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. Mehul Shah **Date:** 10/09/2006

Organization : Vascular Medicine Center

Category : Physician

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

1. RVUs have consistently been reduced from 2005 levels:

a. 2006: 46.91

b. 2007: 43.53

c. 2008: 40.84

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

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

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

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:

a. 2006: 51.5

b. 2007: 47.77

c. 2008: 44.52

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

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

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

Respectfully submitted,

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

Organization : **American Diabetes Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-642-Attach-1.DOC

#642

AMERICAN DIABETES ASSOCIATION COMMENTS ON
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 American Diabetes Association strongly opposes the provision of Proposed Rule CMS-1321-P which would modify 42 C.F.R. 424.24(f) to require physicians to certify each individual blood glucose test as being medically necessary as a condition of reimbursement. This administrative barrier will impede the efforts of skilled nursing facilities to provide clinically appropriate care to beneficiaries with diabetes, and will likely lead to poorer health outcomes for an already-frail population.

The Association's *Standards of Medical Care in Diabetes* asserts that "[g]lycemic control is fundamental to the management of diabetes."[1] Studies have shown that patients who maintain healthy blood glucose levels are more likely to avoid long-term complications of diabetes, including retinopathy, nephropathy, neuropathy, and cardiovascular disease. Blood glucose monitoring can help patients and their diabetes care team delay the onset of these costly complications, prevent them entirely, or -in cases where a complication has begun to develop- even reverse some of the effects of those complications . It can also prevent serious short-term complications such as hypoglycemia, particularly in patients using insulin to manage their diabetes.

Effective management of blood glucose levels is crucial for all Medicare beneficiaries with diabetes, but especially for those residing in skilled nursing facilities. This population of Medicare beneficiaries is particularly frail and prone to costly and life-threatening complications of diabetes. Approximately 1 in 5 residents of skilled nursing

[1] Standards of Medical Care in Diabetes - 2006. Diabetes Care, Vol. 29 Supp. 11 (January 2006).

facilities have been diagnosed with diabetes - and 90% of these residents with diabetes show signs of serious complications, including coronary artery disease, stroke, and/or peripheral artery disease.[2]

42 C.F.R. 424.24(f) currently allows for reimbursement of medical services provided on a continuing basis. Under this rule, the provider may certify that a series of services, such as multiple blood glucose tests performed over the course of a day, week, or month, are medically necessary and thus eligible for reimbursement. The current rule does not require recertification of continued need for services.

The Proposed Rule, on the other hand, amends the existing regulation to require a separate order for each blood glucose test performed on beneficiaries with diabetes who reside in skilled nursing facilities. While the Association appreciates the need to protect against fraud and ensure that patients are truly benefiting from tests which are billed to CMS, this approach creates a bureaucratic and administrative process which will hamper appropriate diabetes care for those patients requiring multiple blood glucose tests each day. But more importantly, this additional administrative requirement could limit patient access to blood glucose testing, which will result in sicker patients with more expensive health problems.

The Association is especially disappointed that CMS would propose a provision so contrary to the spirit and intent of recent CMS initiatives regarding diabetes. Efforts to improve the quality of care provided to beneficiaries with diabetes would be undermined by a rule which requires official certifications for routine blood glucose testing several

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[2] Resnick, Barbara. Diabetes Management: The Hidden Challenge of Managing Hyperglycemia in Long-Term Care Settings. Annals of Long Term Care, vol. 13 no. 8 (August 2005).

times a day. Patient access to medically necessary diabetes care should never be jeopardized by bureaucratic concerns over payment rates and procedures.

The amendment contained in the Proposed Rule would deprive skilled nursing facilities of the resources necessary to manage the diabetes of their residents by placing unnecessary and clinically inappropriate regulatory barriers in place. Thus, the Association strongly urges CMS to maintain the current rule governing reimbursement of covered medical and health services currently codified at 42 C.F.R. 424.24(f). In the alternative, we ask CMS to create an exemption within the Proposed Rule that will specifically protect daily glucose monitoring from this excessive bureaucratic burden.

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

Organization : Texas Oncology, P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-643-Attach-1.DOC

#643

October 6, 2006

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

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1321-P), published in the Federal Register on August 22, 2006.

Our radiation oncology center is deeply concerned with the proposed cuts for the RVUs associated with the delivery of breast brachytherapy. Breast brachytherapy is an important alternative to whole breast external radiation therapy (WBXRT) for a number of reasons. Breast brachytherapy delivers radiation to the tissue at greatest risk for recurrence, decreases time and inconvenience of WBXRT (shorter therapy duration: 4-5 days), reduces acute and chronic toxicity, and eliminates scheduling problems with chemotherapy. Breast brachytherapy is well established, having greater than five year follow-up, with recurrence rates equivalent to WBXRT. The alternative is women having to endure 6 weeks of radiation when receiving WBXRT.

Radiation therapy after breast conservation surgery is considered the standard of care in the industry. Yet, in the last fifteen years, there has been a 250% increase of patients who receive breast conservation surgery without radiation therapy. As published in the *Journal of the National Cancer Institute* and *Lancet*, omission of radiotherapy is associated with a threefold increase of ipsilateral breast tumor recurrence. The use of radiotherapy is associated with a 5 – 8% breast cancer mortality reduction. No subset of patients has been identified that can forgo radiation following lumpectomy, yet 46% of patients with DCIS, who are potential BCT candidates, receive lumpectomy alone. At five years, use of radiotherapy following lumpectomy for DCIS reduces the risk of recurrence from 16% to 8%. The inconvenience of a six week regimen of radiation

therapy associated with WBXRT is a major factor in the decision making process for these patients. In the November 2005 edition of *Cancer*, Voti et al found that the odds of a patient completing a course of WBXRT dropped by 3% with every 5-mile increase in distance to a radiation facility.

The RVUs for WBXRT are proposed to increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 higher than HDR Breast Brachytherapy. HDR treatment is extremely beneficial for the patient because it irradiates considerably less healthy tissue and allows the patient to return back to their life activities in just five days. However, HDR breast brachytherapy does require more time for the radiation oncologist to plan and calculate the patient's treatment. The proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in limited access to this radiation treatment for women who are Medicare beneficiaries.

Specifically, CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for HDR breast brachytherapy. The RVUs are proposed to be reduced by more than 50% by 2010 for breast brachytherapy treatment. THESE PROPOSED REDUCTIONS WILL NEGATIVELY IMPACT THE ABILITY OF MEDICARE ELIGIBLE WOMEN TO BE TREATED WITH HDR BREAST BRACHYTHERAPY. These proposed cuts are illustrated in the table below.

TABLE 1

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%
TOTALS				$12,562		*($7,049)*	*-56%*

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

In summary, there are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a maximum of no more than 5% reduction and this maximum should remain in effect during the time necessary 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 professional society so that they may 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.

Texas Oncology/US Oncology is the nation's largest provider of cancer care and radiation services. Our cutting-edge technologies, treatments and research are offered in welcoming and comfortable environments. We maintain comprehensive quality oversight and responsible financial management. The proposed reductions to reimbursement will significantly limit our ability to treat Medicare beneficiaries with HDR breast brachytherapy.

Sincerely,

Mark A. Engleman, MD

Mark A. Engleman, MD
Texas Oncology, PA
Plano West Cancer Center
4708 Alliance Blvd., Ste. 150
Plano, TX 75093

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee

Representative Joe Barton, Chairman, Energy and Commerce Committee

Representative Michael Burgess, Energy and Commerce Health Subcommittee

Representative Kay Granger, Appropriations Labor-HHS Subcommittee

Carolyn Mullen, Deputy Director, Division of Practitioner Services

W. Robert Lee, MD, President, American Brachytherapy Society

James Rubenstein, MD, Chairman, American College of Radiation Oncology

Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

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

Organization : **Kansas City Urology Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

i.e. See Attachment

CMS-1321-P-644-Attach-1.DOC

CMS-1321-P-644-Attach-2.DOC

CMS-1321-P-644-Attach-3.DOC

CMS-1321-P-644-Attach-4.DOC

Comment #644-1
October 9, 2006

RE: File Code: CMS-1320-P

I am and have been a practicing urological surgeon for 31 years in North Kansas City, Missouri. Six years ago our group of 3 urologists merged our practice with 4 other smaller groups in order to form a larger group that could be more cost efficient and financially survive in today's medical practice climate. Kansas City Urology Care, PA is an 18-Dr. urology group located in the greater Kansas City area.

I am writing to express my deep concern over sections of the CMS proposed physician fee schedule that addresses reassignment and Stark rules relating to laboratory services.

In order to assure that we could provide the best and most cost efficient laboratory services, our practice helped found a company called Uropath in 2003 to develop, implement and manage a specialized urological laboratory facility. Unfortunately a highly specialized urological pathology service was not available locally. We own the lab, located in Leesburg,FL and Uropath provides the management services essential to providing world-class specialty pathology.

As part of the physician fee schedule rule issued on August 22, CMS has proposed two rules related to diagnostic services that if adopted would possibly force us to drop our relationship with Uropath and close our specialized lab that Uropath operates for us.

Our concerns are as follows:

1. The Reassignment Rule and the Self-Referral rule are unclear and difficult to understand. Some rules are proposed, some are considered, and other concepts are simply thrown out for discussion. The text of some rules is not in final form. This lack of clarity and focus suggests a rush to propose rules before CMS has a clear understanding of what it seeks to address or a full appreciation for the consequences that will result from implementing these rules. Their implementation should be delayed.

2. CMS proposes these rules to address perceived program abuses caused by pod labs, however there exists no evidence to support the assumption that pod labs have resulted in the over-utilization of services, the provision of unnecessary services, kickbacks, fee-splitting, or any other program abuses. In fact our groups positive biopsy rate (the ratio of positive biopsies divided by the total number of biopsies) is close to 40%. Urological literature supports a positive biopsy rate of around 25%. If we were over-utilizing our lab, our positive biopsy rate would be below the accepted standard.

3. Opponents of Uropath and pod labs are universally non-physician reference lab owners, pathology group practices, or special interest groups who stand to lose revenue with in house urological pathology. The proposed changes in the law are budget neutral. This is a physician "food fight" that the government should not try to legislate. Competition is always good for a free market economy.

4. Several factors other than profit can account for increased prostate biopsy services including a change in the standard of care related to the number of biopsies taken per patient. The old standard was six. The new standard adopted around 2003, is 10-12. The old standard resulted in a significant number of missed cancers and this fact is supported by the urological literature. Also some prostate cancer patients are treated with watchful

waiting and require repeated biopsies. A common finding of high-grade PIN requires repeated biopsies until a diagnosis of frank prostate cancer can be obtained as PIN is a pre-malignant condition. Demographics have resulted in increased prostate biopsies as the numbers of men over age 50 increases yearly.

5. Ironically, pod labs are being criticized in the CMS document for receiving specimens from out of state. Before we had our own lab, the large reference labs almost always shipped our biopsies out of state, usually to a state where Medicare reimbursement codes are higher, sometimes up to 20% higher. This can result in costing Medicare an extra $10 to$20 per slide. Our slides were almost always read by several different pathologists unknown to us. Inconsistent quality in interpretation resulted from this practice.

6. Our pathologist is well known in urological pathology circles for the excellent works he has authored. He is liscensed in the states of Missouri, Kansas, and Florida which ensures compliance with state laws, a prerequisite for billing Medicare. Large reference labs receive specimens from many states and may or may not have specimens interpreted by a pathologist that is liscensed in that particular state.

7. The Uropath model, utilizing an independent contractor relationship, ensures that our pathologist has a working relationship with us. We can talk directly to him if needed. We routinely visit our lab and meet directly with the pathologist and the lab managers. Dr. Murphy-our pathologist- has traveled to our location to give lectures and interact with us at a level that cannot be duplicated with the national lab model. This interaction creates a level of trust and familiarity that result in an increased quality of care that cannot be measured. Medicine is still an art not just a science.

8. The Uropath pod lab arrangement houses between 12 and 15 labs in a single complex. This requires the full time services of two or more pathologists, all of whom are dedicated exclusively to urological pathology. This means at least two experts are working in close proximity to each other. This allows for professional consultation and high quality second opinions. It also results in consistently in slide interpretations and less need for special stains which are expensive and get charged to the patient.

9. The pathologist has direct supervisory control over the non-professional personnel responsible for preparing the slides. This means the pathologist is in the best possible position to influence best practices regarding the preparation of human tissues for pathological interpretation.

If the present law was changed, we would have to move our lab to our central office building here in Kansas City. We would be unable to duplicate the high quality we have now with our present arrangement with Uropath and Dr. Murphy simply because 18 urologists are not enough to support a world class urological pathologist full time. The "pod" arrangement allows accomplishing this. Our patients appreciate it that our world class pathologist is interpreting their tissue samples and to have to give this up would lower our standard of care.

This proposed rule is not needed. Its sole purpose seems to be to eliminate the pod lab model, which I believe is a Center of Excellence in our urologic practice. These proposed changes are budget neutral and will only result in increased revenue to the large commercial pathology labs while decreasing the quality of care given to our patients.

Thank you for listening to our side of the issue.

Sincerely yours,

A.R. Weide, M.D.,FACS

Comment #644-2

October 6, 2006

Re: CMS Proposed Physician Fee Schedule Rules Regarding Reassignment & Stark Rules

To Whom It May Concern:

I urge you to recommend to Lesslie Norwalk, Director of CMS. On August 22nd, 2006, CMS issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2007. The proposed new rules view small centralized pathology laboratories as significant fraud & abuse risks. Nowhere in the proposal is an explanation for the basis of this new conclusion.

I am a urologist in Kansas City Urology Care, PA. We are one of the largest urology groups in the United States. Our mission is to provide the highest quality care possible.

In January 2005, we employed a Harvard trained pathologist to focus only on urological pathology. Dr. Murphy has published many urological pathology books, abstracts, articles, etc. He authored the Armed Forces Institute of Pathology Fasicle on Urine Cytologies. He specializes in examining only our patients' prostate needle biopsies, bladder biopsies and urine cytology specimens'.

Enclosed is only one of the more recent errors made by employees of a national commercial laboratory.

My patient, Mr. Ronald Detwiler, has given me his permission to share with you his story.

On September 12th, 2006, I biopsied his prostate gland in Kansas City. His insurance plan obligated me to send his tissue to Hays, Kansas for examination. A pathologist, whom I have never met and whose compentency I have no means to assess, concluded that Mr. Detwiler has high grade prostatic intraepithelial neoplasia. This is a precancerous condition with a 25% to 50% likelihood of developing into prostate Cancer. This would be very bad news to have to tell a patient. Imagine the psychological stress you would feel with such new, if it were your receiving my call. Fortunately, I questioned this pathology report and got a second opinion from a nationally esteemed urological pathologist, David Bostwick, MD.

counsel a patient about the proper treatment for their newly diagnosed prostate cancer, including possibly removing their prostate.

6. Opponents of Uropath and pod labs are universally non-physician reference lab owners, pathology group practices, or special interest groups who stand to lose revenue with the in housing of urological pathology. The proposed changes in the law are budget neutral. This is a physician "food fight" that the government should not try to legislate.

7. The Uropath model, utilizing an independent contractor relationship, ensures that our pathologist has a working relationship with us. We can talk directly to the pathologist if needed. We routinely visit our lab and meet face to face with the pathologist and the lab managers. The pathologist has traveled to our location to give lectures and interact with us at a level that could never be duplicated with the national lab model. This creates a level of trust and familiarity that results in an unmeasured quality of care.

8. The Uropath pod lab arrangement houses between twelve and fifteen labs in a single complex. This requires the full time services of two or more pathologists, all of who are dedicated exclusively to urological pathology. That means at least two experts are working in close proximity to each other. This allows for professional consultation and high quality second opinions. It also results in consistency in slide interpretations. And the need for special stains to assist the pathologist in their slide interpretation is less. Special stains are expensive and get charged to the patient.

9. The pathologist has direct supervisory control over the non-professional medical personnel responsible for preparing pathology slides for interpretation. This means the pathologist is in the best position to influence best practices regarding the preparation of human tissue for pathological interpretation.

If the law were changed, we would consider possibly moving our lab to the Kansas City area, but the quality of pathology services could not be matched by the arrangement that we have now. Eighteen urologists are simply not enough to support a urologic pathologist full -time. Uropath's business model allows us to support a urologic pathologist full-time. The "pod" arrangement gives the pathologist the volume to support his subspecialty. By virtue of this volume, the pathologist is an expert in his field. This is exactly what our patients are looking for when they come to see us, the urological surgeons. "Doctor, how many of these operations have you done and what are

your out comes." This laboratory arrangement creates a Center of Excellence. It allows the pathologist to focus on prostate cancer and become an expert in interpreting prostate biopsies. This is higher quality care for our patients.

This proposed rule is not needed. Its sole purpose seems to be to eliminate the pod lab model, which I believe is a Center of Excellence in our urologic practice. These changes are budget neutral and will only result in increased revenue to the national pathology labs while decreasing the quality of care given to our patients.

Thank you for listening to our side of the story.

Sincerely,

Thomas B. Herrick, M.D., FACS

Comment #644-4

October 6, 2006

Re: CMS Proposed Physician Fee Schedule Rules Regarding Reassignment & Stark Rules

To Whom It May Concern:

I would like to vigorously protest the proposed new regulations regarding physician owned laboratories. We have owned our own pathology laboratory for the past three years. We have contracted a nationally known pathologist to read our biopsies. Dr. William Murphy is Harvard trained and his focus has been on urological pathology.

This has dramatically improved the quality of patient care we are able to deliver. We previously had to use a reference lab with a faceless group of pathologists and no continuity of care. We had numerous biopsies that we had to have reviewed by outside pathologists. Many of the diagnoses made at the reference lab were changed from benign to malignant and vice versa. This undermined our faith and trust significantly. Patients could easily have been given the wrong diagnosis, and inappropriate treatment or lack of it delivered.

We no longer face this issue.

Clearly this is an economically motivated push by reference labs and hospital labs to capture this business. All studies indicate the number of biopsies sent were the same whether the specimens were sent to a physician owned lab or a reference lab. Thus there would be no cost savings by reverting to the old system, only a decline in the quality of care for the patient.

Please consider abandoning the new proposed regulations that would in effect put most of our labs out of business.

Thanks for any assistance you can provide.

Sincerely yours,

Gary Leifer, M.D.

Submitter : Dr. Sandra Dickerson **Date:** 10/09/2006

Organization : Covenant Medical Arts Clinic

Category : Physician

Issue Areas/Comments

Background

Background

The revisions as proposed will impact negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will 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 CPT 36479 CPT 36476 and CPT 36475 regarding RF and 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

As practice expenses continue to 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 employe a Registered Vascular Technologist (RVT) to provide imaging services. (This is by CMS mandate.) These highly skilled technologists are in drastic shortage so are in high demand. Therefore they command extremely high salaries, usually more than $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 these CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

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.

I have also reviewed the values for codes 36475 and 36476, radiofrequency vein ablation. These 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.

Thank-you.

I would be glad to discuss any of these issues with members of your committee.

Impact

Impact

See Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Comment below.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHEMENT" ALAN BASSIN MD

CMS-1321-P-646-Attach-1.DOC

Comment #646

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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS Administrator,

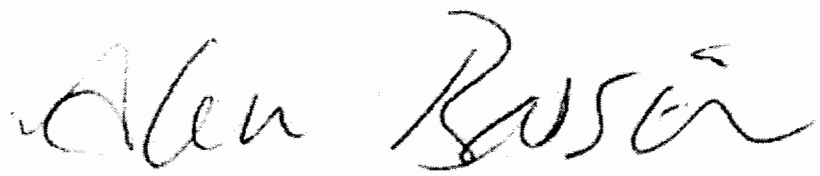
Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

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
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Phil Rumbaoa** **Date: 10/09/2006**

Organization : **Vein Clinics of America**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

1. RVUs have consistently been reduced from 2005 levels--2006, 46.91; 2007, 43.53; and 2008, 40.84
While practice expenses consistently rise (salaries, supplies, utilities, etc.), it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employ a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and, therefore, are in high demand and, as such, command extremely high salaries (in excess of $70,ooo per year plus benefits). It will be extremely difficult 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 than those for laser ablation-- 2006, 51.5; 2007, 47.77; and 2008, 44.52
Each of these technologies are comparable expecially when one looks 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 RF procedure kits plus disposable sterile--supplies such as draped, gowns, anesthetic solution, IV bags, and IV tubing just to name a few). Whils the per patient supply cost may be slightly higher for 36475 (RF), the siginificantly higher acquisition cost for 36478 (laser) raises the overall physician's cost of delivering the service to the same level (and 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,

Phil Rumbaoa, MD

Submitter : Mr. Douglas Myking **Date:** 10/09/2006

Organization : Radiosurgery Medical Group

Category : Other Health Care Professional

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.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"see attachment" Melvin Pann MD

CMS-1321-P-650-Attach-1.DOC

Comment #650

SHACHNER & ZARAGOZA, M.D., P.A.
GENERAL & LAPAROSCOPIC SURGERY • SURGICAL ONCOLOGY
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MARK S. SHACHNER, M.D., F.A.C.S.
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KENDRICK D. MCARTHUR, D.O.
MELVIN E. PANN, M.D., F.A.C.S.
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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Thank you in advance for your assistance,

Melvin E. Pann, 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
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

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

Organization : Joint Council of Allergy, Asthma and Immunology

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-651-Attach-1.PDF

JCAAI

Joint Council
of Allergy,
Asthma and
Immunology

50 N. Brockway Street
Suite 3-3
Palatine, IL 60067
Voice: 847-934-1918
Fax: 847-934-1820
E-Mail: info@jcaai.org

October 9, 2006

SUBMITTED ELECTRONICALLY AT
HTTP://WWW.CMS.HHS.GOV/ERULEMAKING

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007

Dear Ms. Norwalk:

The Joint Council of Allergy, Asthma and Immunology appreciates this opportunity to submit comments on the proposed *Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007*, as published in the August 22, 2006 Federal Register. JCAAI is an organization sponsored by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. It represents the interests of over 3,000 physicians board-certified in allergy and immunology.

JCAAI supports the proposal to change the test substance in CPT Code 95015 to venom, to use $10.70 as the price per one ml, and to change the number of mls from 0.1 to 0.3, as per our recommendation.

We appreciate the opportunity to submit these comments. If you have any questions, please contact our Washington representative, Rebecca Burke, at 202-466-6550.

Sincerely,

Robert Nathan, MD
President

Submitter : Mr. Douglas Myking **Date:** 10/09/2006

Organization : Radiation Medical Group

Category : Other Health Care Professional

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.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"see attachment" Bernard Zaragoza MD

CMS-1321-P-653-Attach-1.DOC

#653

SHACHNER & ZARAGOZA, M.D., P.A.
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KENDRICK D. MCARTHUR, D.O.
MELVIN E. PANN, M.D., F.A.C.S.
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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Thank you in advance for your assistance,

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Senator Sam Brownback, Co-Chair, Senate Cancer Committee
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Carol Bazell, MD, Director, Division of Outpatient Care
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" MARK SHACHNER MD

CMS-1321-P-654-Attach-1.DOC

#654

Comment #654

SHACHNER & ZARAGOZA, M.D., P.A.
GENERAL & LAPAROSCOPIC SURGERY • SURGICAL ONCOLOGY
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MARK S. SHACHNER, M.D., F.A.C.S.
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October 4, 2006

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Thank you in advance for your assistance,

Mark S. Shachner

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Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Mr. Michael Skowronski** **Date: 10/09/2006**

Organization : **Montgomery Cancer Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing medical physicist at the Montgomery Cancer Center in Montgomery, Alabama. As required by Section 5102(b)(1) of the Deficit Reduction Act, beginning January 1, 2007, CMS will cap the physician fee schedule payment amount for the technical component of imaging services.

I agree with CMS decision to exclude radiation oncology services that are not imaging or computer-assisted imaging services since radiation therapy services clearly cannot be considered imaging. However, I believe CMS has misinterpreted Congressional intent by including on the list of imaging services codes that describe services performed in conjunction with radiation therapy that are never performed for diagnostic purposes. As a member of ASTRO, I agree with their recommendation that CMS remove the following radiation oncology services from the list of services subject to the DRA cap because they are associated with the treatment and not the diagnosis of cancer:

" 76370; Computed tomography guidance for placement of radiation therapy fields;
" 76950; Ultrasonic guidance for placement of radiation therapy fields;
" 76965; Ultrasonic guidance for interstitial radioelement application;
" 77417; Therapeutic radiology port film(s); and
" 77421; Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Michael Skowronski, MS
Medical Physicist

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" ROBERT DONNOWAY MD

CMS-1321-P-656-Attach-1.DOC

#6056

SURGICAL ONCOLOGY ASSOCIATES
OF
SOUTH FLORIDA, Inc.

Robert B. Donoway, M.D., F.A.C.S., F.S.S.O.
Arthur H. Pomerantz, M.D., Ph.D., F.A.C.S.
Gary M. Onik, M.D.
Associate

October 2, 2006

Practice Specializing in
Surgical Oncology and Breast Diseases
Breast Surgical Oncology
Thoracic Surgical Oncology
Endocrine and Advanced Laparoscopic Surgery
Minimally Invasive Image Guided Tumor Ablation Surgery
Genetic Cancer Counseling

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,

Robert Donoway MD

Robert B. Donoway, M.D., F.A.C.S., F.S.S.O.

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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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

[redacted]

Submitter : Dr. Andrej Zajac **Date:** 10/09/2006

Organization : St.Catherine Hospital Cyberknife Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-657-Attach-1.PDF

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.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"see attachment" Armand Katz MD

CMS-1321-P-658-Attach-1.DOC

#658

CYPRESS SURGICAL ASSOCIATES

General Surgery, Surgical Oncology, Colon and Rectal Surgery
Advanced Laparoscopic and Minimally Invasive Procedures
Endocrine and Breast Surgery

Armand H. Katz, MD, FACS
Mufa T. Ghadiali, MD

Joseph J. Casey MD, FACS
John E. Roberts III, MD, FASCRS, FACS

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

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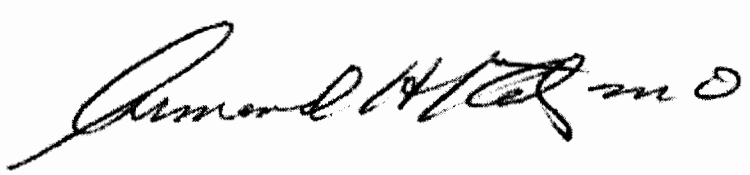
There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor equal to a 5% reduction and that this floor remain in effect during the time required for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I am willing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



cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Senator Sam Brownback, Co-Chair, Senate Cancer 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 ATTACHED" MARY BETH TOMASELLI MD

CMS-1321-P-659-Attach-1.DOC

#659

Mary Beth Tomaselli, M.D.
Comprehensive Breast Center of Coral Springs
1283 University Drive
Coral Springs, Florida 33071
954-345-2718

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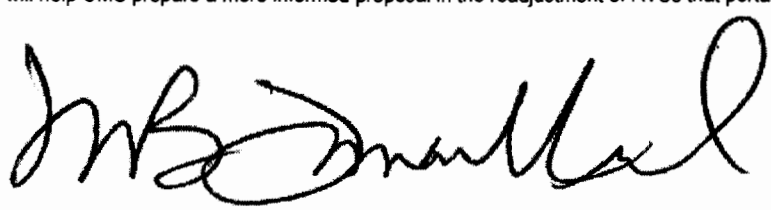
There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor equal to a 5% reduction and that this floor remain in effect during the time required for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I am willing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



Mary Beth Tomaselli, MD

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
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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

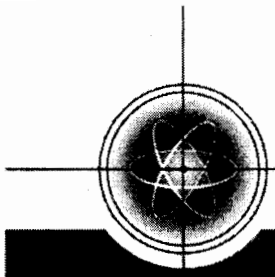
GENERAL

GENERAL

"SEE ATTACHMENT" PATRICK FANCKE MD

CMS-1321-P-660-Attach-1.DOC

#660



21st Century Oncology

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

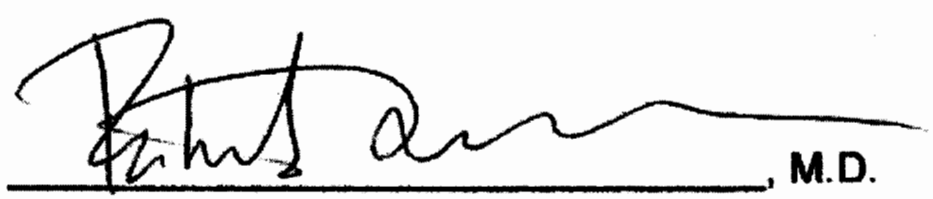
These rates are unacceptable and will prevent for Medicare breast cancer patients from having a five-day partial breast irradiation therapy treatment option. The alternative radiation treatment is Whole Beam External Radiation Therapy (WBXTR) where women must endure 6-8 weeks of radiation therapy.

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. Shawn Glisson** **Date: 10/09/2006**

Organization : **Kentucky Cancer Caucus**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Our organization would not support any change in the ASP calculation that would penalize our ability to negotiate with the manufactures. If CMS sets these arbitrary penalties it will limit our accessibility to competitive products, intern limiting our clinical choice.

We use products like Neupogen?, and Neulasta? that provide similar flexible dosing and allow us to provide complimentary therapeutic and supportive care therapies to patients. We also use, Procrit? and Aranesp? because they often have clinical and administrative advantages for our patients. Products like these provide flexibility in dosing and fewer injections making it easy to synchronize with the majority of chemotherapy regimens (weekly, every two week, and every three weeks).

Any proposed change like Proposed ASP calculation would penalize products that often offer clinical benefit and impacts the care of patients. The current ASP system already compensates for discounts, and we feel this change would not only limit competition, but limit our ability to provide the best care for our patients.

If you have any questions, or need additional information, feel free to contact me at (502)561-8200.

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

Organization : Cardiovascular Services of America

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-662-Attach-1.PDF

#1662

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
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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 Services of America and our 105 practicing cardiologist partners, 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 two issues—the payment method proposed for cardiac catheterization related procedures and the proposal to require standards for Independent Diagnostic Testing Facilities (IDTFs).

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.

320 SEVEN SPRINGS WAY, SUITE 220 • BRENTWOOD, TENNESSEE 37027 • PHONE: 615-250-1680 • FAX: 615-250-1644
WWW.CSAHEART.COM

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. The Cardiovascular Outpatient Center Alliance (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.

IDTF Standards

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.

IDTFs represent a diverse group of providers, including free standing diagnostic cardiac catheterization labs. In fact, IDTFs represent 61.5 percent of the utilization for CPT code 93510 TC, described as left heart catheterization. We commend CMS in proposing the application of standards for IDTFs, comparable to those that were developed for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The standards addressed in the proposed rule reflect the general standards related to operational and financial management issues. We believe that CMS needs to work with the various types of IDTFs to ensure that additional standards are developed, consistent with the approach taken with the DMEPOS standards where there are a set of specific requirements for each type of DME supplier. For example, these standards address the specific needs of oxygen suppliers compared to suppliers of monitors and supplies for diabetic patients.

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 service providers 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 practice expense RVUs 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 this family of procedures 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 this opportunity to submit comments and we would appreciate your thoughtful consideration and approval of our request.

Sincerely,

Timothy P. Martin
President and Chief Executive Officer

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

:SEE ATTACHMENT" jOSEPH CASEY MD

CMS-1321-P-663-Attach-1.DOC

#663

CYPRESS SURGICAL ASSOCIATES

General Surgery, Surgical Oncology, Colon and Rectal Surgery
Advanced Laparoscopic and Minimally Invasive Procedures
Endocrine and Breast Surgery

Armand H. Katz, MD, FACS
Mufa T. Ghadiali, MD

Joseph J. Casey MD, FACS
John E. Roberts III, MD, FASCRS, FACS

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,

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 : **Dr. Ruben Sierra** **Date: 10/09/2006**

Organization : **Columbia Basin Hematology and Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs/Madams:
I am responding regarding to the proposed rule'Medicare Program:Revisions to Payment Policies Under the Physician fee schedule for 2007.
I am concerned about the attempts to change the ASP+6 % rule.This rule was mandated by the Congress.It has changed the way we practice medicine and has cut our profits to the bare bones.
Now,why intervene with the acquisition of drugs when they are bundled??
All the calculations are the same,you continue to maintain the ASP+6% .Why to change the rules in the middle and make it more complicated.We use them all ,Neulasta,Neupogen,Aranesp and Procrit.We use one vs. the other depending on the situation .It can be one of many circunstances;effectiveness,less expensive ,convenience for patients who can not travel to the office among many other reason.
Please do not complicate our lives more and consider not to change those policies,let the market decide.

Ruben Sierra,MD

Submitter : Mr. Michael Becker **Date:** 10/09/2006

Organization : GE Healthcare

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1321-P-665-Attach-1.DOC

#6605

GE Healthcare

Michael S. Becker
General Manager, Reimbursement

3000 N. Grandview Blvd., W-400
Waukesha, WI 53188

T 262-548-2088
F 262-544-3573
michael.becker@med.ge.com

October 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare physician fee schedule (MPFS) payment system for calendar year (CY) 2007 (*Federal Register*, Vol. 71, No. 162, August 22, 2006).

Our comments focus on the following issues relating to reimbursement for bone mass measurement procedures:

- Work RVU CPT 76075- DEXA (Dual Energy X-Ray Absorptiometry)
- Practice Expense CPT 76075 & CPT 76077
- Deficit Reduction Act of 2005
- Bone Mass Measurement Test

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries. Lunar, a division of GEHC is a leading manufacturer of bone densitometry equipment.

Our detailed comments follow.

We remain deeply concerned about the impact of the proposed changes to the Medicare Physician Fee Schedule, which we believe will reduce the availability to high quality bone mass measurement and have a profound adverse impact on patient access to appropriate skeletal health care. The survey conducted by the American Medical Association (AMA) supports our concerns.[1] The results showed 45% of their members stated they would be forced to reduce the number of Medicare patients they see or stop seeing them altogether.

In addition, we find it troubling that the proposed rule did not specify the calculation and /or the global rates for services affected by the Deficit Reduction Act (DRA). We commend CMS for requesting comments relating to proposed cuts, but would encourage CMS to extend the comment period until an addendum can be published outlining the global rates for services affected by the DRA and the 10% budget neutrality adjuster. It is our opinion that, physicians, beneficiaries, the public, and national organizations are entitled to all the information so they can accurately comment on the various proposals. On behalf of your contracted providers, our customers and their patients, we request that the following information be considered and researched prior to the determination of the final rule.

Clinical Importance of Bone Densitometry

The World Health Organization has identified osteoporosis as a priority health issue, as did the Surgeon General in October of 2005. Osteoporosis affects more than 10 million Americans with an additional 34 million that have low bone mass (osteopenia) and are at risk for future fracture. ***Osteoporotic fracture, a disease that is largely preventable through early diagnosis and treatment, occurs more often in women than that of a heart attack, stroke, and breast cancer combined.*** In fact, 95% of people who suffer an osteoporotic fracture are never evaluated or treated for this disease according to NIH Consensus Statement (2000). The cost associated with osteoporotic fractures range from $12.2 to $17.8 billion each year.[2] Federal initiatives continue to focus on reducing the costs associated with osteoporosis and to improve quality of life through prevention, early detection and treatment. Bone density testing using central DXA (dual energy X-ray absorptiometry) is currently the gold standard and the only technology accepted for diagnosing osteoporosis by World Health Organization criteria as well as outlined in the proposed rule under Section K, titled "Coverage of Bone Mass Measurement Test." Therefore, ***we believe that the proposed reductions to the Relative Value Units and the impact of the Deficit Reduction Act will severely undermine CMS's own initiative to increase diagnosis and treatment as well as President Bush declaration of 2002-2011 as the "Decade of Bone and Joint".***

5-Year Review of Work – CPT 76075 – BMD DEXA

The American College of Radiology (ACR) surveyed a broad range of radiologists to perform the physician work and recommended that the work remain at the current 0.30 RVU.[3] It is important to note that the majority of medial specialties performing DXA scans are Rheumatology, Endocrinology, Internal Medicine, OB/GYN, Family Practice and Freestanding Imaging Centers.

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[1] American Medical Association (AMA), New AMA Survey Shows Medicare Cuts Will Harm Seniors, 3/16-06.
[2] NIH Consensus Statement Online (2000). Osteoporosis Prevention, Diagnosis, and Therapy. 17(1):1-36.
[3] American College of Radiology, CMS-1512-PN Comment Letter Dated August 21st, 2006.

The RUC subcommittee was comprised of a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, and a family physician. Out of the six physicians on the subcommittee only one may or may not be knowledgeable about interpreting DXA scans. Interpretations of DXA scans involve review of complex data, which is critical to accurate diagnosis and determination of appropriate therapy. This requires a high level of skill and physicians' time, as reflected in the American College of Rheumatology (ACR) survey data as well as the International Society of Clinical Densitometry (ISCD) survey.[4] The ISCD surveyed 453 physicians from multiple specialties, which demonstrated a substantially higher work RVU of .50.

CMS's determination to agree with the RUC recommendation is puzzling since the proposed changes to Bone Mass Measurement testing states BMD-DXA remains the single best predictor of fracture risk. BMD-DXA (76075) is the most widely accepted method for measuring BMD at the axial skeleton (hips and spine), but the work component at a Peripheral Site (76076) has a higher work value. One would suggest the value of the preferred method and site requires a greater level of complexity. **The determination on the skill level, intensity and physician time should be based on the information from the medical specialties utilizing the technology. We request CMS to reconsider the survey conducted by the ACR as well as the ISCD and at the very least re-instate the work value to 0.30.**

Practice Expense – CPT 76075 – BMD DEXA & CPT 76077- VFA DEXA

Our review of the practice expense data for DXA has identified inaccuracies and omissions that we bring to CMS attention. ***We implore CMS to review the information below and postpone proposed revisions to the payment rate for DXA until a more thorough analysis can be conducted and the data accuracy can be confirmed.***

- **Equipment Cost**: While the equipment cost and description is accurately reflected for VFA- DXA (76077) as a fan beam densitometry with a cost of $85,000, the type and cost listed for BMD-DXA (76075) is listed at a cost of $41,000 based on pencil beam technology which represents only 20% of the total DXA machines purchased today. Specifically, fan beam densitometers make up 75% of the total units sold by GEHC. Therefore, the PE RVU should accurately reflect the current type of equipment for BMD-DXA (76075) as fan beam.

- **Utilization Rate:** Based on Medicare's 2002 data, 70% of DXA studies are performed in the office setting. We are concerned that observed variation in the utilization rates for DXA studies provided in the physician office setting results in the systematic under-valuation of practice expenses for these procedures. For example, the recent International Society for Clinical Densitometry survey noted that the utilization rate is 21% rather than the 50% utilization rate in the current Practice Expense calculation for these services. We urge CMS to consider these effects on the payment level for DXA procedures.

- **Omitted Costs:** There are additional indirect costs associated with DXA scans that were omitted which include, but are not limited to, the cost of phantoms, necessary for service contracts, software upgrades and office upgrades to allow digital image transmission.

Deficit Reduction Act of 2005 (DRA)

[4] International Society of Clinical Densitometry (ISCD), CMS-1512-PN Comment letter of August 18th, 2006 pg 7.

Congress enacted special payment rules limiting reimbursements, beginning in 2007, for the technical component of imaging services performed in the office setting. Under the DRA, coupled with proposed practice expense methodology, BMD (76075) would experience a reduction to the technical component for the first year of 39 percent. GEHC is concerned that reductions of this magnitude will force some physicians to discontinue providing BMD testing in their offices, thereby resulting in diminished access to these important services for Medicare beneficiaries. Reduced access, in turn, may result in a higher number of patients at risk of Osteoporosis or Osteoporotic fracture going without an evaluation or treatment. **We strongly encourage CMS to consider the cumulative impact of the DRA and how this impact will affect BMD (76075) testing. This vital service should be removed for the list of DRA affected codes.**

Bone Mass Measurement Tests (BMM)

As the leading manufacturer of bone densitometry equipment, we agree with the CMS proposal to remove coverage of Single Photon Absorptiometry (SPA) as these machines are obsolete. We also agree with the proposed requirement change for individuals receiving or about to receive long-term glucocorticoid steroid therapy to 5.0mg.

The National Osteoporosis Foundation states "Today, 2 million American men have osteoporosis, and another 12 million are at risk for this disease. Despite the large number of men affected, osteoporosis in men remains under diagnosed, under reported, and inadequately researched." We encourage CMS to consider the following additional indications as suggested by the International Society of Clinical Densitometry (ISCD).

- Any women 65 or older
- Any man 70 years or older
- Any adult with a fragility fracture
- Any adult with a disease or condition associated with low bone mass or bone loss
- Any adult taking medications associated with low bone mass or bone loss
- Anyone being considered for pharmacological therapy
- Anyone being treated, to monitor treatment effect

Summary

Osteoporosis remains a major health issue in the United States with one in three women and one in five men over the age of 50 years will suffer from an osteoporotic fracture. Federal initiatives to identify patients with osteoporosis have led to the increased utilization of BMD-DXA and VFA; however the vast majority of affected individuals continue to remain undiagnosed and untreated. Thanks to the development of bone mineral density testing, fractures need not be the first sign of poor health. It is now possible to detect osteoporosis early and to intervene before a fracture occurs. With the increasing age in the United States, CMS needs to ensure patients continue to have availability and access to bone density testing by keeping the reimbursement at the current RVU level. This would not only keep with the various initiatives set at the Federal level but would also keep in line with CMS's preventive service initiative. The national medical associations of Family physicians, Endocrinologists, Rheumatologist, OB/GYN, Internal Medicine as well as the World Health Organization, NOF, ISCD, and the ACR have identified the importance of early diagnosis and intervention relating to

Osteoporosis. In order for this to be accomplished, it is critical that physicians can financially afford to implement BMD and VFA testing in their office.

We appreciate that problems in the field of health care are complex and costly. However, cutting payments for low cost services in the primary care arena such as BMD-DXA and VFA would only increase that cost by patients being forced to the emergency room and hospitalizations. Our findings of the flaws with the data input and data omissions in the calculation of the physician work and practice expense are supported by the survey conducted by the ISCD. Our goal has been to work with Medicare and the insurance industry to improve technology that will have a profound effect on a patients' outcome and to reduce the cost of healthcare. The effect on technology should these proposed cuts be implemented will unquestionably slow this process down. **We request that CMS refrain from making changes to the work and practice expense RVUs for DXA procedures in 2007 and, instead, to revisit the data for BMD-DXA to ensure that it accurately reflect the type and cost associated with BMD.**

GEHC thanks you for the opportunity to comment on the proposed changes to the physician fee schedule. We look forward to working with The Centers for Medicare and Medicaid Services in the fight against Osteoporosis. Should you have any questions regarding our comments or would like further details, please contact Mike Becker, General Manager, Reimbursement at 262-548-2088.

Sincerely,

Michael S. Becker
General Manager, Reimbursement

Submitter : **Mr. Andrew Radoszewski** **Date: 10/09/2006**

Organization : **Langhorne Cardiology Consultants, M.D.'s, PA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

On behalf of our group of 26 cardiologists and cardiovascualr surgeons, 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 requirc 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 Mcdicare 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.

Sincerely,
Andrew Radoszewski, MBA, MPH, CMPE
Administrator

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" JOHN ROBERTS MD

CMS-1321-P-667-Attach-1.DOC

#667

CYPRESS SURGICAL ASSOCIATES

General Surgery, Surgical Oncology, Colon and Rectal Surgery
Advanced Laparoscopic and Minimally Invasive Procedures
Endocrine and Breast Surgery

Armand H. Katz, MD, FACS
Mufa T. Ghadiali, MD

Joseph J. Casey MD, FACS
John E. Roberts III, MD, FASCRS, FACS

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,

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 ATTACHMENT" ARMON MEDINA MD

CMS-1321-P-668-Attach-1.DOC

#668

Michael and Dianne Bienes Comprehensive Cancer Center
Holy Cross Hospital

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: Physician Fee Schedule Rule# CMS-1321-P

Dear CMS Administrator:

Thank you for the opportunity to provide comments about the CMS proposed rule #CMS-1321-P published in the Federal Register on August 23, 2006. This letter is written to share my concerns regarding the proposed reduction in professional fees for Radiation / Oncology Brachytherapy services.

With the prevalence of breast cancer, I urge CMS to reconsider the proposed Work RVU reduction for Brachytherapy. What CMS is proposing - a 2007 work RVU slated to be 0.33 - is a drastic cut in the professional component for breast brachytherapy services. Of note, the work RVU for 2006 was 0.53.

The reduction CMS is proposing will have a detrimental impact on my ability to offer the Brachytherapy / Partial Breast Irradiation Therapy treatment to my Medicare patients. Access to Brachytherapy is critical. Brachytherapy allows the radiation process to move quickly so that other treatments such as chemotherapy can be started in a timely fashion. The preparation and effort for planning & treatment is quite time consuming and proper catheter placement must be confirmed before each fraction is given. The CMS proposed reduction to all Brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for Brachytherapy. I must stress that if the reduction does take place, CMS will be limiting access to Brachytherapy for Medicare patients.

CMS should implement a goal is to preserve the Work RVU on the professional side. Please leave the Brachytherapy codes as they currently stand in 2006, and, if needed, make only a slight reduction in the conversion factor. I appreciate your careful review and analysis of this important matter. I strongly urge CMS to reconsider the significant, negative impact that would result from the proposed reductions.

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. Thomas Stringer** **Date: 10/09/2006**

Organization : **Citrus Urology Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : **Dr. Lawrence Fanelly** **Date: 10/09/2006**

Organization : **The Ohio Society of Pathologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-670-Attach-1.RTF

#670

Comments of the
*****
On the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007
[CMS–1321–P]

The Ohio Society of Pathologists (OSP) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). OSP is a professional society of pathologists practicing in the state of Ohio. OSP members perform a variety of services that are reimbursed under the physician fee schedule. Thus, OSP members will be significantly affected by the changes in the Proposed Rule. OSP's comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

The OSP is very pleased that CMS is taking action designed to curb the growth of so-called "pod" or condo laboratories. *Id.* at 49054. These arrangements give referring physicians the opportunity to earn revenues based on their own referrals for services performed by other physicians. The Medicare program has always expressed concern about such arrangements and has numerous provisions in place to curb such abuses. CMS is taking an important step in its revision to the reassignment rules and the Stark self-referral laws as a way of curbing these abusive arrangements. However, OSP believes that in order to be effective in addressing the pod issue, CMS must implement not only the independent contractor reassignment revisions that pertain to the technical and professional components of anatomic pathology, but also measures that would limit the use of part-time employee pathologists in such arrangements.

As CMS recognizes, there are two different, but related, means of curbing these practices: first, clarify the provisions of the prohibition on reassignment, which is designed specifically to prevent Medicare from paying physicians for work performed by others, except in limited situations and second, modify the Stark self-referral law, which is designed to prevent physicians from profiting by referring business to entities with which they have a financial relationship. As CMS notes, many pod arrangements are established either in contravention of these requirements or by taking advantage of ambiguities that exist. Generally, OSP is supportive of the changes that CMS is making, but we are aware of additional helpful proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees.

Changes to the Reassignment Rule

In the area of the changes to the prohibition on reassignment, CMS makes the following proposals:

- Clarify that physicians acting pursuant to the contractual arrangement exception must still meet the requirements applicable to the purchase of diagnostic testing, with regard to the professional component.

**** **position**: **supports** applying current purchased-service limitations in situations of reassignment

- CMS requests comments on what additional limitations should be put on the purchase of the professional component.

**** **Position**: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting

- CMS asks whether all diagnostic testing in the designated health services ("DHS") category should be covered or whether it should apply specifically to pathology; and whether any of the provisions should apply to services performed on the premises of the billing entity, and if so, how to define the premises appropriately.

**** **position**: **no comment**

Stark Self Referral Provisions

As CMS recognizes, in order to limit these types of practices in all areas, it is also necessary to further clarify certain specific provisions or exceptions in the Stark self-referral law. OSP agrees that this is imperative. We are especially concerned that in response to changes in the reassignment rules, discussed above, many pod arrangements will simply restructure and hire pathologists as part-time employees, which could circumvent the purpose of many of these changes. OSP believes that the Stark law may provide the most direct way of curbing these new abuses. Therefore, before discussing the other changes proposed by CMS to the Stark provisions, we wish to make one additional proposal designed to limit part-time pathologists.

Part-Time Employment of Pathologists

OSP is concerned that in response to the provisions in the Proposed Rule, existing and new arrangements may be restructured so that pathologists will be retained as part-time employees rather than independent contractors. For example, a pathologist could become a part-time employee of several different groups under arrangements that potentially satisfy both the reassignment rules and the physician

service or in-office ancillary services exceptions to the Stark self-referral provisions. From the standpoint of the group practice and the retained pathologist, the arrangement need not differ significantly from an independent contractor relationship. Thus, OSP considers it to be essential that CMS address both structures in its rulemaking.

OSP recognizes that some groups may decide to hire their own pathologist, but they should be required to make the same investment in salaries and capital that any other business would have to make in that endeavor and undertake the same type of business risk. They should not be able to avoid that requirement by re-characterizing an "independent contractor" pathologist as a "part-time employee" pathologist, without incurring the additional costs and risk attendant to hiring that person. Without some limitation on this practice, groups will simply restructure without any risk and continue to profit from their own referrals. OSP believes that the part-time employee concern could be addressed through modifications in the "group practice" requirements under the Stark self-referral rules or, potentially, through changes in the employee reassignment provision.

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. OSP would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

*OSP believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "*For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology

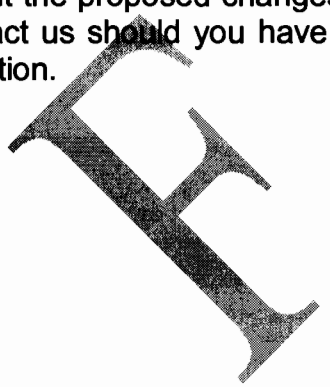
services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

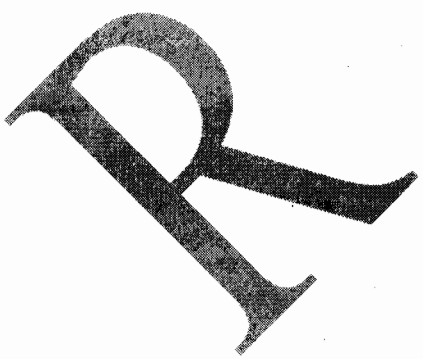
CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,



Lawrence J. Fanelly, D.O.
President, Ohio Society of Pathologists
October 9, 2006



Submitter : Dr. RL Worthington-Kirsch **Date:** 10/09/2006

Organization : Image Guided Surgery Associates

Category : Physician

Issue Areas/Comments

Background

Background

The proposed revisions will adversely affect the ability of Medicare (and other) patients to obtain health care services. Reductions in reimbursement (particularly in areas such as Philadelphia which have relatively low reimburesement rates and extremely high practice/living expense costs will drive physicians out of the market.

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 continue to rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. It will become 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

These technologies are comparable. The initial capital acquisition cost is higher for laser (~$37,900) than for RF (~$25,000). The per patient supply costs are ~$360 for laser and ~$750 for radiofrequency (procedure kits PLUS disposable sterile supplies such as drapes, gowns, anesthetic, 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,

Robert L WOrthignton-Kirsch, MD, FSIR, FASA, FCIRSE, RVT, RPVI
Image Guided Surgery Associates
5735 Ridge Avenue, Suite 106
Philadelphia, PA 19128

215-508-5261

kirsch@igsapc.com

Impact

Impact

See below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See below