutic procedure.

## IV. ASP Issues

### A. Substitution of WAMP or AMP for ASP

As set forth in previous comments, ACCC has serious concerns about the substitution of WAMP or AMP for ASP and the effect this lowering of reimbursement would have on the ability of physicians to continue to provide advanced cancer therapies to Medicare beneficiaries.6 We are pleased CMS appreciates that there are complex issues involved in substituting a lower payment amount for a drug if the OIG finds that the ASP exceeds the WAMP or AMP by more than the established threshold and urge CMS to move cautiously, if at all. CMS' authority in this area is discretionary, and we ask that any consideration to substitute WAMP or AMP for ASP be accompanied by procedural and substantive safeguards, such as notice and comment rulemaking, identification of the specific sources of information used to make such determinations, and explanations of the methodology and criteria for selecting such sources, as Congress intended.7 It is vital that stakeholders have an opportunity to provide input and participate in this decision to ensure that cuts in reimbursement rates do not adversely affect beneficiary access to cancer care.

### B. Payment for Compounding of Drugs

ACCC is concerned about the lack of guidance from CMS to its contractors regarding pricing for compounded drugs and the resulting variation in policies around the country, including one contractor who has discontinued payment of a compounding fee. 8 This is particularly important with respect to pain drugs that often are administered intrathecally.

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6 Letter from E. Strode Weaver, President, ACCC, to Mark McClellan, Administrator, CMS (September 30, 2005), available at: http://www.accc-cancer.org/PUBPOL/pubpol_physissues.asp

7 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H. Rep. No. 108-391, at 592.

8 https://www.noridianmedicare.com/p-medb/news/bulletins/docs/Medicare_B_News_Issue_227_April_4,_20061.pdf (Noridian discontinues payment of compounding fee effective May 1, 2006).

When a drug or biological requiring compounding is ordered, time and effort are required to safely and accurately mix the products according to specification and in compliance with extensive state and federal regulations. In particular, intrathecally administered products for pain management usually are purchased from the manufacturer and must be compounded by specially trained pharmacists. Special equipment, including a laminar flow hood, is required. Physicians then typically purchase the product from the pharmacy and bill Part B. Sterile compounding is expensive and time consuming, but it is an essential service to provide quality patient care and should be reimbursed. These costs should be taken into account, and contractors should not have complete discretion on pricing for compounded drugs.

CMS has acknowledged the costs associated with compounded drugs in the Part D arena, stating that "labor costs associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees."[9] We ask CMS to direct its contractors to include the costs associated with compounding when pricing drugs and to encourage more standardization in contractor policies regarding compounded drugs.

## V. Conclusion

In summary, ACCC continues to be concerned that the expected substantial reduction in the conversion factor, combined with other cuts in reimbursement pursuant to the MMA and DRA, will have a serious negative effect on patients battling cancer. Physicians simply cannot continue to absorb the significant cuts in payment rates for cancer services without substantial ramifications for patient care. In order to ensure that Medicare patients continue to have access to essential cancer services, we respectfully request that CMS adopt the following recommendations:

1. Take any action possible to prevent the expected 5.1 percent cut in the conversion factor and work with Congress to address the ongoing problems with physician payment updates permanently pursuant to the SGR methodology in order to maintain beneficiary access to essential cancer care while also improving the quality of care provided;

2. Prior to implementation, carefully assess the effects of the proposed significant cuts in payment for drug administration, in conjunction with the reduction in the conversion factor and other payment changes

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9 70 Fed. Reg. 4194, 4232 (Jan. 28, 2005).

pursuant to the MMA and DRA, to ensure that beneficiary access to cancer care won't be adversely affected;

3. Continue to pay physicians for preadministration-related services for standard and specialty IVIG to ensure these services are available to beneficiaries and that these essential drugs are provided as safely as possible;

4. Continue to study the resources involved in performing multiple imaging services before imposing any further payment adjustments and take into consideration the added effect of expected reductions in the conversion factor and other changes in payment policies affecting imaging;

5. Implement adequate safeguards and allow stakeholder input prior to any decision to substitute WAMP or AMP for ASP-based payment and provide us with the information we need to ensure the accuracy and validity of the data used and to protect against harm to beneficiary access to care;

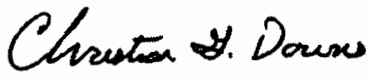
6. Continue the oncology demonstration project and work with ACCC and other oncology specialty groups to identify appropriate quality measures and payment incentives to improve access to quality cancer care;

7. Ensure continued beneficiary access to the best and most appropriate pain medications by providing guidance to CMS contractors to include the costs associated with compounding when pricing compounded drugs.

* * *

ACCC appreciates the opportunity for offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact me at 301-984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



Christian G. Downs
Executive Director

**Submitter :** **Dr. Ildefonso Mas Jr.** **Date: 10/09/2006**

**Organization :** **Miami Cardiopulmonary Institute, LLC**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-613-Attach-1.WPD

#613

MIAMI CARDIOPULMONARY INSTITUTE, LLC
JCAHO Accredited

October 9, 2006

Dear Dr. McClellan:

On behalf of Miami Cardiopulmonary Institute, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective

3200 Ponce de Leon Blvd. Coral Gables, FL 33135

payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 18, 2006, and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates

be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Dr. Ildefonso Mas Jr., FACC
President
Miami Cardiopulmonary Institute

**Submitter :** **Date: 10/09/2006**

**Organization :** **Bay Area Heart Center**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-1321-P-614-Attach-1.DOC

#614


# *Bay Area Heart Center*

5398 Park Street North, St. Petersburg, FL 33709
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4805-49th Street North, St. Petersburg, FL 33709
Phone: (727) 526-6624 Fax: (727) 545-8263

| | | |
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| Sol Fishman, M.D. | Jeffrey M. Lehr, M.D. | M. Fernando Salazar, M.D. |
| Mohan S. Reddy, M.D. | Marek T. Mikulski, M.D. | Octavio Cosme, M.D. |
| Ravi Kethireddy, M.D. | Dilip J. Mathew, M.D. | Bruce E. Rice, PA-C |
| Bruce E. Rice, PA-C | Tiffani Massingill, PA-C | Alicia M. Koenig, PA-C |
| Diana Walter, PA-C | Lynn Lybrand, PA-C | Anna P. Orr, Administrator |


October 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of the Bay Area Heart Center, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule. We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

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We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

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Marek T. Mikulski, M.D.

Octavio Cosme, M.D.

Ravi Kethireddy, M.D.

Dilip J. Mathew, M.D.

**Submitter :** **Date: 10/09/2006**

**Organization :** **Bay Area Heart Center**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-1321-P-615-Attach-1.DOC

#615


# *Bay Area Heart Center*

5398 Park Street North, St. Petersburg, FL 33709
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October 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
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Department of Health and Human Services
Attention: CMS-1321-P
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Dilip J. Mathew, M.D.

**Submitter :** **Dr. Charles Jones** **Date: 10/09/2006**

**Organization :** **Commonwealth Gynecologic Oncology**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Monday, October 09, 2006

Re: Proposed reinterpretation of CMS guidelines for Oncotech s Extreme Drug Resistance (EDR) Assay

To Whom It May Concern:

I am writing on behalf of my patients concerning the above noted reinterpretation of Medicare reimbursement for EDR assays. I have been practicing gynecologic oncology for eighteen years. EDR assays are an integrated part of my medical practice as it relates to decisions in the appropriate chemotherapy agents delivered to a particular patient. The specimens harvested for this assay provide significant data to allow me and my partners to make these critical decisions for our patient s out-patient chemotherapy. EDR assays identify patient who are resistant to a specific chemotherapy drug and therefore highly unlikely (<1%) to respond to the specific agents in an out-patient clinical setting.

By utilizing the EDR assay we, as surgical and medical oncologists, are able to spare the patient the physical toxicities and health care system the financial burden of ineffective chemotherapy.

Currently, Oncotech s EDR assay is eligible for Medicare Part B reimbursement and is reimbursed directly by Medicare. The proposed re-interpretation would require Oncotech to bill their laboratory services directly to the a hospital as part of the Medicare Part A program, as opposed to the current out-patient billing. As a result, the financial costs of the EDR Assay would fall under current Drug s, and Hospitals would be responsible for the cost of the assay and would not be reimbursed for the payment to Oncotech.

To pay for the EDR assay, hospitals would therefore have to take payment from its Medicare DRG payment. It is unlikely that any hospital could or would pay these costs, as the cost of the EDR assay would not be considered as a hospital service directed to clinical care of the patient. Consequently the result of this re-interpretation policy would be to make EDR assay testing unavailable to Medicare beneficiaries.

The Oncotech EDR assay is an integral part of the out-patient chemotherapy treatment planning for my patients. The assay is performed on specimens obtained at the time of surgery with the sole purpose of assisting in treatment decisions as they relate to the out-patient chemotherapy for my patients. Without this tool my patient would risk incurring toxicities by undergoing unnecessary/ineffective chemotherapy. Furthermore, as the medical peer-reviewed literature supports, directed chemotherapy via the EDR assay saves our healthcare system significant expense.

I thank you for your time and reconsideration of this policy change.

Charles M. Jones, III, M.D., F.A.C.O.G.

CMS-1321-P-616-Attach-1.DOC

#616

Monday, October 09, 2006

Re: Proposed reinterpretation of CMS guidelines for Oncotech's Extreme Drug Resistance (EDR) Assay

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By utilizing the EDR assay we, as surgical and medical oncologists, are able to spare the patient the physical toxicities and health care system the financial burden of ineffective chemotherapy.

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I thank you for your time and reconsideration of this policy change.

Charles M. Jones, III, M.D., F.A.C.O.G.

**Submitter :** **Dr. Douglas Joyce** **Date: 10/09/2006**

**Organization :** **Joyce Vein & Aesthetics Institute**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

These revisions will limit the ability of physicians to provide these treatments for Medicare patients.

**GENERAL**

GENERAL

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
Proposal dated August 8, 2006 ·

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Douglas H. Joyce, D.O.
1695 Tamiami Trail
Port Charlotte, Florida 33948
941 766-0750
E-Mail drjoyce@msn.com

**Impact**

Impact

See General Comment

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comment

**Submitter :** **Dr. Charles Jones** **Date: 10/09/2006**

**Organization :** **Commonwealth Gynecologic Oncology**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-618-Attach-1.DOC

#618

Monday, October 09, 2006

Re: Proposed reinterpretation of CMS guidelines for Oncotech's Extreme Drug Resistance (EDR) Assay

To Whom It May Concern:

I am writing on behalf of my patients concerning the above noted reinterpretation of Medicare reimbursement for EDR assays. I have been practicing gynecologic oncology for eighteen years. EDR assays are an integrated part of my medical practice as it relates to decisions in the appropriate chemotherapy agents delivered to a particular patient. The specimens harvested for this assay provide significant data to allow me and my partners to make these critical decisions for our patient's out-patient chemotherapy. EDR assays identify patient who are resistant to a specific chemotherapy drug and therefore highly unlikely ($<1\%$) to respond to the specific agents in an out-patient clinical setting.

By utilizing the EDR assay we, as surgical and medical oncologists, are able to spare the patient the physical toxicities and health care system the financial burden of ineffective chemotherapy.

Currently, Oncotech's EDR assay is eligible for Medicare Part B reimbursement and is reimbursed directly by Medicare. The proposed re-interpretation would require Oncotech to bill their laboratory services directly to the a hospital as part of the Medicare Part A program, as opposed to the current out-patient billing. As a result, the financial costs of the EDR Assay would fall under current Drug's, and Hospitals would be responsible for the cost of the assay and would not be reimbursed for the payment to Oncotech.

To pay for the EDR assay, hospitals would therefore have to take payment from its Medicare DRG payment. It is unlikely that any hospital could or would pay these costs, as the cost of the EDR assay would not be considered as a hospital service directed to clinical care of the patient. Consequently the result of this re-interpretation policy would be to make EDR assay testing unavailable to Medicare beneficiaries.

The Oncotech EDR assay is an integral part of the **out-patient** chemotherapy treatment planning for my patients. The assay is performed on specimens obtained at the time of surgery with the sole purpose of assisting in treatment decisions as they relate to the **out-patient** chemotherapy for my patients. Without this tool my patient would risk incurring toxicities by undergoing unnecessary/ineffective chemotherapy. Furthermore, as the medical peer-reviewed literature supports, directed chemotherapy via the EDR assay saves our healthcare system significant expense.

I thank you for your time and reconsideration of this policy change.

Charles M. Jones, III, M.D., F.A.C.O.G.

**Submitter :** **Dr. David Bizousky** **Date: 10/09/2006**

**Organization :** **Center for Orthopaedics and Sports Medicine**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-619-Attach-1.PDF

**Submitter :** **Dr. Douglas Fugate** **Date: 10/09/2006**

**Organization :** **Center for Orthopaedic and Sports Medicine**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-620-Attach-1.PDF

#620

**1265 Wayne Ave, Suite 307**
**Indiana, PA 15701**
**724.465.2676**

October 6, 2006

Center for Medicare & Medicaid – Baltimore, MD

*Re: Document 1321-P: via email*

We are writing regarding CMS-1321-P Proposed 2007 Physician Fee Schedule that would negatively impact our Medicare reimbursement for DXA procedures, i.e. bone mass measurement tests.

As a multi-specialty orthopaedic physician practice we provide DXA bone density testing to patients of all ages, particularly the senior population. This testing is used to identify bone mass and risk of "thinning of the bones" or osteoporosis. The prevalence of osteoporosis can increase an individual's risk of bone fractures.

In our office, experienced X-ray technicians perform bone density testing. These are well-trained professionals who provide the type of individualized care that is important to all patients. If this bill is passed, it may impact our ability as a physician practice to assist patients in the prevention and treatment of osteoporosis. It is likely that our costs in performing these tests would exceed reimbursement.

We would not be in favor of a reduction in the proposed Medicare reimbursement. We would like to provide additional dietary & supplemental consultations for patients as part of our service and a reduction in reimbursement would mean that we could not provide this service; or we may not be able to continue to provide DXA tests at all.

We are asking you to vote no on this bill so that we can continue to provide this valuable service that allows us to diagnose osteoporosis and improve quality of life for our patients. We contend that any further decision on this proposal should be accompanied by a through analysis and conducted using cost figures on the appropriate technology.

Thank you for taking the time to read of our concerns.

Sincerely,

**Submitter :** **Dr. Craig McKirgan** **Date: 10/09/2006**

**Organization :** **Center for Orthopaedics and Sports Medicine**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-621-Attach-1.PDF

#621

**1265 Wayne Ave, Suite 307**
**Indiana, PA 15701**
**724.465.2676**

October 6, 2006

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We are asking you to vote no on this bill so that we can continue to provide this valuable service that allows us to diagnose osteoporosis and improve quality of life for our patients. We contend that any further decision on this proposal should be accompanied by a through analysis and conducted using cost figures on the appropriate technology.

Thank you for taking the time to read of our concerns.

Sincerely,

CMS-1321-P-622

**Submitter :** **Dr. Jagadeesha Shetty** **Date: 10/09/2006**

**Organization :** **Center for Orthopaedics and Sports Medicine**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-622-Attach-1.PDF

#622

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We are asking you to vote no on this bill so that we can continue to provide this valuable service that allows us to diagnose osteoporosis and improve quality of life for our patients. We contend that any further decision on this proposal should be accompanied by a through analysis and conducted using cost figures on the appropriate technology.

Thank you for taking the time to read of our concerns.

Sincerely,

**Submitter :** **Mrs. Senia Hussong** **Date: 10/09/2006**

**Organization :** **Bellevue Heart and Vascular Center**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-1321-P-623-Attach-1.DOC

#623

Mark McClellan, M.D., Ph.D.
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

Sent via email

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of Bellevue Heart and Vascular Center and Bellevue Cardiology Clinic, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 21, 2006 and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data

can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Senia Hussong
Chief Administrative Officer
Bellevue Heart and Vascular Center

**Submitter :** **Dr. Michael Dzeda** **Date: 10/09/2006**

**Organization :** **Christiana Care Health Services**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-1321-P-624-Attach-1.DOC

CMS-1321-P-624-Attach-2.DOC

#624-1

Helen F. Graham Cancer Center

October 9, 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 your 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 with vastly differing resource requirements. 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 F. Dzeda, MD

Christiana Care Health Systems
Helen F. Graham Cancer Center
Department of Radiation Oncology
Suite 1110
4701 Ogletown-Stanton Rd
Newark, DE 19713

Phone number: (302) 793-4150

E mail address: mdzeda@christianacare org

#624-2

Helen F. Graham Cancer Center

Comment #624-2

October 9, 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 your 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.

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 F. Dzeda, MD

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**Submitter :** **Kit Haake** **Date: 10/09/2006**

**Organization :** **Crossroad Community Hospital**

**Category :** **Other Technician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE:CMS-1321-P

I appreciate the opportunity to comment on the Proposed Notice published by CMS in the Federal Register of August 22, 2006, which describes proposed changes to the practice expense relative value units used to establish payment for services to Medicare patients under the Physician Fee Schedule. I am concerned about the projected 39% reduction of the Medicare payments for CAD when used with Mammography (CPT 76082 and 76083) by the year 2010.
Cad systems for mammography are important diagnostic tools which can increase breast cancer detection rates, especially in early stages. The use of CAD requires the purchase ad maintenance of medical equipment which is operated by certified mammography technologists. The process of digitizing images for CAD is time and labor-intensive. There is no rationale to reduce a valuable service by 39% because of modifications of payment calculations. I am deeply concerned that the combined effect of all the proposed changes in reimbursement, along with an anticipated reduction of the conversion factor of 5.1% will make it economically impossible for me and my colleagues to continue to provide mammography with CAD analysis to our Medicare patients.
Please consider withdrawing the proposed reduction, or at the minimums delay the implementation of the new practice expense methodology, especially in the light of the other payment reductions planned of other imaging procedures.

Thank You for your consideration.

**Submitter :** **Mrs. Senia Hussong** **Date: 10/09/2006**

**Organization :** **Seattle Heart and Vascular Center**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-1321-P-626-Attach-1.DOC

#626

Mark McClellan, M.D., Ph.D.
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

Sent via email

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of Seattle Heart and Vascular Center and Seattle Cardiology Clinic, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 21, 2006 and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data

can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Senia Hussong
Chief Administrative Officer
Bellevue Heart and Vascular Center

**Submitter :** **Dr. Terrence Fitzgibbons** **Date: 10/09/2006**

**Organization :** **Dr. Terrence Fitzgibbons**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Making the proposed fee reduction will make it difficult to care for Medicare patients.

**GENERAL**

GENERAL

I am responding to the CMS proposal of 8/8/06 to reduce the reimbursement for CPT 36478 and36479 Endovenous laser ablation. This procedure requires a significant investment by the physichian for the equipment, supplies, and ultrasonograpy technical support. If the reimbursement is reduced, medicare recepients will be denied this out patient procedure, possibly resulting in a return to widespread varicose vein stripping, which will result in more expense to medicare for hospital and anesthesiologist payment.

**Impact**

Impact

see comments below

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

see general comments below

CMS-1321-P-628

**Submitter :** **Dr. Robert Kenney** **Date: 10/09/2006**

**Organization :** **Renal Associates of Baton Rouge**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

The effects on reimbursement for services provided to Medicare beneficiaries (particularly radiological imaging services) based on this proposed CMS rule coupled with the mandated changes from the Deficit Reduction Act of 2005 may in reality shift the financial incentive back to the hospital setting. This is something that CMS has publicly stated it does not want to see happen, yet the changes which will occur over the next two years may do just that. My particular concern is in the realm of out-patient management of vascular access situations in patients on dialysis. Out-patient management has been welcomed by patients and physicians alike, with overall more expeditious, more efficient care with less cost and inconvenience. Thank you. Robert Kenney, MD

CMS-1321-P-629

**Submitter :** **Mr. Sam Finkelstein** **Date: 10/09/2006**

**Organization :** **Riverain Medical**

**Category :** **Device Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-629-Attach-1.DOC

#629

Riverain MEDICAL

Early. Detection. Now.

October 9, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Office of the 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

**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**

Dear Dr. McClellan:

Riverain Medical is pleased to submit the following comments to the Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule. We hope Centers for Medicare and Medicaid Services (CMS) finds our recommendations helpful as it finalizes the physician fee schedule for 2007.

Riverain Medical is a healthcare company that offers the only chest radiography computer-aided detection (CXR CAD) software for early lung cancer detection approved by the Food and Drug Administration (FDA). Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical wishes to comment on the Deficit Reduction Act (DRA) Proposals in the proposed rule.

**DRA Proposals**

The DRA requires the CMS to implement a payment cap for the technical component (TC) of certain imaging services. Specifically, if the amount determined under the physician fee schedule (PFS) is greater than the amount payable under the hospital outpatient prospective payment system (OPPS) for the same service, then CMS must substitute the OPPS amount for the PFS amount.


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In its proposal on this issue CMS states that, "We also excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap."[1] The list of codes that CMS proposes to include under the DRA cap is printed in Addendum F of the proposed rule.

We note that CPT code 0152T, Computer chest add-on, is included in Addendum F. We wish to point out that 0152T has a status indicator of "N" in the OPPS, is not separately paid and that CMS is proposing in CMS-1506-P to maintain this packaged status for CY 2007.

We also note that imaging services for which separate payment is *not* made under the OPPS are proposed to be excluded from the DRA cap. Therefore, we request that CMS remove 0152T from Addendum F in the final rule.

We would like to point out that 0152T will be deleted as of January 1, 2007, and that it will be replaced by CPT codes 0174T and 0175T. We have requested that CMS assign 0174T and 0175T to APC 1492 with a status indicator of "S" or "Q" and a payment of $15.00. However, if CMS decides not to make separate payment for 0174T and 0175T and assigns them status indicators of "N," we request that both those codes not be included in Addendum F and that they not be subject to the DRA cap.

For your convenience the following are the CPT codes that are referenced above. The code that will be replaced has strikeout text:

~~+0152T Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; chest radiograph(s) (List separately in addition to code for primary procedure)~~

+0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation

0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation

[1] 71 *Fed. Reg.* 48997.


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We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1321-P and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Sincerely,

**RIVERAIN MEDICAL**

**Sam D. Finkelstein**
**President**
**Riverain Medical**


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"(B) Imaging Services Described. For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography."

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury. CMS considered the CPT® 7XXXX series codes for radiology and nuclear medicine services and added other CPT codes and alphanumeric HCPCS codes that describe imaging services. CMS correctly excluded some of the non-Imaging 78XXX nuclear medicine codes such as uptake only or radioisotope lab CPT codes. However, CMS incorrectly lists several Non-Imaging nuclear medicine codes and should remove (see Table 1) these CPT codes from impact of the DRA. The SNM believes that the list of procedures affected by the DRA should not include non-imaging nuclear medicine codes.

Based on the definition above, the **SNM believes that the DRA list needs to be further refined to exclude additional Non-Imaging nuclear medicine codes as we believe that the DRA explicitly excludes these procedures.**

**Table 1 Additional Non-Imaging Nuclear Medicine Codes Remove from Addendum F**

| CPT Code | Long Description |
|---|---|
| +78020 | *Thyroid carcinoma metastases uptake (List separately in addition to code for primary procedure)* |
| 78135 | *Red cell survival study; differential organ/tissue kinetics, (eg, splenic and/or hepatic sequestration)* |
| 78140 | *Labeled red cell sequestration, differential organ/tissue, (eg, splenic and/or hepatic)* |
| 78190 | *Kinetics, study of platelet survival, with or without differential organ/tissue localization* |
| 78282 | *Gastrointestinal protein loss* |

**B. Practice Expense**

The SNM appreciates CMS proposal to accept Practice Expense Review Committee practice expense recommendations for all new codes that went through the Relative Value Update Committee September 2005 through April 2006.

The SNM believes the new CMS practice expense methodology has caused inappropriate reductions in payment for certain procedures. The SNM believes that as we review the causes for these reductions that further refinement of direct inputs may be appropriate and requests that CMS support a society's ability to take these codes back to the PERC for review if necessary to insure accurate inputs and equipment costs.

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**C. DRA Methodology Flaws**

Like the RUC the SNM has concerns with some provisions in the implementation of the Deficit Reduction Act (DRA). Chief among these are the arbitrary cap on imaging services, as well as the universal reduction of all practice expense RVUs by 0.3%. While we understand that there are legislated statutory requirements compelling CMS to enact these provisions, the SNM is of the opinion that each contributes to the undermining of the resource-based relative value scale (RBRVS) as neither of the required changes are resource-based.

To elaborate, the SNM is concerned with the proposed decision of CMS in implementing the DRA to directly crosswalk an imaging CPT code to the averaged APC payment rate when comparing the Medicare Physician Fee schedule rate to the HOPPS rate. The APC groupings are intended to set an averaged payment where some CPTs are lower cost procedures are paid at a higher averaged rate and some higher cost procedures are paid at a lower averaged rate. In fairness, in comparing unlike payment systems **CMS should consider a crosswalk to the median cost by CPT code and not use the median cost per the APC grouping payment**. We believe this is a better proxy to comparing the procedures across the varying payment systems.

Additionally, **we caution CMS regarding comparing and using unlike payment systems and assuming direct crosswalks simply using the CPT codes for this crosswalk.** For some imaging procedures in the HOPPS system there are bundled drugs or radiopharmaceuticals included in the rate setting. If CMS were to use the rates including bundled products they would likely be somewhat double paying for those drugs and radiopharmaceuticals that are included in the APC rates. We encourage CMS **to determine what portion of the procedures is attributed to packaged drugs and radiopharmaceuticals.** The APC panel and the general public have asked for this data and CMS should consider this data in their crosswalks. Moreover, in the physician office setting most drugs and radiopharmaceuticals are paid separately in addition to the procedures. We **encourage CMS to unpackage all drugs and radiopharmaceuticals in the HOPPS system if the DRA is implemented so there is more parity in the payment system rate setting used.**

A reverse situation occurs in a hand full of States. For example where a single carrier may set payment for a radiopharmaceutical as bundled in the procedure, such as with FDG and PET studies in Florida, and this is opposite in the HOPPS. Again, we caution CMS in using direct crosswalks in varying systems. We encourage CMS to instruct carriers to set separate payment for radiopharmaceuticals from drugs for all nuclear medicine procedures in both settings. We are deeply concerned that these variations in payment methodologies will inappropriately pay for imaging procedures in the future. These issues are complex and we suggest that CMS should not rush to implement flawed methodologies and crosswalks.

Payments related to both practice expense and professional liability insurance (PLI) would be deleteriously impacted as a result of incorrect assumptions on the allocation of PLI RVUs. The false assumptions must be corrected by CMS. While the total PLI RVU for these services may be correct, the allocation of the PLI RVUs between the technical component and professional component portion is inappropriate. The current PLI RVUs have this relationship reversed, with

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the higher PLI portion applying to the technical component portion and the lower PLI portion applying to the professional component portion. The **SNM supports previous recommendations by ACR and RUC to reverse the technical component and professional component PLI relative value allocations**, while exploring a long-term strategy to allow technical component PLI RVUs to reflect resource-based professional liability costs.

**2.) Proposed Payment for Covered Outpatient Drugs and Biologicals (ASP) Issues**

The **SNM supports CMS clarification and guidance on the treatment of administrative fees, service fees and fees paid to pharmacy benefit managers (PBMs) in the ASP calculation.** CMS stated that in the absence of specific guidance in the Social Security Act or Federal regulation, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the federal requirements. These assumptions should be submitted along with the ASP data. We encourage CMS to continue to work with manufacturers to identify and clarify all appropriate inputs into the ASP calculation to ensure adequate pricing.

The SNM supports alternative payment methodologies for drugs and radiopharmaceuticals, which adequately cover all providers' costs including service fees, transportation, waste, spoilage and required on-site calibrations. The SNM looks forward to working closely with CMS staff offering our assistance and nuclear medicine expertise and knowledge to clarify crosswalk and translation issues (ie conversions from mCi to uCi or per dose) to achieve and establish appropriate reimbursement for radiopharmaceuticals under any proposed payment framework. This issue is of paramount importance to the nuclear medicine community, and key to continued availability of the radiopharmaceuticals that are the fundamental component of our specialty. To this end, we remain committed to offering education and assistance to CMS staff regarding radiopharmaceuticals to achieve adequate and appropriate payment rates.

**3.) Publishing Relative Value Units (RVUs) for carrier priced CPT codes**

The SNM remains concerned about the failure of CMS to recognize or publish services and/or the RUC-approved relative values for numerous CPT codes that remain non-covered or carrier priced by Medicare. **The SNM has repeatedly requested that CMS publish the RVUs for PET and PET/CT codes that have been reviewed by the RUC,** but that were not included in schedule published on August 22.

**4.) Independent Diagnostic Testing Facilities (IDTF)**

CMS proposes that each IDTF be required to be in compliance with the proposed 14 supplier standards in order to obtain or retain enrollment in the Medicare program. In addition to the following comments on the specific elements of this proposal, the **SNM recommends that CMS consider a requirement for all non-facility diagnostic testing to comply with IDTF rules.**

1. Operate in compliance with all applicable licensure and regulatory requirements

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The SNM believes that this proposed standard needs further clarification and details. The SNM recommends that CMS draft minimum federal requirements, which go through a pubic comment period prior to implementing.

2. Provide complete and accurate information on its enrollment application;

The SNM believes that this standard is not necessary and should already be in place under the current IDTF and enrollment rules.

3. Maintain a physical facility (not a post office box or commercial mailbox);

The SNM supports this standard as it will be useful, especially with regard to conducting inspections as suggested in proposed standard 14.

4. Have all applicable testing equipment available at the physical site, excluding portable equipment;

The SNM believes that this proposed standard needs further clarification and details. Providers hire mobile services if volumes would not support on site equipment. Additionally, providers may hire external companies to provide ongoing maintence on equipment, these companies will bring in testing equipment as necessary and requiring on site testing equipment in this capacity is expensive and not necessary.

5. Maintain a primary business phone under the name of the business;

The SNM believes that this standard should already be in place under the current IDTF rule.

6. Have a comprehensive liability insurance policy of at least $300,000 or 20 percent of its average annual Medicare billings, whichever is greater, that covers both the place of business and all customers and employees;

The SNM recommends CMS explain how insurance for IDTFs advances the stated purpose of protecting beneficiaries and the Trust Fund. The SNM also recommends CMS more precisely define the type of insurance an IDTF should carry, and boost the minimum threshold of comprehensive liability coverage.

7. Agree not to directly solicit patients;

The SNM supports this proposed standard. We encourage CMS to be more specific on the definition of "solicit". We request CMS to provide clarification to the question; would this standard mean that an imaging-only facility could not advertise to the general public or work with physicians who do not have a financial interest in the facility to arrange a referral relationship?

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8. Answer beneficiaries' questions and respond to their complaints;

The SNM recommends CMS develop a standard that requires an IDTF to have a written standard operating procedure for responses to patient questions and complaints and a requirement to keep such questions and complaints on file.

9. Openly post these standards for review by patients and the public;

The SNM supports this standard.

10. Disclose to the government any person having ownership, financial or control interest, or any other legal interest in the supplier;

The SNM supports this standard.

11. Have its testing equipment calibrated per equipment instructions and in compliance with applicable national standards;

The SNM supports this standard, but recommends that it be modified to state that all equipment be evaluated by a qualified medical physicist.

12. Have a technical staff on duty with the appropriate credentials to perform tests;

The SNM supports this standard. We request that CMS also identify all appropriate credentials such as NMTCB (CNMT) or ARRT RT(N) certification for nuclear medicine technologists.

13. Have proper medical record storage and retrieval capabilities; and

The SNM supports this standard, but, considering the rapid evolution but sporadic prevalence of digital image storage capacity, would like to have significant input into what would constitute "proper medical record storage and retrieval capabilities."

14. Permit CMS or its agent/contractor to conduct unannounced on-site inspections.

The SNM supports this standard.

***Supervision***

The **SNM supports the proposal** to limit the number of IDTFs a physician can supervise to no more than three sites.

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*Place of Service*

**SNM proposes to define the "point of the actual delivery of service" as the correct "Place of Service" for the claim form in the case of diagnostic testing performed outside the IDTFs physical location.**

For reasons of patient safety, quality of examination, and potential environmental hazard, the SNM believes that there should be no medically necessary reason to perform radiological or other medical imaging procedures at a beneficiary's residence.

**5.) Reassignment Rule and Physician Self-Referral**

The SNM agrees with CMS concern "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse." **We strongly support the intent of CMS to address this issue. The SNM agrees with CMS proposed language to amend § 424.80 of its regulations.**

The SNM supports adoption of further amendments to § 424.80(d) that CMS is considering in regard to when a physician or medical group can bill for a reassigned professional component (PC) of a diagnostic test, and recommends that diagnostic tests in the DHS category of radiology and certain other imaging procedures not be excepted from those amendments. The SNM believes that an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement. In response to the request for comments on "how to determine the correct amount that should be billed to the Medicare program", the SNM suggests that CMS use the same language it has proposed for the TC anti-markup provision, i.e. "the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group
- The billing physician's or medical group's actual charge
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly

The SNM agrees with CMS's efforts to change the definition of "centralized building" in the regulations to address certain space ownership or leasing arrangements that seek to meet the "physician services" or "in-office ancillary services" exceptions. However, we are concerned that inclusion of a minimum 350 square feet in the definition of "centralized building" would not effectively deter potential program or patient abuse that could occur through provision of diagnostic tests in the DHS category of radiology and certain other imaging services. The SNM therefore suggests that CMS consider a larger and more appropriate minimum square footage in the definition of "centralized building" for those specific DHS. Alternatively, the SNM would recommend that CMS require that all "non-facility" provision of diagnostic tests in the DHS

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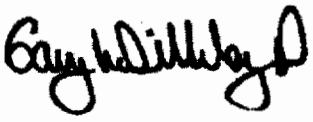
category of radiology and certain other imaging services be subject to the rules for Independent Diagnostic Testing Facilities (IDTF) as mentioned earlier in this letter.

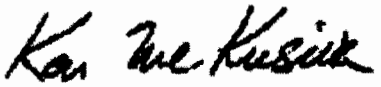
Finally, the SNM also supports amending the regulation to allow the reassigning supplier to have unrestricted access to claims information submitted to Medicare by the billing entity, irrespective of whether the supplier is an employee or an independent contractor of the billing entity.

Again, the SNM appreciates the opportunity to comment on this Medicare Physician Fee Schedule 2007 Proposed Rule to the CMS. Should you find it appropriate to do so, the SNM is ready to discuss any of its comments on the above issues. Please contact the Society of Nuclear Medicine coding and reimbursement advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124.

Respectfully Submitted,



Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee



Kenneth McKusick, M.D., FACR, FACNP
Member. AMA CPT
Advisory Committee

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
Pam West, CMS
Carolyn Mullen, CMS
SNM Coding & Reimbursement Committee

**Submitter :** **Dr. Robert Cushing** **Date: 10/09/2006**

**Organization :** **R. Cushing, MD - Phlebology/Vein Care**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

The diminution of physician reimbursement for CPT code 34678 combined with the continued decreased overall reimbursements for those physicians still providing patient care under the Medicare Program will continue to make it prohibitive for those providers to continue to care for this increasing number of patients leading to no care or less than satisfactory care for them ( i.e. care provided by rushed time constrained conscientious physicians, or "medicare mill" care).

**GENERAL**

GENERAL

there ( short of micra) have been few enabling legislations or
other measures which facilitate or make it easier or less expensive for physicians to provide care. this is yet another encumberance. the ability to accomplish this procedure in an office setting markedly reduces the cost to medicare of its accomplishment since the huge hospital facility fees are avoided. this office based procedure saves the medicare program money and those undertaking it such should be encouraged and assisted, not discouraged by continued cuts in reimbursement for a procedure which is already reimbursed at 2/3rds for the usual and customary fee for this service.

if medicare continues to make it harder and harder, and regularly continues ot reduce reimbursement, you will find increasing numbers of physicians dropping out of the program and thus severelky limiting medicare patient access to medically indicated care - i sincerely hope that that is not your intent

**Impact**

Impact

decreased reimbursement of cpt code 36478 by the annual devaluation of the rvus allotted for that service.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

endovenous laser thermal ablation is a much less noninvasive precedure for treating the root cause of peripheral venous disease - it allows this care to be provided in an office setting with minimal risk, improved long term results and increased safety, than with prior treatment options. the cost to the physician provider of provision of such has not diminished, only increased. the proposal to cut this reimbursement further does not consider the continued rising physician costs, nor does it consider what such will do to medicare patient affordable access to care - it will decrease physician participation and thereby limit access.

**Submitter :** **Mrs. Karen Grogan** **Date: 10/09/2006**

**Organization :** **Mission Hospitals**

**Category :** **Nurse**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-634-Attach-1.RTF

#634

October 4, 2006

**Electronic Submission**

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.

The success of image-guided robotic stereotactic radiosurgery technology, thus far, has been very positive and well accepted by patients with various tumors. However, we believe we will soon be able to successfully treat many other types of cancers using this technology if reimbursement is

reasonable and institutions can afford to make this technology available to their patients. Dramatic reductions in Medicare rates will deter use of this therapy and will delay advances in a very promising, less invasive and effective method of cancer treatment.

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 your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology. 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.

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,

Karen Grogan, RN, MSOM, OCN
Director Cancer & Infusion Services
Mission Hospitals
Asheville, NC 28801
Tel: (828)213-5030

**Submitter :** **Dr. David Porter** **Date: 10/09/2006**

**Organization :** **Dr. David Porter**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Proposed revisions will result in decreased access to care for eligible patients. Fewer physicians will be able to afford to care for Medicare patients.

**GENERAL**

GENERAL

When a new, less invasive, effective treatment for a chronic disease becomes available, it is natural to expect demand for services to increase. Just because codes 36478 and 36479 are being submitted more frequently, does not mean they are overpriced. It simply means the old alternative treatments were not as good. Reducing reimbursement in the face of increasing practice costs will not serve the public good. It may result in decreased access to care for Medicaid recipients. These procedures are 'physician intensive' and medically complex. Each case involves careful ultrasound planning and monitoring, accurate anesthetic placement and counseling before, during and at completion of the procedure. Equipment costs are not trivial, either in initial outlay or in disposable supplies.

Please do not further reduce the RVU valuation of these procedures. RVU values for 36478 should be increased to 51.5, as with 36475.

**Impact**

Impact

Reductions in the RVU's as proposed will negatively impact physicians' ability to provide care to Medicare patients.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

CMS has already planned reduced RVUs associated with codes 36478 and 36479. Practice costs continue to rise. The development of these new procedures has resulted in increased patient demand for endovenous treatment of venous insufficiency. There is already a discrepancy in the reimbursement for laser vs. radiofrequency treatment.

**Submitter :** **Dr. Mark Skellenger** **Date: 10/09/2006**

**Organization :** **Dr. Mark Skellenger**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

See General Comments.

**GENERAL**

GENERAL

CMS-1321-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calender Year 2007 and other Changes to Payment Under Part B ,dated August 8, 2006. I am responding to this CMS proposal regarding the proposed changes in the Physician Fee Schedule for CPT codes 36478 and 36479. As a Vascular Surgeon, I have performed the traditional vein stripping procedure on patients prior to the recent developement of Endovenous Laser Ablation. This procedure required a hospital setting and general anesthesia. The experience was risky and much more traumatic to the patient. Endovenos Laser Ablation is so easy on the patient that it can be performed in the office with a tremendous reduction in costs to Medicare and the patient. One of my patients, an 86 year old lady, was able to walk home with her husband three blocks away after this procedure. However, I must pay for all the equipement including the laser and ultrasound machine(over $69000), the rising practice expenses of my office space, the nurses and technologists, and the supplies including the laser fibers and sterile suppies such as drapes, gowns, local anesthetic solution, IV bags, tubing, gloves and surgical instruments. With futher reduction in the reimbursement for non-facilities as is my practice, I will be unable to perform these procedures in the cost cutting environment of my office. The costs to Medicare and the patient will be much higher. I request no further reductions to the non-facility practice expence RUV and physician fee schedule for CPT codes 36478 and 36479. Respectfully submitted, Mark E. Skellenger, M.D., 445 Bay Area Blvd Houston, Texas 77058

**Impact**

Impact

The reduction in the reimbursement for the treatment of symptomatic varicose veins in the Medicare population will limit the use of the safest, most effective, least tramatic and cost effective office procedure indicated for the correction of this debilitating disease. This procedure is a very effective way to reduce the costs to Medicare and the patient.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comments.

**Submitter :** **Dr. Bill Moses** **Date: 10/09/2006**

**Organization :** **Southern Surgical/ The Vein Clinic**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

Making these revisions as propsed will impact negatively on the Medicare populations' access to quailty health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

**GENERAL**

GENERAL

See Attachment

**Impact**

Impact

See General Comment Below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comment Below.

CMS-1321-P-637-Attach-1.WPD

#637

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
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Bill Moses Jr.
Dublin, Georgia 31040
southernsurgical@bellsouth.net

**Submitter :** **Dr. Nelson Maldonado** **Date: 10/09/2006**

**Organization :** **Dr. Nelson Maldonado**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

These proposed revisions will impact negatively on the medicare patients' access to quality health care. This drastic and continous reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

**GENERAL**

GENERAL

CMS-1321-P

Medicare Program; REvisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Chabges to payment Under Part B Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and 36479 Endovenous Laser Ablation.
I have reviewed the proposed 2007 fully implemented, non-facility practice expence (PE) RVUs for CPT 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 expences consistently rise, (salaries, utilities, supplies, 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 employs a Registered Vascular Technologist (RVT)to provide imaging services. These highly skilled technologist are in drastic shortage and therefore are in high demand and as such comand extremely high salaries in excess of $70,000 per yea plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with MCS 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 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, radiofrecuency vein ablation have been consistently higher than 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 initrial capital acquision cost ($37,900 for Laser and $25,000 for RF) and the per patient suplly costs ($360 for Laser procedure kits and $750 for the RF procedure kits PLUS the cost of disposable sterile supplies such as drapes,gowns,Anesthetic solutions, IV solution bags and tubing to name just a few).
While the per patient supply cost may be SLIGHTLY higher for 36475 (radiofrecuency 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 am requesting that the fully implemented,non-facility practice expence RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be incresed to this same level.

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

Respecfully submitted,

Nelson Maldonado, MD
Grass Valley, California 95945
nmbig1160@hotmail.com

**Impact**

Impact

see General Comment below

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

see General Comment below

**Submitter :** **Dr. Randall Singleton** **Date: 10/09/2006**

**Organization :** **Urology San Antonio**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

The signed original letter will follow by mail.

CMS-1321-P-639-Attach-1.DOC

CMS-1321-P-639-Attach-2.DOC

Comment #639-1
October 9, 2006

Centers for Medicare/Medicaid Services
Dept. of Health and Human Services
ATTN: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: **"REASSIGNMENT AND PHYSICIAN SELF-REFERRAL"**

To Whom It May Concern:

I am writing to give my endorsement and recommendation for the use of our pod lab in pathology. I am in a group practice of 21 urologists and we formed our pod lab in 2003 with the hiring of the best professor of urologic pathology from the medical school to obtain the best pathology services in our area. We also developed the pod lab to utilize his skills. This has only increased our quality of care by having a pathologist read our prostate biopsies on a daily basis, of which he has a huge volume, and he has special expertise in this area versus having a local pathologist who sees a few prostate biopsies occasionally do this. It also is more convenient than having a national firm who is out of this state which requires shipping and handling. This lab has caused no added cost to Medicare in any aspect.

It has also improved our patient care and the fact that we have a known pathologist who we know and can converse with easily who is readily available for a phone call and who comes to our conferences. This has improved the quality of our patient care with prostate biopsies and the diagnosis of prostate cancer. It is also noted in our data that our prostate biopsy rate per patient visit has actually dropped through the years. Our biopsy per visit ratio in 2001 was 27.5 and in 2003, dropped to 22 biopsies per thousand visits, and it has slowly decreased through the years until last year, it was down to 20.8 biopsies per thousand visits. It also, in the first six months of 2006, has even dropped further to 17.7 biopsies per thousand visits. This has shown an overall decrease in the number of biopsies due to the quality of reading and our competence level of the pathologic services.

Also the pod labs have been formed and meet all standards under current law and there is nothing illegal about them. The main complaint from the large national labs is just because we are taking business from them which they feel they are entitled to. This is giving the best medical care on a local level which is what we all strive for.

If you have any questions, please let me know.

Sincerely,

Randall P. Singleton, M.D.

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Job : 91
Date: 10/10/2006
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Comment #639-2
October 9, 2006

Centers for Medicare/Medicaid Services
Dept. of Health and Human Services
ATTN: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: **"REASSIGNMENT AND PHYSICIAN SELF-REFERRAL"**

To Whom It May Concern:

I am writing to give my endorsement and recommendation for the use of our pod lab in pathology. I am in a group practice of 21 urologists and we formed our pod lab in 2003 with the hiring of the best professor of urologic pathology from the medical school to obtain the best pathology services in our area. We also developed the pod lab to utilize his skills. This has only increased our quality of care by having a pathologist read our prostate biopsies on a daily basis, of which he has a huge volume, and he has special expertise in this area versus having a local pathologist who sees a few prostate biopsies occasionally do this. It also is more convenient than having a national firm who is out of this state which requires shipping and handling. This lab has caused no added cost to Medicare in any aspect.

It has also improved our patient care and the fact that we have a known pathologist who we know and can converse with easily who is readily available for a phone call and who comes to our conferences. This has improved the quality of our patient care with prostate biopsies and the diagnosis of prostate cancer. It is also noted in our data that our prostate biopsy rate per patient visit has actually dropped through the years. Our biopsy per visit ratio in 2001 was 27.5 and in 2003, dropped to 22 biopsies per thousand visits, and it has slowly decreased through the years until last year, it was down to 20.8 biopsies per thousand visits. It also, in the first six months of 2006, has even dropped further to 17.7 biopsies per thousand visits. This has shown an overall decrease in the number of biopsies due to the quality of reading and our competence level of the pathologic services.

Also the pod labs have been formed and meet all standards under current law and there is nothing illegal about them. The main complaint from the large national labs is just because we are taking business from them which they feel they are entitled to. This is giving the best medical care on a local level which is what we all strive for.

If you have any questions, please let me know.

Sincerely,

Randall P. Singleton, M.D.

**Submitter :** **Mr. Timothy Martin** **Date: 10/09/2006**

**Organization :** **Cardiovascular Services of America**

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

**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

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