Submitter : **Ms. Carolyn Semrow** **Date: 10/06/2006**

Organization : **South Plains Clinical Vascular Services, Inc**

Category : **Other Health Care Professional**

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 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 have the following concerns:

1. RVUs have consistently been reduced from 2005 levels, while practice expenses have consistently risen (salaries, utilities, etc.). Making it has become increasingly difficult to provide the 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. Because the RVT credential was never intended to imply competence, only a degree of literacy, there is a drastic shortage of highly skilled Sonographer and those who are competent in specialty venous and operative procedures can command salaries in excess of $70,000/ yr plus benefits. The average physician does a limited number of these procedures per year the additional costs imposed by the proposed CMS guidelines make it is impossible to comply 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:
Each of these technologies are comparable especially when we look at both the initial capital acquisition and the per patient supply costs. 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 or higher level.

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,

Carolyn M. Semrow
Carolyn M. Semrow
Lubbock, Texas
cmsemrow@sbcglobal.net

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : **Dr. Charles Martin** **Date: 10/06/2006**

Organization : **Dr. Charles Martin**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

Several of the purposed changes will make it exceedingly difficult to provide care to medicare patients.

Impact

Impact

Please allow me to list the various areas in which CMS purposes to decrease reimbursment.

A. RVU rates continue to plumet from 2005 levels:
1. 2006: 46.91
2. 2007: 43.53
3. 2008: 40.84

B. 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)

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

D. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
1. 2006: 51.5
2. 2007: 47.77
3. 2008: 44.52

Despite all of these changes, CMS expects office to deal with the need to have RVTs and the increasing costs of wages, materials, etc. The result is that the proceedures would be so unprofitable, that providers will not offer them. This would relatgate patients to the painful and more expesive method of care know as vein stripping and ligation. Such invasive surgical proceedures have recurrence rates that approach 70%. Office based endovenous thermal ablation has less than a 2% recurrence rate.

Thus, maintaining rates of reimburment for office based Endovenous thermal ablation is better financially for CMS and both financially and medically for patients.

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

Respectfully,

Charles F. Martin, M.D., FACEP

Date: 10/06/2006

Submitter : Mr. Scott Gollinger

Organization : NorthEast Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

Submitter : Mrs. Elizabeth Yee **Date:** 10/06/2006

Organization : Community Healthcare System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1321-P-546-Attach-1.DOC

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

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

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

CY 2002

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

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

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

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

[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

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[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 w ith vastly differing resource r equirements. A

clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

Elizabeth Yee, Division Director, Clinical Ancillary Services
Community Hospital
901 MacArthur Blvd
Munster, IN 46321

Submitter : **Jennifer Carmichael** **Date: 10/06/2006**

Organization : **Jennifer Carmichael**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Dexa was recently added as a preventive service
The cuts go against their own initiative to increase utilization
The cuts diminish the impact of their own "Healthy People 2010" initiative
The cuts won't cover the tech's salary and the supplies needed for the exam.

Submitter : **Dr. Manuel Gonzalez** **Date: 10/06/2006**

Organization : **vascular surgeon**

Category : **Physician**

Issue Areas/Comments

Background

Background

If fees are lowered for saphenous vein ablation the patient will be required to enter the hopital for alternative therapy

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I have treated many medicare patient who require ablation instead of stripping. The modality is great for the patient both in eliminating hopital stay but is of great benefit to the patient. The patient greatly benefits from this procedure and also eliminates hospital costs. If payment is lowered, we will be unable to deliver is service and must return to long hospital stay and increase in morbidity

Submitter : **Dr. Arnold Rosenbaum** **Date: 10/06/2006**

Organization : **Dr. Arnold Rosenbaum**

Category : **Physician**

Issue Areas/Comments

Background

Background

The reduction in reimbursement will have a negative impact for those requiring quality health care.The access to practioners will drive the medicare population to the more hazardous, more expense in hospital treatment of vein ligation and stripping procedures.

GENERAL

GENERAL

CMS-1321-P
I am responding to the CMS proposal to reduce the reimbusement for CPT codes 36478 and 36479, Endovenous Laser Vein Ablation:
The RVU's have been reduced yearly from 2005 while practice costs (salaries, rent, supplies etc.)have risen. The material cost of the Laser, the fiber costs have risen as well.
Highly skilled ultrasound technologists as well as nursing personnel are required for these procedures as well as the trained medical practitioner.
The overall reimbursement is already scheduled for a 5.1% reduction. The cuts in reimbusement will price out the medicare patient from this needed, safe treatment.
It is certainly more cost effective to have this procedure in the office setting rather than in a setting requiring hospital personnel, their facility fees, anesthesia costs, recovery nursing costs,etc.
A reduction in reimbusement will lead to a patient selection away from the medicare beneficiaries
The reimbursment for laser (EVLT) has been below that of RF, yet costs for Laser include a high acquisition cost which makes the procedure as or more costly than that of RF.
The reimbursement for the procedures should be equal (EVLT and RF 0
I request that the implmented , non-facility practise rate remain at the 2006 rate of 51.5 for 36478, the same as that for 36475.

Thank you
Arnold S. Rosenbaum M.D.
125 Heidi Drive
Portsmouth, R.I. 02871
seacrestmr@aol.com

Impact

Impact

Please refer to my general comment below(reduction in reimbursement for a desired less invasive, safer procedure will force treatment to the more costly, hazardous vein ligation, stripping alternative for those on medicare due to the fixed costs of the procedure of equipment, fibers and overhead)

Provisions of the Proposed Rule

Provisions of the Proposed Rule

As a practicing surgeon, I have the option of the surgical ligation or the non-invasive laser/ultrasound vein ablation procedures. There is no question that the excellent result and avoidance of surgery are in the best interest of the patient.

Submitter : **Dr. james sarnelle** **Date: 10/06/2006**

Organization : **Dr. james sarnelle**

Category : **Physician**

Issue Areas/Comments

Background

Background

This proposal will severely impact access to health care. With continued reductions in reimbursements I will no longer be able to provide endovenous treatment to Medicare patients. Reimbursements for vascular surgery and general surgery are LESS than they were in 1987. Since private carriers often follow Medicare I will eventually stop doing it all together in the office. If I am fored to to it in the hosptial setting then Medicare will end up paying a lot more since it will pay for the hospital fee as well as anesthesiology fee.We can not continue to provide services for patients with reductions of fees.

GENERAL

GENERAL

I request that you consider that there are a lot of costs in doing these procedures. It is much better for the patient. It is far less expensive than if we were forced to do this in a facility. The end result will be that access to care will be severely hampered. There is a high level of skill required and high overhead and it needs to be fairly compensated for. Everything that I buy has gone up since 1987 which is the year I started my practice. Please explain why fees are lower now in 2006 than they were 19 years ago. We can not continue to provide services if we are not compensated for them fairly. Thank You.

Impact

Impact

The proposed rule for CPT 36478 and 36479 Endovenous laser ablation for a non facility plans on reducing the RVUs. It is lower in 2006 that 2005 and plans on reduction in 2007 and 2008.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Endovenous laser ablation CPT 36478 and 36479 in a non facility setting such as an office has significant overhead. There is the initial cost of the laser which is over $35,000. Each procedure requires a one time use laser fiber which is $300 per procedure. There is the cost of the guide wire , micropuncture access and preparation kit which includes sterile gowns, towel, local anesthetics, intravenous tubing, and other materials which adds another $250 for the case. Then there is the Registered Vascular Technologis who is required to perform the ultrasound imaging which is needed during the procedure. Employment of an RVT, in which there is a shortage, is over $75,000 per year plus benefits. Then there is the cost of the ultrasound machine itself which costs $80,000 and requires about $8,000 in maintenance fees every year. All of these costs are in addtion to the cost of the office space, secretary, utilities etc. Patients are much happier getting the procedure done in the office. It will cost a lot more if physicians are forced to do this procedure in the hospital. And in fact, they will stop doing it altogether. The reimbursement that is paid the physician if they do it in the hospital is already too low that I do not do this procedure in the hospital.

Submitter : Dr. James Isobe

Date: 10/06/2006

Organization : Alabama Vascular and 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 the 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 procedures and ultimately result in a loss of access to care for Medicare beneficiaries.

2. The proposed conversion factor (CV) 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 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 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 (possible 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 very much for your kind consideration. I will be happy to discuss this further with memebers of your committee.

Respectfully submitted,
James H. Isobe, M.D.
Alabama Vascular and Vein Center
700 Montgomery Highway, Suite 210
Vestavia Hill, AL 35216

Impact

Impact

See general comment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See general comment.

Submitter : Dr. Stephen Murray
Organization : Inland Vascular Institute
Category : Physician
Date: 10/06/2006

Issue Areas/Comments

Background

Background

I anticipate elimination of the availability of these procedures to medicare patients entirely.

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

Keep it up folks. By the time you need to see a physician during your senior years I hope you have a Berlitz translator or can afford to fly to Thailand to see what's left of the english speaking physicians. There is a saying that is attributed to academics which applies here. As you advance through your degrees, you learn more and more about less and less until you know everything about nothing. Applied to the care of medicare patients, you take the most highly trained people in the society, to take care of the sickest segment and continually turn down the spiggot until they get nothing, or can't afford to run a practice.

Officially, 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,

Stephen P. Murray, MD, FACS
Inland Vascular Institute
122 W. 7th Ave, Suite 420
Spokane, WA 99204

Impact

Impact

see general comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see General comments

Submitter : Ms. Ann-Marie Lynch

Organization : AdvaMed

Category : Device Association

Date: 10/06/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1321-P-553-Attach-1.PDF

CMS-1321-P-553-Attach-2.PDF

CMS-1321-P-553-Attach-3.PDF

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#553-1

AdvaMed
Advanced Medical Technology Association

October 6, 2006

Via Electronic and U.S. Mail

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

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS-1321-P)

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (CMS-1321-P, *Federal Register*, Vol. 71, No. 162, Tuesday, August 22, 2006, p. 48981). AdvaMed is the world's largest association representing manufacturers that produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others. AdvaMed supports the establishment of payment rates under the physician fee schedule that are adequate and ensure access to advanced medical technologies by Medicare beneficiaries. We will comment on the following issues raised in the proposed 2007 PFS Rule:

1. Deficit Reduction Act Proposals
2. Bone Mass Measurement (BMM) tests

3. Resource Based Practice Expense RVU Proposals
4. Clinical Diagnostic Lab Tests
5. ASP Issues

PROVISIONS

I. DRA Proposals

Proposed Adjustments for Payment to Imaging Services

A. Payment for Multiple Imaging Procedures for 2007

The Deficit Reduction Act (DRA) of 2005 contained two provisions affecting imaging services paid under the Medicare physician fee schedule. Among these was a mandate that budget neutrality provisions be waived for reductions in payment for contiguous body part imaging. Initially, CMS proposed to reduce payments for these services by 50 percent beginning in 2006. However, in the final rule CMS decided to phase in the 50 percent reduction over a period of two years. Consequently, a 25 percent reduction went into effect for 2006 and an additional 25 percent reduction was expected to be phased in as of January 1, 2007.

In the proposed 2007 PFS rule, CMS has indicated that it would be prudent to maintain the imaging discount at 25 percent for 2007 while continuing to evaluate the appropriate payment for the multiple image procedures subject to the discount. AdvaMed is pleased with this decision and commends CMS for not moving to the 50 percent discount. AdvaMed encourages CMS to be vigilant in obtaining and evaluating data relating to the costs of these procedures so that the most accurate cost information can be used in making any future determinations regarding reductions in the price of imaging services.

B. Reduction in Technical Component for Imaging services Under the PFS to OPD Payment Amount

The DRA requires that, effective January 1, 2007, the payments for the technical component of certain imaging procedures performed in a physician office be capped at the lesser of the Medicare physician fee schedule or the outpatient department (OPD) reimbursement rate. AdvaMed is concerned that capping the technical component payment at the OPD rate will lead to significant reductions in the payment for imaging procedures performed in the physician office setting and may reduce beneficiary access to these procedures.

These findings are supported by a recent report conducted by The Moran Company (Moran) in which they analyzed the impact of the DRA provisions.[1] The Moran report

1 See Assessing the Deficit Reduction Act Limits on Image Reimbursement: Cross-Site Comparisons of Cost and Reimbursement, The Moran Company, September 2006
http://www.imagingaccess.org/reports/index.cfm

found that 87% of the procedures whose payments will be affected by the DRA caps would be paid at an amount that is less than the estimated cost of performing the procedure in the office setting. According to the Moran report, several procedures including image guided ultrasound procedures used in the diagnosis of breast cancer, PET/CT exams used to diagnose cancerous tumors, bone density studies used to diagnose osteoporosis, and MR angiography used to locate aneurysms will be cut 35% to upwards of 50% if the DRA changes are enacted. These cuts may result in diagnosis and treatment delays, increased wait times, and reduced access for patients in rural areas to critical imaging services.

AdvaMed is concerned with the impact of the DRA provisions on image guided treatment procedures. CMS has interpreted the DRA provisions regarding imaging issues as relating to both "*diagnostic*" and "*image guided*" procedures. However, this interpretation is not borne out by the MedPAC recommendations, which focus specifically on increased utilization of diagnostic imaging services. In fact, in its March 2005 report to Congress MedPAC cites the efficacy of two image guided procedures, biopsies for bone-cancer and coronary angioplasty, as examples of image guided procedures which benefit patients.[2] The MedPAC analysis did not determine whether growth in imaging utilization was due to over-utilization or appropriate expansion of imaging as a diagnostic tool.

The March 2005 MedPAC report makes several recommendations based on its review of *diagnostic* imaging services including the imposition of coding edits to detect unbundled *diagnostic* imaging services and setting standards for physicians who bill Medicare for interpreting *diagnostic* imaging studies.[3] The content of the MedPAC report coupled with their recommendations suggest that they did not identify issues related to image guided treatment procedures.

AdvaMed is concerned that capping the technical component of imaging procedures, in accordance with the DRA mandate, may interfere with patient access to necessary care. We therefore recommend that caps to the technical component of imaging services not be applied to image guided treatment procedures.[4] In order to reduce adverse patient impact, we further recommend that any caps to the technical component of imaging services be applied in the most prudent manner possible.

AdvaMed is also concerned that several Category III CPT imaging codes are incorrectly included on the list of DRA cap-eligible procedures (Addendum F). Category III CPT codes are dedicated to emerging technologies, are primarily intended for tracking purposes only, and are not assigned RVU values at the national level. While some Category III

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2 See Report to the Congress: Medicare Payment Policy, MedPAC, Page 155 (March 2005).

3 See Report to the Congress: Medicare Payment Policy, MedPAC, Pages 159 and 163 (March 2005).

4 Approximately 18 image guided treatment procedures would be affected by the DRA caps. These codes are all done in conjunction with a surgical or other procedure. Eliminating these codes from the DRA cap would have nominal impact, estimated at 2%, on total projected savings.

CPT codes are covered under Medicare and are Medicare Carrier-priced, they do not have physician fee schedule technical components and therefore would not be subject to the DRA mandated caps. Therefore, AdvaMed urges CMS to remove all Category III CPT codes from the proposed CPT/HCPCS imaging codes list.

C. Interaction of the Multiple Imaging Payment Reduction and the OPPS Cap

The proposed rule recommends that the 25% multiple procedure imaging reduction be applied prior to the OPPS cap in the case of procedures impacted by both the multiple procedure discounts and the OPPS cap. The OPPS cap would then be applied to the reduced amount. CMS has indicated that this method is being applied because the OPPS rates may already include implicit discounts. The proposed methodology would be implemented while CMS continues to explore the issue. Given the uncertainty of the OPPS data we encourage CMS to take an approach that fairly reflects the costs involved in performing imaging tests.

Proposed Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

AdvaMed is pleased that, pursuant to DRA requirements, CMS will be including screening for AAA as a covered benefit for Medicare beneficiaries meeting the established criteria effective January 1, 2007. Providing this potentially life saving screening exam is important to beneficiaries. The coverage criterion for the benefit identifies and adequately addresses the needs of the Medicare population most at risk for AAA. AdvaMed is also pleased with the recommendation to pay for this service at the same level as CPT code 76775—a service requiring resources and work intensity comparable to that of the screening procedure.

II. Bone Mass Measurement (BMM) Tests

The proposed rule revises the definition of bone mass measurement (BMM)to remove coverage for single photon absorptiometry (SPA) and to include coverage for axial skeleton measures (DXA). This change is guided by the shift in technology from SPA to DXA. AdvaMed is please that CMS recognizes the technological developments which have led to the use of DXA and other technology in accurately assessing BMM. As such, AdvaMed would also like to commend CMS for its proposal to allow use of the NCD process to identify other BMM systems which can be used to monitor patients with osteoporosis and those requiring confirmatory baseline measurements. An NCD is already in place relating to the identification of BMM indications and coverage. Allowing new devices to go through the NCD process will create consistent coverage determinations for these treatments.

AdvaMed strongly supports CMS's coverage improvement, but is concerned that reductions in the reimbursement for BMM procedures utilizing DXA technologies may compromise patient access to the technology. Specifically, we are concerned with proposed reductions in the payments for CPT codes 76075, 76077, and 76977 in 2007. In

the proposed regulation, CMS supports its decision to use DXA to monitor bone mineral density by stating that, "DXA is precise, safe, and low in radiation exposure, and permits more accurate and reliable monitoring of individuals over time." However, continuing reimbursement decreases for procedures utilizing DXA technology may limit patient access to this monitoring method and the benefits associated with its use. Therefore, AdvaMed encourages CMS to take steps to correct and prevent further reductions in payment for procedures utilizing DXA technology.

III. Resource-Based Practice Expense (PE) RVU Proposals

Payment for Splint and Cast Supplies

AdvaMed supports CMS' proposal to reinstate separate coding and payment for cast, splint, and strapping supplies under the Medicare Physician Fee Schedule in calendar year (CY) 2007. We agree with CMS' conclusion that these supplies are considered medically necessary not only for the management of fractures and dislocations, but also for serial casting, wound care, and protection. Assigning distinct HCPCS billing codes for these supplies, when furnished incident to specified professional services, will enable contractors to identify with greater accuracy those instances in which cast, splint, and strapping supplies are medically necessary and eligible for payment.

CMS has requested input from medical specialties and contractors on its proposal to pay separately for splint and casting supplies billed with Q-codes. See Federal Register, Vol. 71, No. 162 page 48987. AdvaMed is aware of a related coding issue that may result in underpayment for supplies used in wound care procedures.

As proposed, CMS' refinements to the practice expense (PE) database would exclude cast, splint, and strapping supplies used in compression therapy for venous leg ulcers from the list of separately paid supplies. Currently, CMS proposes to use HCPCS Q-codes to identify those supplies that would receive separate fee schedule payment amounts, and for which supply inputs would be excluded from the PE database. However, paste bandage supplies (also referred to as Unna-boot supplies) are currently assigned HCPCS A-codes, not HCPCS Q-codes. As a result, contractors would be unable to determine whether to make separate fee schedule payments for these supplies when billed with CPT 29580, application of paste boot. In addition, because payment for paste bandage supplies would be excluded from the PE database for CPT 29580, physicians would be underpaid for use of these supplies. AdvaMed recommends that CMS instruct contractors to make separate payment for paste bandage supplies when reported on the CMS-1500 claim form with the HCPCS A-codes listed below.

HCPCS	Paste bandage supply
A6441	Padding bandage, width >=3" but <5", per yard
A6442	Conforming bandage, non-sterile, width <3", per yard

HCPCS	Paste bandage supply
A6443	Conforming bandage, non-sterile, width >=3"but <5", per yard
A6444	Conforming bandage, non-sterile, width >=5", per yard
A6445	Conforming bandage, sterile, width <3", per yard
A6446	Conforming bandage, sterile, width >=3" but <5", per yard
A6447	Conforming bandage, sterile, width >=5", per yard
A6448	Light compression bandage, width <3", per yard
A6449	Light compression bandage, width >=3" but <5", per yard
A6450	Light compression bandage, width >=5", per yard
A6451	Moderate compression bandage, width >=3" but <5", per yard
A6452	High compression bandage, width >=3" but <5", per yard
A6453	Self-adherent bandage, width <3", per yard
A6454	Self-adherent bandage, width >=3" but <5", per yard
A6455	Self-adherent bandage, width >=5", per yard
A6456	Zinc paste impregnated bandage, width >=3" but <5", per yard

Impact of Practice Expense Changes

Changes in the PE relative value units resulting from the incorporation of supplemental survey data are expected to have a significant impact on some specialties. Other specialties' PE values will be negatively impacted as a result of the transition to a bottom-up methodology. The impact of the PE changes, though anticipated, is especially difficult given the proposal to reduce the conversion factor by 5.1% in 2007.[5] CMS has proposed to phase in the PE changes over a four-year period, 2007-2010, to avoid adverse impacts on specialty fees. However, the proposed changes will result in significant reductions in the reimbursement for several procedures and could adversely impact patient access. For example, Medicare payments for a complete course of partial breast irradiation in a freestanding center would decrease by (19% in 2007 and 56% in 2010). These decreases could result in both reduced access and options for Medicare beneficiaries. AdvaMed urges CMS to take steps to ensure that patients continue to have access to the treatments and technologies that improve their quality of life and encourages implementation of the PE changes in the most practical manner possible.

IV. Clinical Diagnostic Lab Tests

AdvaMed also wishes to comment on the implementation of section 942 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which specified improvements to CMS's current process for developing clinical laboratory fee schedule (CLFS) payment rates for new or substantially revised pathology or laboratory CPT codes. Many of AdvaMed's member companies develop clinical laboratory tests that substantially improve the quality of life for Medicare beneficiaries through the prevention and early diagnosis of disease.

5 Prior to publication of the proposed PFS rule the conversion factor was expected to be reduced by approximately 4.6%.

We appreciate the progress CMS has made to date in improving its process for developing payment rates for new or substantially revised CPT codes for clinical laboratory services under the Clinical Laboratory Services Fee Schedule (CLFS). We commend the agency for holding its annual "Laboratory Public Meeting," which provides the public a forum to present views on the tests and services that will be included in the following year's edition of CPT. We have appreciated the opportunity to present our comments at this annual public meeting for the past few years.

We believe that providing opportunities for public discussion of agency payment policy activities is crucial to an open, transparent process. The expertise that stakeholder groups offer at these meetings has resulted in more clinically appropriate payment determinations. Further, we appreciate and commend the action the agency has taken to post proposed new clinical lab payment determinations for comment, after receiving public input at the open public meeting. These measures are consistent with MMA section 942, and we believe they represent a significant improvement to CMS's process for determining new test payments.

Notwithstanding these improvements, the MMA included other provisions relating to the process for determining payment for new clinical laboratory tests that must be addressed. We will identify these provisions as we comment on the following areas: (i) the general CMS payment process for developing CLFS payment rates for new or substantially revised CPT codes; (ii) the gap-fill process; (iii)the cross-walk process ; and (iv) other overarching issues.

A. General Process Issues

a. Rationales, Data and Responses to Comments

In the preamble to the proposed PFS rule, CMS states that the "current process for providing public consultation on the establishment of payment amounts . . . is consistent with the requirements of section 1833(h)(8)(B)" of the Social Security Act (section 942 of the MMA) [71 Federal Register 49063 (Aug. 22, 2006)]. While CMS asserts that it is in full compliance with the statutory requirements, we note that both the law, and the proposed regulations [42 C.F.R. section 414.406], require that CMS post on the internet a list of proposed and final determinations of the payment amounts for tests "with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public."

We support incorporation of this language in CMS's regulations. However, we note that CMS's current practice differs from this requirement. At present, CMS posts its proposed and final determinations, but does not post the rationale, data, or responses to comments from the public. Thus, there appears to be a discrepancy between what is required by law and CMS's assertion in the preamble to these regulations that they are currently complying with the law.

Making public the rationale and the data on which CMS's proposed and final determinations are based, in addition to the CMS responses to comments from the public, would be an additional positive step towards increasing transparency and openness in CMS's payment process. This is the approach CMS follows for its other payment systems, and we strongly urge CMS to conform its practices to both the statutory requirements and its own proposed regulatory language in implementing MMA section 942. Providing this information and an explanation for specific payment determinations via the CMS website (similar to the way CMS provides this information and explanation in the regulation preambles for other payment systems, including the physician fee schedule and the hospital outpatient prospective payment system) would be one way to implement this legislative requirement. If CMS is not able to provide the rationale, data, and its responses to public comments on the internet and elsewhere, we ask that CMS explain why the information is not publicly available.

b. Web-Posting of All Public Comments or Suggestions

Additionally, we note that in the past, CMS has not posted on the internet all of the public suggestions made to the agency regarding payment rates for new or substantially revised CPT codes. Posting all such comments or suggestions made to the agency, whether before or shortly after the Laboratory Public Meeting that CMS holds annually, would be another practice that could improve the CMS payment process.

c. Announcement of Meetings and Codes to be Discussed

While we recognize that CMS is required by the MMA to announce its annual Laboratory Public Meeting in the *Federal Register* "not fewer than 30 days" prior to the meeting, we recommend announcing the meeting – and making public the new or substantially revised CPT codes that will be the subject of the meeting earlier in the year – at least 60 days in advance of the meeting. Providing such advanced notice of the codes to be discussed at the meeting will allow for the development of more meaningful and well-considered public comments. We note that these comments often require technical expertise that is often difficult to obtain within only 30 days and thus extending the notice to 60 days in advance of the meeting would be a significant improvement.

B. Gap-Fill Issues

We are disappointed that CMS did not address the methodology that contractors should use in establishing local gap-fill payment rates for new test codes. AdvaMed members believe that it is imperative that CMS set forth a clear approach to pricing these new tests. As we have stated on record at several of the open public meetings for the CLFS, stakeholders often suggest that the cross-walk process be used for new test codes instead of the gap-fill process because the gap-fill methodology is neither well-defined, nor monitored by CMS.

In the limited, previous instances when gap-fill has been used, carriers made use of a wide variety of pricing techniques. Individual carriers set prices based on the following types of information or techniques, which illustrate some of the concerns we have with the gap-fill process:

- A consultant's recommendations;
- The payment level assigned to "related code(s)" already on the fee schedule, even though Medicare officials had chosen not to cross-walk the test and issued instructions to carriers to "gap-fill" the test;
- Carrier pricing formulas based variously on relative values imputed to the test, the customary charges associated with the test, and so forth;
- Considering prevailing charge data in the carrier area, and reducing these charges to a previously set NLA for the test to which it had been "cross-walked" (this was a test that had been cross-walked initially, but then subsequently gap-filled);
- Applying an arbitrary percentage reduction in local laboratory charges for the new test;
- Carrier surveys of the rates set by other carriers for the test, which were the basis for subsequent questionable "calculations" to set carrier "gap fill" rates (e.g., these "calculations" produced rates set at the median, average, or some arbitrary percentage of the carrier rates collected);
- Carrier surveys of physicians who may not have had any experience with the test at issue;
- Carrier use of unverified data from the internet that may not reflect actual cost of providing the test in a CLIA-approved laboratory;
- Contacting only one patient to determine the time associated with the test;
- Following the personal opinion of another Carrier Medical Director; and
- Carrier Medical Director discretion.

Without guidance from CMS on the methodology that should be used by carriers in setting "gap fill" payment rates for new tests, there will continue to be uncertainty and variation in the rates that are set by carriers, leading to issues with the new test payment rates. Unless the "gap fill" price-setting methodology is based on accepted principles, the payment rates that are computed will be viewed as arbitrary. Consequently, we recommend that CMS make the following changes to improve the gap-fill process:

- Provide more specific, step-by-step direction on the methodology Carriers should use when conducting data collection, including the incorporation of external data

provided by laboratory providers (of varying size, setting, and patient mix), manufacturers, private payers, and other stakeholders;

- Provide instructions on how to incorporate charges for a given new test,
- Specify the minimum requirements this data shall meet to ensure that the data collected is valid, meaningful, and unbiased, including establishing a reasonable standard for the volume of claims that a carrier should process in developing the gap-fill payment rate;
- When newer data is available, contractors should use that data, rather than using the least costly alternative or similar standard;[6]
- Monitor the carrier's (contractor's) methodology and data reporting, providing, where needed, oversight and feedback to contractors to ensure compliance with CMS instructions and that appropriate data is being collected;
- At the close of the data collection time period, make available for public inspection and comment the proposed new national payment amount. Using informal mechanisms for requesting comment, such as the agency's web site --
    i. To facilitate meaningful comment, provide the data and methodology upon which the gap-filled amount is based;
    ii. If based on claims data, provide specific information on the number of claims, and the localities from which those claims were filed;
    iii. Provide principles to be employed to ensure that the data used by carriers are statistically significant and alternatives to follow if statistically significant data are unavailable; and
    iv. Provide any other information or data that was factored into the decision-making;
- In cases where such a contractor fails to comply with some or all of CMS-prescribed directions on the gap-fill methodology (e.g., to address instances where contractors simply cross-walk or rely on prices determined by other contractors, as opposed to collecting data individually according to CMS-set methods), that contractor's payment rate (and any "data" used to calculate it) should be excluded from the calculation of the NLA;
- Establish a mechanism to receive and review additional data, including data provided by the laboratory industry, manufacturers, and other stakeholders, in order to adjust the proposed national payment amount for the new test. This is particularly important in cases where a substantial number of contractor payment rates are excluded from the NLA calculation due to concerns with the methodology used;
- After taking into account additional data and comments received, publish the final national payment amount for the new test, with a clear explanation of the basis for

6 In particular, we note that the Conference Report to the MMA specifies that "carriers and CMS cannot substitute an alternative service for a gap filled amount." Accordingly, the least costly alternative approach is inconsistent with this report language.

its determination, again using informal publication mechanisms, such as the web site; and

- Make public the specific data and methodology upon which the gap-filled amount was based, including a listing of the local amounts used to arrive at the NLA, and any additional data or information provided during the comment period, with an opportunity for public comment thereon.

We note that CMS is currently using the gap-fill process to develop a payment rate for CPT code 83037. We believe that CMS has discretion to accept and implement many of the above-mentioned recommendations, even for the current, on-going gap-fill process. We recommend that CMS evaluate and consider additional, external data in this context.

Absent the provision of additional direction to contractors and changes to the gap-fill process as recommended above, we recommend that CMS consider an alternative approach to setting payment rates for new clinical laboratory test codes. AdvaMed supports H.R. 5369, the Clinical Laboratory Fee Schedule Improvement Act of 2006, which authorizes a demonstration project that would test a new approach to setting payment for molecular diagnostic tests. This approach would set up a stakeholder panel to advise CMS on appropriate pricing of such tests through a deliberative process that takes into account relevant data, the expertise of stakeholders with an understanding of the complexity of the tests, clinical laboratory resources involved, and the estimated impact of the test on patient care management. We have attached H.R. 5369 for your reference. We urge CMS to consider undertaking such an alternative pricing approach for unique new tests to address the longstanding problems with the gap-fill process.

C. Cross-Walk Issues

As we mentioned above, the cross-walk process is the primary method recommended by interested parties for use in pricing new or substantially revised test codes for the Medicare Clinical Laboratory Fee Schedule. This is in part because some cross-walks are suggested by stakeholders because the gap-fill process is fraught with uncertainty. Nevertheless, we commend CMS for the way it has used the cross-walk process since it began considering stakeholder comments at open public meetings and has given careful consideration to public comments and expert opinions expressed at these meetings.

Nevertheless, we see two areas for improvement in the cross-walk process:

- First, we recommend that when CMS chooses to cross-walk new or revised codes to existing codes, the cross-walk should be made to the national limitation amount (NLA) of the existing code on the fee schedule, rather than the local carrier fee schedule amounts which often vary significantly from one geographic area to another. If CMS chooses to cross-walk new tests to the NLA of existing tests on the fee schedule, this policy will prevent the geographic variation problems inherent in the CLFS from worsening.

- Second, provided that CMS makes significant changes to the gap-fill process to improve its predictability (as recommended above), we recommend that CMS provide more regulatory specificity to guide the cross-walk process. A specific definition of what "comparable" means, with the particular criteria that CMS considers, would improve the payment process overall and would provide a framework for CMS ultimately to provide the rationale for its particular cross-walk decisions. For example, it would be helpful to receive clarification regarding whether "comparable" refers to resources involved in performing the test or service (e.g., supplies, equipment, lab staff time, etc.), the type of test or service performed, or clinical similarity, among other potential factors.

We note that MMA section 942 requires CMS to set forth criteria for making new payment determinations. The MMA conference report specified that such criteria "include whether a payment rate should be established through gap-filling or cross-walking to an existing code." Clarity on the definition of what is "comparable" would also shed light on the basis for CMS's decision to cross-walk or gap-fill a new or substantially revised test code. Clarification on this point would be helpful once CMS has made significant improvements in the gap-fill process as noted above.

D. Other Overarching Issues

In addition, we urge CMS to establish a formal, timely reconsideration process to allow stakeholders to seek review of the payment determinations made by CMS or its contractors in relation to a given test code. Stakeholders should be able to request and receive a reconsideration of:

- A CMS decision to crosswalk or gap-fill a new or revised test code;
- A CMS crosswalk determination;
- A contractor determination of a gap-fill price; and/or
- A CMS calculation of the NLA for a new test.

Finally, there is considerable uncertainty surrounding how Medicare contractor reform will affect the CLFS and the process for developing payment amounts for new or substantially revised CPT codes. To improve predictability in this area, we request that CMS clarify the following:

- How will local fees be handled when new Medicare Administrative Contractors (MACs) are chosen? Will the various local fee schedules be maintained or will they be collapsed into a single price for each of the new jurisdictions? If so, what process will be used to do this?
- If a new test is gap-fill priced where there is a new MAC, will gap-fill prices continue to be set for each of the previous contractor jurisdictions?
- Will the new MACs have a separate medical director for each of the previous contractor jurisdictions who will set gap-fill prices for new test codes and maintain existing local fee schedules?

V. ASP Issues

The proposed rule recommends changes in the way Group Purchasing Organizations (GPOs) administrative fees are recognized. CMS proposes to treat GPO fees that do not satisfy the definition of bona fide service fees as price concessions.[7] AdvaMed seeks to clarify whether the proposed changes could impact the ability of manufacturers and other entities to comply with the GPO safe harbor to the anti-kickback statute found at 42 C.F.R. §1001.952(j) and requests that implementation of any changes in the treatment of administrative fees not affect the existing GPO safe harbor.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by our member companies, as they provide a unique source of information in developing appropriate PFS and clinical diagnostic lab test payment rates. We appreciate the opportunity to submit comments on the August 22, 2006 proposed PFS rule, and look forward to working with CMS to address our concerns.

Sincerely,

Ann-Marie Lynch
Executive Vice President

cc: Herb Kuhn
Tom Gustafson
Terry Kay
Liz Richter
Laurence Wilson

Enclosures

7 CMS proposes to define the term bona fide service fee as fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not that entity takes title to the drug.