Submitter : **Dr. Bradford Tan** **Date: 10/06/2006**

Organization : **Cancer Treatment Centers of America**

Category : **Laboratory Industry**

Issue Areas/Comments

Background

Background

Please see attached letter

CMS-1321-P-496-Attach-1.DOC

Attachment
496

Cancer Treatment Centers of America
at Midwestern Regional Medical Center
Winning the fight against cancer, every day.

Bradford A. Tan, M.D.
Medical Director of Laboratory
2520 Elisha Avenue
Zion, IL 60099

tel 847-872-6238
fax 847-872-1594
web cancercenter.com

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Independent Lab Billing

Sir/Madam:

Oncotech's Extreme Drug Resistance (EDR) Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (< 1% as reported in published literature) to respond to specific drugs in a clinical setting. I use this test to assist me in the management of my cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy.

Presently, Oncotech's EDR Assay is eligible for Medicare Part B reimbursement and is therefore reimbursed directly by Medicare. CMS is re-interpreting an existing policy which may have a harmful effect on Oncotech Inc and other laboratories. The re-interpretation would require Oncotech to bill their services to a hospital as part of the Medicare Part a program, instead of as an outpatient service, directly to Medicare Part B. As a result, the EDR Assay would fall under current Drug's and Hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech. It is very unlikely that any hospital would pay, as it would not consider drug testing a hospital service, and also would have to take the payment from its Medicare DRG payment, which is a flat fee. The foreseeable result of this policy would be to make chemo response testing unavailable to Medicare beneficiaries. The consequence is a result of EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patients' hospital stay); linking our services to the Part A program.

I understand that the new interpretation was not directed specifically at Oncotech or similar laboratories but the labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because Oncotech's services will be unfairly classified as a Medicare Part A procedure. I would respectfully request that a review of the re-interpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

Thank you for your consideration.

Bradford A. Tan, M.D.

Submitter : Mr. Frederic Simmons **Date:** 10/06/2006

Organization : Clearwater Cardiovascular and Interventional Consu

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-1321-P-497-Attach-1.RTF

Attachment #497

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Electronically

http://www.cms.hhs.gov/eRulemaking

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 Clearwater Cardiovascular and Interventional Consultants, its 19 physicians and 150 employees, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and

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

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

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

Sincerely,

Frederic R. Simmons, Jr. CPA
Chief Executive Officer

Submitter : **Mr. George Roman** **Date: 10/06/2006**

Organization : **American Medical Group Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-498-Attach-1.DOC

Attachment 498

AMGA
American Medical Group Association

October 10, 2006

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
Baltimore, MD 21244-8014

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

Dear Dr. McClellan:

AMGA is an association that represents medical groups, including some of the nation's largest, most prestigious multi-specialty practices and integrated health care delivery systems. AMGA members' 65,000 physicians deliver health care to more than 50 million patients in 40 states, including 15 million capitated lives. Thank you for the opportunity to comment on the proposed rule regarding revisions to the payment policies under the Medicare Physician Fee Schedule (PFS) and other changes to payment under Part B.

Reassignment and Physician Self-Referral

The issue of "condo" laboratories in the realm of anatomic pathology is a focused problem and appears to be the genesis of proposed changes to the Stark regulations and reassignment rules. The nature and scope of changes proposed stands to interject additional complexity into an already highly intricate set of laws and rules. While CMS seeks to clarify existing rules, to stem abuse and the potential for abuse, there is the real risk of unintended consequences. These may inadvertently lead to the disruption of routine, normal and non-abusive business arrangements involving the absolutely legitimate engagement of independent contractor physicians, such as the emergency department company physician arrangements you referred to.

The proposed Stark changes to the definition of "centralized building" represent yet another example of refining the Stark law exceptions for the narrow purpose of stopping impermissible referrals or other abuses in anatomic pathology practice, that make no sense in other, non-abusive settings. The 350 square foot rule may rule out otherwise legitimate ancillary buildings that simply do not need to be that large. Groups will end up buying or renting more space than they actually need to deliver some services "in-office." Furthermore requiring equipment to be in place 90% of the time will require some practices to buy or lease equipment permanently even though they only need it on a

temporary or part-time basis. It may also force them to abandon those ancillary services that currently rely on mobile equipment.

As a preliminary step, CMS could ask the Health and Human Services Department's Office of Inspector General to issue a special fraud alert specifically directed to the practice of anatomic pathology and "pod" lab practices. Furthermore, we suggest that the missing element in addressing abuses in this area lies in enforcement, not refinement of existing regulations. **We recommend that the agency employ tools already available to investigate abuses and take remedial action where warranted.**

As an additional alternative we propose that rather than risk adding unnecessary complexity, hence confusion and heightened risk of unforeseen, negative repercussions on the broader and non-fraud and abuse problematic practice of medicine, that CMS focus strengthening its interpretation to maximize the enforcement utility of 42 USC 1395 nn (g) (4):

> (4) Civil money penalty and exclusion for circumvention schemes
>
> Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

If, after due consideration CMS decides to promulgate a final rule along the lines of the proposed amendments, we believe that the best available course is to make them applicable only to pathology services, the primary source of the vulnerabilities.

IDTF Issues

Independent Diagnostic Testing Facilities (IDTF) regulations were originally put in place to secure the fraudulent and abusive practices rampant in their predecessor entities, the Independent Physiological Laboratories (IPLs). Recently, the Department of Health and Human Services Office of Inspector General (OIG) undertook and published results of an audit of claims billed by IDTFs.

The OIG's report found that Medicare IDTF services were not always reasonable and necessary, were also often not ordered by a physician, nor sufficiently documented.

Additionally, the majority of IDTFs surveyed did not operate in accordance with their initial enrollment applications and succeeding filings. The OIG's investigation estimated that over $71.5 million in overpayments were made by the ten Carriers sampled, which it will attempt to recover.
As the Medicare Payment Advisory Commission (MedPAC) has recognized, the rate of growth in utilization for IDTFs from 2000-2002 was double that of physicians' offices. It was in part the extraordinary rate of growth in IDTF services that prompted the most recent OIG investigation.

In spite of extant rules and requirements, Medicare program integrity at IDTFs remains at risk. The expected remediation of abusive practices of the past has not happened. The creation of the IDTF entity has done nothing to ensure the quality or appropriateness of diagnostic testing. In fact, the OIG findings reveal significant failures of compliance in virtually every aspect of the IDTF regulation. The success at reducing Medicare program fraud and abuse vulnerabilities of the proposed regulations and new business practice standards for IDTFs, if implemented, will not be evaluated or known for what may be years.

In the proposed rule CMS noted that these additional standards might lead some IDTFs to withdraw from the Medicare program rather than comply adding: "... [W]e emphasize that services provided by an IDTF are also readily available to beneficiaries through other avenues such as physicians' offices, outpatient laboratories, outpatient radiology facilities, and outpatient clinics."

Given the history of this troubled entity, ongoing fraudulent and abusive practices there, and the wide availability of services offered in other quarters, we suggest that CMS fundamentally reexamine the need for IDTFs rather than prolonging existence of this source of program integrity problems.

Promoting Effective Use of Health Information Technology (HIT)

While we applaud the regulatory exceptions to the Stark II (Stark) and Anti-Kickback (AKB) laws for HIT recently issued by the Department of Health and Human Services (HHS), the new regulatory exceptions are sufficiently vague and complex to deter many potential institutional providers from utilizing them.

Legal Barriers to HIT Adoption

Increased adoption and implementation of HIT, which can range from electronic patient registries to sophisticated electronic medical record systems (EMRs), has the potential to increase quality and decrease costs. However, substantial legal barriers to encourage HIT adoption exist.

Fraud and Abuse Laws

Because HIT has the potential to dramatically improve the quality and safety of patient care, some hospitals and medical groups with sophisticated HIT systems are ready to begin exchanging clinical data with community physicians. While many hospitals and medical groups already have web portals that allow physicians access to patient data, there is little two-way exchange of data. Therefore, these providers would like to assist physicians to take the next step and adopt EMRs. Increased physician adoption of HIT begins to create a culture of use and reliance on sophisticated HIT systems, easing the transition to a wholly electronic system in the future. Of course, not all hospitals and medical groups are in a position to help physicians adopt EMRs, but those that would like to cannot, due to, in large part, to the Stark and AKB laws.

Creating links between large providers and their affiliated and unaffiliated physicians involves the provision of computer hardware, software, support, education, etc. Unless these HIT items and services meet certain criteria, including that they are provided at fair market value, these arrangements implicate federal fraud and abuse laws (e.g., Stark and AKB). Because of the draconian sanctions associated with these laws (including incarceration, financial penalties, and mandatory or permissive exclusion from Federal health care programs), providers remain reluctant to enter into these arrangements.

Notably, a number of government agencies, including the General Accountability Office (GAO), the Office of the National Coordinator for Health Information Technology, and the Congressional Research Service, have stated that federal fraud and abuse statutes present barriers to arrangements between providers that would otherwise promote adoption of HIT.

New Regulatory Exceptions to the Stark and AKB laws

On August 1, 2006, HHS issued final regulatory exceptions to the Stark and AKB statutes related to the dissemination of HIT. While these new rules represent marked improvement over the proposed exceptions, significant obstacles remain which may dramatically limit the number of large providers that utilize the exceptions to disseminate HIT. Consequently, the policy driving the issuing of these new exceptions, namely, creating usable regulations that will incentive disseminating HIT to small physician practices, will be thwarted.

Problematic aspects to the new rules include new interoperability requirements. Despite best attempts at clearly defining "interoperability", the new rules are subject to interpretation which does not offer many large providers with the comfort needed to disseminate HIT without fear of violating Stark or AKB.[1]

---

[1] Under the rules, providers must donate HIT that is interoperable as defined in the regulations or donate technology that is "deemed" interoperable by a "certifying body." HHS recognized that interoperability standards are evolving and thus are requiring providers using the regulatory definition to ensure that the donated technology is as "interoperable as feasible given the prevailing state of technology at the time" the HIT is provided.

We also believe it is inappropriate to interject non fraud and abuse policy issues, in this case, an interoperability requirement, in the Stark and AKB laws. These statutes are designed, appropriately, to deter and punish fraud and abuse and should not be used to promote an altogether different policy goal.

Also, the new exceptions include a five year "sunset" provision. We are not aware of any other statutory or regulatory exception to Stark or AKB laws that includes a sunset provision. Again, addition of such a requirement will give large providers pause before they decide to invest in disseminating HIT to community physicians. Similarly, the rules do not allow providers to provide "hardware" to physicians. Solo and small physician practices may opt not to accept EMR software because of contamination issues related to downloading software into existing office based computer systems.

Provider – Physician Relationships

Another concern raised suggests that the provision and support of HIT will lead to subtle, yet preferred, relationships between hospitals, medical groups and providers. Many other factors influence hospital-physician relationships, such as patient preference, insurer restrictions on patient choice, perceived quality of the hospital, and special services that a particular hospital may have available. In any circumstance, the physician is still subject to the fraud and abuse statutes. Furthermore, a computer-based system can help federal law enforcement agencies track possible violations of law much more readily than the current paper-based environment.

HIT as a Cost of Doing Business

AMGA members have pioneered the use and application of HIT in their practices and have, by and large, made heavy investments in this important infrastructural element both as a practical matter and for philosophical reasons. The Administration has taken the stance that it supports the adoption of HIT as a normal cost of doing business and as such, does not support "paying" for physician's to acquire HIT capabilities. The realities of the realm belie that notion and strongly suggest that this "normal" cost of doing business is deemed unnecessary or unaffordable by most physician Medicare providers. It is in any event, not being done.

We believe that appropriate incentives will have to be forthcoming to advance broad adoption and implementation of HIT to realize its potential for reducing medical errors, improving patient safety, enhancing care coordination, etc. **However, we believe that any financial support, direct or indirect, that may evolve over time, must take into consideration the investments and leadership demonstrated by those entities,**

including many AMGA members, by recognizing and repaying them for having had the vision to install and apply HIT.

Healthcare Information Transparency Initiative

AMGA has taken no position *vis a vis* health care information pricing transparency. We echo cautions offered by many that making publicly available prices of physician services must be done in such a way to make the information understandable and useable for consumers. That suggests providing context, education, and full comparisons of costs, i.e., charges, reimbursement levels, and some method by which the full course of treatment costs may be known, a formidable challenge given the fact that intensity and breath of services are often impossible to determine on a prospective basis.

We support efforts to reward physicians and medical groups for delivering quality care. The probable vehicle for data gathering is the Physicians Voluntary Reporting Program (PVRP). Currently, participation by physicians is elective and involves the use of HCPCS G-codes, or as an alternative, submission of already existing data via the Doctor's Office Quality - Information Technology (DOQ-IT). vehicle available via Quality Improvement Organizations (QIOs).

There are barriers, impediments and limitations inherent in both of these approaches that pose problems for our members and other medical groups and may preclude participation in the PVRP. Retooling existing sophisticated, and often unique electronic capabilities to accommodate the keying of G-codes on each generated bill is prohibitively expensive and administratively burdensome.

The DOQ-IT vehicle has too many limitations to make it a broadly available alternative. While technical capabilities may indeed exist, structural limitations caused by funding limitations, make this approach "hit or miss". Depending on local QIO capacity, some of our members, although willing to submit their data, may be unable to take the DOQ-IT route.

We realize that PVRP is a building block, a first step, in the development of Medicare value-based purchasing and we look forward to continuing the dialog on its evolution into P4P or whatever precursor pay-for-reporting systems that may emerge.

Large multi-specialty group practices are quite different from other types of physician practices. They are, by and large, organized care delivery systems, and as such have built into their fabric an advanced model for performance measurement, quality control and continuous quality improvement. Some are members of fully integrated delivery systems and have hospitals already participating in the hospital voluntary reporting program, in various CMS demonstrations and other projects dealing with "quality" and related matters. They are integrated groups providing integrated care, furnished by a team rather than by an individual physician. Within this kind of delivery, multiple physicians, and

other health care professionals, provide care that crosses traditional specialty lines—it is truly coordinated care, internally.

These groups have in place internal systemic quality controls, based on continuous peer review and unified medical records, for most, an electronic medical record (EMR) and other infrastructural support systems. Such groups perform as a single entity and therefore should be measured as a single entity. They are large enough for sampling to provide sufficiently robust data to measure quality. They also have a proven track record as efficient providers of care. **As such, we request that CMS allow us, along with other medical groups that want participate in PVRP, to submit aggregated, group statistics and receive aggregated, group feedback reports.**

Finally, medical groups have existing mechanisms to distribute data and rewards. As the PVRP develops into P4P, we would also like any incentives they earn to be rendered in an aggregated form, with distribution and allocation decisions, left to extant group processes.

We recommend that PVRP be revised to include a mechanism to allow multi-specialty group practice physicians to submit data directly. For many of the groups, the reporting would initially involve manual abstraction from the patient medical record, similar to what is currently done for the hospital quality reporting, but could eventually be converted to automated reports. Most group practice physician organizations would be able to participate in the PVRP if the quality data could be collected and submitted manually or electronically and periodically in one of two ways:

1. **Submit Directly to CMS.** The easiest and least intrusive approach would be to create a separate file that would be submitted directly from the group practice to CMS. This file could be submitted quarterly. It would contain patient-level information for all relevant patient encounters during the quarter. The information would be organized so that the encounter, the patient, the physician could be tied back to the specific billing, if required.

2. **Submit to Carrier.** The second approach would also involve periodic reporting, but in this case to the carrier. For many medical groups, four of the sixteen measures could be automatically extracted from the group practice EMR on an interim basis, without additional physician administrative work. Nine of the measures could be reported with additional chart abstractions, but would require additional staff (approximately 1 FTE per group practice).

AMGA appreciates the opportunity to offer its perspectives for CMS' consideration. Any questions about our comments should be directed to George Roman, Director, Regulatory Affairs, at (703) 838-0033, extension 342.

Sincerely,

Donald W. Fisher, Ph.D.
President and CEO

Submitter : **Dr. Dominic Pedulla** **Date: 10/06/2006**

Organization : **The Oklahoma Vein and Endovascular Center**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

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

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

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

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

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

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

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

Each of these technologies is a vital component to the overall performance of this greatly needed service.

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,

Dominic M. Pedulla MD, FACC, ACPh, CNFPMC
The Oklahoma Vein and Endovascular Center
Oklahoma City
email:PedullaD@aol.com

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : **Dr. C. Erik Anderson** **Date: 10/06/2006**

Organization : **Premier General Surgery**

Category : **Physician**

Issue Areas/Comments

Background

Background

See comment below

GENERAL

GENERAL

I am responding to the proposed reduction in RVU's for CPT codes 36478 and 36479. RVU's have been consistently reduced from the 2005 levels, while operational expenses have consistently increased over the same time period. The initial capital expenses necessary for performing these necessary procedurees is quite substantial, on the order of $85,000 for my practice alone with purchase of all necessary equipment to safely and effectively perform endovenous laser ablation (CPT 36478). The per procedure expenses have also risen, consistently being greater than $450 per procedure. Consistently lowering the RVU's for this procedure would make it prohibitive to continue providing this necessary service to the Medicare patient community. My patients suffer greatly from their ailment and have gained a significant improvement in quality of life after undergoing this procedure. I would like to continue to offer this service, but fear that reduction in RVU's over time will make it too cost prohibitive. Furthermore, the RVU for procedure code 36475 remains elevated over the RVU for procedure code 36478, while the expense for performing CPT code 36478, taking into account initial capital investment, is equal to, if not higher than that of its counterpart code, CPT 36475. I would respectfully submit that both codes should be held at 2006 levels. With the proposed across the board reduction in RVU reimbursement, this will negatively impact providers offering this service as it is, and further reduction in RVU's would limit the ability of many providers to continue performing these procedures. I would also request that RVU's for CPT code 36478 be elevated to the same level as CPT code 36475 to account for the similarity in the two procedures, both technically and financially.

C. Erik Anderson, M.D.
Premier General Surgery
3920 N. Union Blvd, Suite 160
Colorado Springs, CO 80907
(719) 475-0270

Impact

Impact

See comment below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See comment below

Submitter : Dr. ANTON SCHITTEK **Date:** 10/06/2006

Organization : KING CITY SURGERY CENTER

Category : Physician

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

General Comment

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Anton Schittek MD
Mt Vernon, IL 62864
anton@schittekmd.com

Impact

Impact

see general comment above

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see general comment

Submitter : **Ms. Christina Witsberger** **Date: 10/06/2006**

Organization : **Ms. Christina Witsberger**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-502-Attach-1.DOC

Attachment 502

TO: Centers for Medicare and Medicaid Services, DHHS
DATE: October 6, 2006
SUBJECT: Comment on NPRM published 8/22/06 on Part B Payment Changes
REFERENCE: File code CMS-1321-P
ISSUE Identifier: ASP Issues

As a consultant working in the health insurance reimbursement field, especially for public payers, I frequently use Medicare files and rates for research, analysis, and I know some insurers other then Medicare (both public and private) are also using the ASP file for setting reimbursement rates. It is very useful information that would be difficult to obtain otherwise, and a good standard source of rates.

However, there are a couple things that are unclear about the rates, which affect their use, and which could be made clear on the CMS website or in the description of the rates in the ASP payment file. I would find it very helpful, as I'm sure others would who use these data, if CMS could consider the following enhancements to the ASP methodology and rate file:

1) Medicare has a web page on the ASP system with rates for download at this address: http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/

In addition to that URL name, there are links to download what is called "ASP Pricing File", and there is a section entitled "2006 ASP Drug Pricing File" with some brief explanation, and this sentence is towards the bottom of that explanation (fifth paragraph): <<Where applicable, the payment amounts are 106 percent of the Average Sales Price (ASP) calculated from data submitted by drug manufacturers.>>

When you download the file, it is entitled "Payment Allowance Limits for Medicare Part B Drugs" on the Excel spreadsheet itself, although notes say that unless noted otherwise, they are based on the ASP methodology. There is then a column labeled "Payment Limit" with rates, and some exemption notes for those injectable drugs paid by AWP (e.g., flu vaccines).

Because of all those references to ASP rates, I have always assumed that with the exception of the AWP rates listed, the others were based on the ASP. However, it has come to my attention that any given payment limit in that table may not actually be the ASP, but could have been obtained from other calculations (e.g., WAC). This would be potentially important and useful for others to know -- when the rates are ASP and when they are something else.

I am therefore suggesting that this file would be improved if there were a column noting the basis of the payment limit (ASP, WAC, etc.). At the least, some notes on it might state that for those based on the ASP methodology (not AWP), the rate shown may not be the ASP.

2) Most importantly, I would also urge CMS to make clear in the explanation of the ASP, and in the directions to the manufacturers when submitting data, whether or not the Federal 75 cent per dose vaccine excise tax should or should not be including when reporting the sales price. This is a Federally mandated tax on certain vaccines which is then put into the Vaccine Injury Compensation Fund. Because it is per dose, it can amount to $2.25 for a vaccine that covers three diseases, for example (e.g., MMR), and

that amount is not inconsequential in the final rate. This excise tax must be paid by every purchaser of the vaccine, so is an integral part of the price, although the tax would not be part of a manufacturer's "list price" for a vaccine, or charged on a bill for the vaccine line item itself. The tax would be added as a separate line item, but is required and an essential part of the price that any provider must pay for it.

The National Vaccine Injury Compensation Act established the collection of this excise tax, which is described in IRS publication 510 as to the vaccines covered, and the legislative authority is Internal Revenue Code 26 USC, Section 4131. This tax is levied on diphtheria, pertussis, tetanus, polio, measles, mumps, rubella, HIB, Hep B, chicken pox, and trivalent flu vaccines, among perhaps others.

Whether the Federal Excise Tax is or is not included in the ASP shown for these vaccines is important for users to know, and for providers to be compensated fairly by insurers. CMS does list prices in their injectable drug pricing file for almost all of these vaccines, even though only a few are routinely covered by Medicare Part B. Almost all of those vaccines covered by Medicare are priced by AWP (e.g., flu) so ASP is not shown for them, but not all (e.g., tetanus). Also, as noted, rates are shown for almost all vaccines, even when not covered by Medicare (e.g., MMR), so other payers may be using those rates for payment. I understand that some manufacturers may include this tax in their submission under the "reasonable assumptions" they are allowed to make when submitting data, if they are noted on their submission, but I think standardization of policy and directions for submitting sales data would improve the ASP system.

I therefore strongly urge CMS to consider clarifying whether the Federal vaccine excise tax is or is not included in the ASP or other price shown on its pricing files, and to standardize the directions to the manufacturers on this issue for their sales data submissions.

Thank you for consideration of these comments.

Sincerely,

Christina Witsberger
Consultant
Takoma Park, MD 20912
email: MsCWitsberger@aol.com

(doc: CMSASPcomm.doc)

Submitter : Dr. Karen Beasley **Date:** 10/06/2006

Organization : Maryland Laser Skin & Vein Institute

Category : Physician

Issue Areas/Comments

Background

Background

Venous disease affects over 20 million patients. A large majority of these patients are in the Medicare population. Making these revisions as proposed will impact negatively on their access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

GENERAL

GENERAL

CMS 1321-P

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Karen L. Beasley, MD
Hunt Valley, MD
Maryland Laser Skin and Vein Institute

Impact

Impact

please see general comment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

please see general comment

Submitter : Dr. David Rice **Date:** 10/06/2006

Organization : Assn. of Freestanding Radiation Oncology Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-504-Attach-1.DOC

Attachment 304

October 5, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: Proposed CY 2007 Physician Fee Schedule; CMS-1321-P

Dear Dr. McClellan:

The Association for Freestanding Radiation Oncology Centers (AFROC) is delighted to have this opportunity to comment on CMS's proposed policies and rates under the Physician Fee Schedule for CY 2007, which was published on August 22, 2006 in the Federal Register (the "Proposed Rule"). AFROC is an association representing non-hospital providers of radiation oncology services throughout the country.

Preliminarily, we note that the proposed payment rates set forth in the Proposed Rule result in part from proposed decisions made by CMS with respect to the five year review and certain proposed changes in the practice expense RVU (PE-RVU) methodology. For this reason, we are incorporating by reference (and attaching for your convenience) the comments filed by AFROC on these issues earlier this year. Attachment A.

Our comments on the Proposed Rule now subject to comment focus on several issues:

- CMS's budget neutrality adjustment methodology
- The Medicare conversion factor
- Medicare allowances for certain physics services.
- The application of the DRA to radiation oncology services.
- Changes in the Stark Law and Reassignment Rules.

I. CMS's Budget Neutrality Methodology

We understand that, in response to CMS's prior notice announcing five year review and PE-RVU methodology changes, a number of professional associations, including the American

Medical Association, have objected to the budget neutrality adjustment methodology, under which the five year review changes are to be absorbed exclusively through a 10% reduction in W-RVUs. While we are sympathetic to the plight of those physicians who will not see the full increases that they had anticipated as the result of the five year review, we are concerned that shifting the budget neutrality adjustment resulting from the five year review to the conversion factor, while leaving the budget neutrality adjustment for PE methodology changes to be absorbed exclusively by PE-RVUs, will unfairly disadvantage technical component services.

For this reason, we urge CMS to ensure that technical component services, which are subject to extraordinary reductions under the Proposed Rule, are not disadvantaged by whatever budget neutrality adjustment methodology is chosen. In the event that CMS shifts the budget neutrality adjustment attributable to the five year review to the conversion factor, the budget neutrality adjustments necessitated by the new PE-RVU methodology (and most certainly the 32% reduction in direct cost allowances) clearly should be shifted to the conversion factor as well. The AMA and other organizations argue that the budget neutrality adjustment attributable to PE-RVU methodology changes should be absorbed exclusively by PE-RVUs until certain modifications are made in the equipment utilization and related assumptions and until a multi-specialty survey of indirect costs is completed by the AMA. However, neither changing the equipment -related assumptions nor substituting new indirect cost survey data would affect the 32% direct cost budget neutrality adjustment. There simply is no rational policy reason to treat budget neutrality adjustments made as the result of PE methodology changes differently from those necessitated by the five year review.

And while there may be some technical difficulty in determining the amount of the budget neutrality adjustment for indirect PE RVUs, there certainly is no such difficulty in determining the budget neutrality adjustment for direct costs. As CMS has noted, the PEAC has essentially verified all of the direct cost inputs and CMS considers the refined values sufficiently reliable to make substantial methodology changes based on these values. This data represents real costs, and any adjustment made to ensure that these costs "fit" into the direct cost pool represents a real reduction in payment necessitated by budgetary constraints. There simply is no convincing rationale for requiring such reductions to be born exclusively by technical component and other services that are PE-heavy.

II. Conversion Factor

One of the major concerns arising from the Proposed Notice is a change in the projection for next year's conversion factor. While prior projections suggested that the conversion factor would decrease by about 4.6% in CY 2007, more recent projections indicate that, unless Congress acts, the conversion factor will decrease by 5.1%.

With respect to this issue, we incorporate by reference the comments made by the American Medical Association with respect to the SGR calculation, and urge CMS to recalculate

the conversion factor in accordance with the methodology recommended by the AMA, which will minimize the conversion factor reduction required under the current SGR formula.

III. Physics Services

We note that the proposed RVUs for certain physics services are based on direct cost data that is incomplete and inaccurate in a number of respects. Our specific concerns are set forth in some detail in the comments filed by the American Association of Physicists in Medicine, which are incorporated in these comments by reference. We urge CMS to make the changes recommended by the AAPM before finalizing the CY 2007 RVUs for these services.

IV. Application of Deficit Reduction Act to Radiation Oncology

We applaud CMS's proposal not to impose the "cap" on medical imaging services authorized by the Deficit Reduction Act to radiation oncology treatment services. Under the CMS proposal, only a handful of radiation oncology codes are subject to the "cap."

We do caution, however, that concurrent medical imaging and radiation treatment has significant clinical benefits to the patient, and that new CPT codes likely will continue to be needed to report radiation oncology treatment that involves concurrent imaging. New technologies are likely to continue to emerge in this area, and we believe that CMS should clearly establish the principle that, where a service involves medical imaging that is clearly incidental to radiation treatment delivery, the service will not be subject to the DRA "cap." A policy that subjects these new services to the DRA payment limit would clearly inhibit the adoption of these new and emerging modalities, which would be inconsistent with the best interests of our patients.

V. Stark Law and Reassignment Changes

The Proposed Rule includes a number of proposed changes to the regulations implementing the physician self-referral law (the Stark Law regulations) and the reassignment rules for diagnostic services. These changes seem to be very complex and we frankly find it difficult to understand and appreciate the full potential impact that they may have on arrangements between radiation oncology centers and providers of diagnostic services that are needed for the appropriate diagnosis, staging, and treatment of cancer patients.

We are particularly concerned about changes in the reassignment and self referral rules that may make it more difficult for radiation oncologists to fully integrate medical imaging into the treatment protocols for our patients. For example, it is unclear to us how the proposed changes might affect the ability of independent contractor radiation oncologists to perform or interpret CT simulations for a radiation oncology group or center, since (a) CT simulations are classified as radiology services for Stark Law purposes; and (b) under the Proposed Rule, such services may be provided only by a physician who does not see the patient. Moreover, it is

unclear how these proposed changes may apply to services involving concurrent imaging and treatment (such as stereotactic treatment) or image-guided treatment of cancer performed by independent contractor physicians.

While we are sympathetic to CMS's need to clarify the rules to preclude certain "pod lab" practices that are abusive, we caution against making broad changes to the Stark Law regulations--violation of which is subject to heavy sanctions--in order to preclude a relatively narrow category of abuses. At the very least, we recommend that CMS (a) modify the reassignment rules only, leaving the Stark Law regulations untouched; and (b) limit the modifications made to apply to pathology services only. We especially caution that great care should be taken to assure that the rules are not modified in a way that may inadvertently preclude radiation oncology centers from fully and completely integrating emerging medical imaging technologies into the care of cancer patients.

We appreciate the opportunity to comment on these issues, and look forward to working with you over the coming years to further refine the Physician Fee Schedule allowances for radiation oncology services.

Sincerely yours,

David Rice/BH

David Rice, M.D.
President
Association of Freestanding Radiation Oncology Centers

Attachment

AFROC
ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS
Our Voice in Washington

August 18, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:

On behalf of the Association for Freestanding Radiation Oncology Centers (AFROC), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on June 29, 2006 in the Federal Register (the "Proposed Rule"). AFROC is an association representing non-hospital providers of radiation oncology services throughout the country. Accordingly, these comments focus primarily on the practice expense (PE) methodology described in the Proposed Rule.

These comments address a number of issues arising from the proposed PE data and methodology. For the reasons set forth below, AFROC respectfully requests that CMS:

- Substitute the PE/hr of $213/hr for the current PE/hr for radiation oncology, for the reasons set forth in the attached report.
- Limit the application of physician work as an allocator of indirect PE-RVUs.
- Maintain the proposed methodology for including non-physician staff time as an indirect cost allocator, and consider eliminating or adjusting the direct and indirect adjustments to maximize the proportion of indirect costs distributed on the basis of direct costs.
- Modify the Indirect Practice Cost Index ("IPCI") methodology, as described below.
- Make the changes recommended by the American Association of Physicists in Medicine (AAPM).

- Either (a) require work RVUs to bear the budget neutrality adjustment resulting from the five-year review and the PE-RVUs to bear the budget neutrality adjustment resulting from the proposed PE changes; OR (b) maintain budget neutrality solely through the conversion factor. In any event, however, budget neutrality adjustments should be done in the same way for both W-RVU and PE-RVU changes.

Each of these issues is described below:

Radiation Oncology PE/Hr.

The PE/hr for radiation oncology is determined differently from that of other specialties. In general, the PE/hr for other specialties is based on a single survey; however, in the case of radiation oncology, the Lewin Group recommended that CMS "blend" the PE/hr for hospital-based radiation oncologists from the survey conducted by the American Society for Therapeutic Radiology (ASTRO) and the PE/hr for radiation oncologists practicing in non-hospital settings from the survey conducted by AFROC. Based on its estimate of the proportion of hospital-based vs. non-hospital-based radiation oncologists, the Lewin Group recommended that this data be "blended" in the proportion 75% (hospital-based)/25% freestanding.

AFROC engaged the services of an independent claims analyst, Christopher Hogan of Direct Research, to determine whether or not the 75/25 "blend" ratio is correct. Direct Research's report is attached. That report demonstrates that the Lewin Group's analysis is flawed, and that the more accurate methodology for blending the AFROC and ASTRO survey results yields a PE/hr for radiation oncology of $213/hr. We respectfully request that CMS substitute this figure for the PE/hr for radiation oncology used in the Proposed Rule.

Indirect Expense Allocation

AFROC strenuously objects to the continued use of work-RVUs as an allocator for indirect costs. It is clear that the intensity of physician work bears no relationship whatsoever to the practice expenses incurred by that physician: While there may be an argument that some portion of indirect costs should be apportioned to services performed outside of the office, there is no basis for determining that the intensity of physician work should be taken into account. For example, is there any reason to believe that more indirect costs (e.g., overhead, administrative costs, billing costs) are associated with the services of an internist who performs a hospital consultation for a half hour than for a surgeon who performs surgery for the same half hour?

The use of physician work RVUs as an allocator for indirect costs is quite simply a political accommodation to those specialties with relatively high W-RVUs. The impact of this political accommodation is extraordinary: We estimate that, if indirect expenses allocated on the basis of staff time are not taken into account, approximately 40% of total practice expense payments are distributed on the basis of W-RVUs. Because technical component services are not associated

with work RVUs, these codes are essentially ineligible for 40% of the total amounts paid under the PFS for practice expenses.

CMS has indicated that because technical component services have very high direct costs, the allocation of some portion of indirect costs on the basis of physician work does not unduly disadvantage technical component services. But what if CMS modifies the direct cost calculations--by, for example, significantly changing the equipment utilization or interest rate assumptions or the equipment acquisition cost data?

We respectfully urge CMS to limit the use of physician work to no more than a designated percentage of indirect costs. (One possible approach might be to limit allocation of indirect costs based on physician work to the percentage of time spent by physicians out of the office to the amount of time spent on in-office services, calculated as an average over some period of years.) Alternatively, the percentage could be established arbitrarily, recognizing that the reason for allocating any indirect costs on the basis of W-RVUs is a political accommodation in the first place.

At the very least, we request CMS to commit to re-examine its allocation methodology for indirect costs when and if it changes any of the major assumptions or data used to determine technical component services, such as the equipment utilization or interest rate assumptions, which may substantially affect payment for technical component services. In the past, CMS has indicated that the proposed indirect cost allocations methodology does not significantly disadvantage these services because of their high direct costs. However, if the direct cost allocations are reduced substantially, this rationale no longer can be used to justify using W-RVUs to allocate indirect costs, and the indirect cost allocation methodology must be revisited.

Non-Physician Staff Time as Indirect PE Allocator

AFROC supports the use of non-physician staff time as an indirect PE allocator, as set forth in the Proposed Rule. As set forth below, we believe that the use of physician work RVUs as an allocator is quite simply a political accommodation to the surgical community. To the extent that the use of non-physician staff time at least moderates some of the impact of this decision, we believe that it is more than justified in the context of the overall methodology.

We also note that direct costs are reduced by about 33% through application of the direct adjuster before they are used as an allocator for indirect costs. In light of the arguments set forth above, we believe that the portion of indirect costs allocated on the basis of direct costs should be increased, and one option might be to eliminate this adjustment for the purposes of indirect cost allocation.

Indirect Practice Cost Index ("IPCI") Methodology

We believe that CMS should closely examine and consider modifying the methodology used to determine the Indirect Practice Cost Index ("IPCI") with respect to radiation oncology. It appears that the IPCI, as presently configured, serves a number of different purposes:

(1) The IPCI adjusts the indirect PE-RVUs of each service to reflect the relative indirect costs of the specialists who provide that service.

(2) The IPCI "ties" each specialty's survey data to the PFS. Since the surveys provide practice expense data per physician hour, a specialty with more physician hours should have more indirect practice expenses.

(3) The IPCI is the mechanism by which CMS maintains the "top down" aspects of its methodology, which serves a budget neutrality function by limiting indirect expense payments made to each specialty to amounts in that specialty's "pool."

It is unclear to us whether the current methodology for determining the IPCI is the best way to achieve any of these objectives.

It is our understanding that one of the primary functions of the IPCI is to ensure that the indirect PE-RVUs are adjusted to reflect each specialty's relative indirect PE/HR, as reflected in each specialty's survey. As we understand it, by the time the IPCI is applied, the direct PE-RVUs for each code have been determined based on the PEAC data and indirect PE-RVUs have been obtained based on direct costs, physician work and (in some cases) non-physician staff time. All that remains at that point is to adjust the indirect RVUs based on the various specialties' relative indirect costs, as reflected in the survey data.

Conceptually, a specialty with indirect expenses substantially higher than the average, such as radiation oncology (with indirect expenses of $73.50/hr (not taking into account the adjustments supported by the attached Direct Research report) compared with the all physician average of $46.30/hr) should have an index factor significantly greater than 1. Yet, the radiation oncology index factor resulting from the CMS methodology is .70. Thus, the current methodology is not a pure measure of the relative indirect costs of the various specialties.

We understand that this result is attributable to the fact that, while radiation oncology's indirect PE/hr is high, the number of radiation oncology physician hours is low--what is unclear is why the number of physician hours should be a factor. It could be argued that the inclusion of physician time in the formula is necessary because each specialty's PE survey reports practice expenses **per physician hour**; therefore, a specialty with twice the number of physician hours should have twice the indirect PE-RVUs. However, it seems to us that the amount of physician time is implicitly included in the calculation of indirect PE-RVUs on a CPT code-by-CPT code

basis before the IPCI is applied, through the inclusion of W-RVUs as an indirect PE allocator. Thus, all other things being equal, a specialty that has twice the number of physician hours might be expected to have substantially higher indirect PE-RVUs, **without regard to the IPCI.**

One alternative is to derive the IPCI by taking the ratio of each specialty's indirect costs (as reflected in that specialty's survey) to the all-physician average indirect PE/hr. Once this IPCI is applied, the "pool" of indirect PE-RVUs for all services can be made budget neutral by an across-the-board adjustment, comparable to the budget neutrality adjustment methodology used for direct costs. This methodology has the advantage of transparency, which CMS has indicated is a major priority. Essentially, the suggested methodology makes it clear what percentage adjustment is necessary to make indirect PE-RVUs budget neutral. Under the current methodology, it is our understanding that some part of the budget neutrality adjustment is essentially built into the IPCI, and is difficult to determine.

Other alternatives might include eliminating the IPSI with respect to radiation oncology, in light of the fact that radiation oncology includes an extraordinary proportion of services with no physician time that do not contribute to the radiation oncology "pool." In addition, adjusting the PE/hr data as set forth in the Direct Research report may help address the IPSI problem by ensuring that, at the very least, the radiation oncology "pool" takes into account an appropriate proportion of technical component providers. Finally, CMS should also consider using staff time in lieu of physician time to determine the contribution of TC services to the radiation oncology "pool" for the purposes of determining the IPSI.

Physics Codes.

We note that the Proposed Notice would result in extraordinary reductions in Medicare payment for physics codes, which are addressed in detail in the comments submitted by the AAPM. We strongly support the recommendations made by AAPM with regard to the physics codes and urge CMS to include these modifications in the final rule.

Budget Neutrality Adjustment for PE-RVU Changes

We support CMS's proposal to make budget neutrality adjustments for W-RVUs and PE-RVUs separately. In the alternative, we believe that it may be appropriate to make all budget neutrality adjustments to the conversion factor. However, we believe that it would be manifestly unfair to make W-RVU adjustments to the conversion factor while continuing to make PE-RVU adjustments to PE-RVUs only, especially in light of the fact that the proposed methodology already imposes a significantly larger budget neutrality adjustment on PE-RVUs that on W-RVUs.

We hope that this letter is helpful and look forward to working with CMS to address these important methodological and data issues.

Sincerely yours,

David Rice /bh

David Rice, M.D.
President
Association of Freestanding Radiation Oncology Centers

Enclosure

cc: AFROC Board
Sheila Gell

Radiation Oncology Centers: Analysis of Weights Used for Medicare Practice Expense Per Hour Calculation.

Final Report
May 4, 2006

Submitted to:
Association of Freestanding Radiation Oncology Centers (AFROC).
C/O Diane Millman
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye Street, N.W., 12th Floor
Washington, DC 20006-5409

Submitted by:
Christopher Hogan, Ph.D
President, Direct Research, LLC
506 Moorefield Rd, SW
Vienna, VA 22180

Executive Summary

The Centers for Medicare and Medicaid Services (CMS) relies in part on survey data when it sets practice expense relative values in its physician fee schedule. Surveys are used to show the average practice expense per hour of physician work, separately by physician specialty. When multiple surveys are available, CMS may take a weighted average of different survey data sources.

The Association of Freestanding Radiation Oncology Centers (AFROC) asked for an analysis of the weighting that was used by Lewin, Incorporated (and adopted by CMS) to generate an average practice expenses per hour for radiation oncology. The Lewin analysis combined practice expense for hospital-based and non-hospital based radiation oncologists, using two different practice expense surveys.

The choice of weights is important because hospital-based physicians have very low practice expenses. (Most of their expenses are paid by the hospital, not the physician.) Modest changes in the weight assigned to hospital-based physicians may have a significant impact on the estimated average practice expense per physician work hour.

I looked at this issue using two different approaches (percent of physicians, percent of physician time) and several years of data. My analysis consistently suggests that the Lewin study overstated the fraction of radiation oncology in hospital-based settings. Where Lewin assumed 75 percent of radiation oncologists were hospital-based, I found that 64 percent of radiation oncologists were hospital-based in 2004, and that 62 percent of radiation oncologists' time was in hospital-based settings (based on their Medicare fee-for-service bills and CMS' 2002 estimates of physician time per procedure). Re-weighting the Lewin-published data to reflect these proportions would raise average total practice expense for radiation oncology from roughly $161 per physician work hour to slightly more than $200 per physician work hour.

Table 1: Hospital-Based Radiation Oncologists, Based on Site Where Majority of Medicare Services Were Provided						
	Count of UPINSs			Percent of UPINs		
Data Year	Not hospital based	Hospital based	Total	Not hospital based	Hospital based	Total
2002	948	1808	2756	34%	66%	100%
2003	1003	1843	2846	35%	65%	100%
2004	1046	1897	2943	36%	64%	100%
Source: Analysis of Medicare 5 percent sample standard analytic file physician supplier file, LDS version, claims lines with CMS specialty code "92", radiation oncology.						

This finding was robust to several alternative ways of measuring procedure volume. The percent of radiation oncologists who were hospital-based did not change more than 1 percentage point from the figures above, whether I:

- counted claims or lines or services;
- used all services or only those in the radiation oncology range (e.g, excluded office visits), or
- ignored bills for technical-component-only services.

The reason for this robustness is simple: the distribution was essentially bimodal: most physicians either did all hospital care or nearly all non-hospital care. For example, the median physician had 100% of services in the hospital. Further, this was not due to small numbers of claims. The median physician had 60 services in the 5 percent sample file.

The overall count of physicians is somewhat lower than might be expected based on other data sources. The Health Resources and Services Administration (HRSA), for example, counted just under 4,000 radiation oncologists in 2000, although the fraction involved in direct patient care was not cited (http://bhpr.hrsa.gov/healthworkforce-/reports/factbook02/FB202.htm). The 2003 UPIN registry showed about 4400 UPINs with specialty 92 (although roughly 30 percent also had a record showing radiology (specialty 30) for the same UPIN). Thus, the roughly 3,000 UPINs appearing on the 5 percent sample claims file is a modest undercount of the actual number of radiation oncologists, based on other sources. This is plausibly attributable to a number of factors, including physicians with multiple Medicare-registered specialties (so the UPIN registry may overcount this specialty), physicians not involved in active patient care or not treating Medicare fee-for-service patients (e.g., administrators, Permanente employees), presence of group UPINs (a single UPIN for a physician group), and similar factors.

My firm conclusion is that, by 2004, if we accept the method of using a weighted average based on counts of physicians, then we should be using 64 percent hospital-based and 34 percent non-hospital-based, in place of the Lewin study's 75%/25% blend.

1.2 A better methodology: time-weighted average.

An alternative method provides good corroboration for the estimates above. CMS is calculating a per-hour practice expense. Given that, if we must construct a weighted average of hospital-

based and non-hospital-based practice expense data, it seems better to weight by the fraction of physician hours in those settings rather than the fraction of physicians.

To do that, I used the 2002 physician time data by CPT code, as posted by CMS with the 2002 practice expense revisions. There, the total physician time per procedure (MDTTIMRG) was provided for roughly 8,000 CPT and modifier combinations.

It is worth noting that the physician time for technical component services (-TC modifier, or radiation treatment delivery services that do not involve physician work) is zero. So this physician-time-weighted analysis properly drops the -TC bills and drops the treatment delivery codes (CPT 77401-77418) that involve no physician work. This is reasonable to do because those codes (-TC and the CPT range 77401-77418) are billed in the carrier file only from non-hospital sites and will not appear in the carrier files billed from hospital-based sites.

Table 2 shows that the fraction of radiation oncologists' time attributable to hospital and non-hospital settings is nearly the same as the fraction of physicians found above. Using 2004 100% claims summary data, 62 percent of radiation oncologists' time was in hospital-based settings, based on the volume of services billed to Medicare by site of service.

Table 2: Share of Radiation Oncologists' Time Treating Medicare Patients, by Site of Service

Site	Total Services	Total Minutes	Percent of Minutes
Total	6,613,227	448,415,010	100%
Hospital	4,110,520	277,862,595	62%
Non-Hospital	2,502,707	170,552,415	38%

Source: Analysis of 2004 Medicare physician/supplier procedure summary master file data for specialty 92 (radiation oncology), matched to 2002 physician time data by CPT and modifier (as posted by CMS for the 2002 practice expense revisions).

1.3 Re-weighting the practice expense data.

The hospital/non-hospital fractions calculated above can be used to re-weight the practice expense data (Lewin study, page 50). Table 3 shows that the higher fraction of physicians or physician time allocated to non-hospital settings raises the weighted average practice expense significantly. I believe that weighting by hours of patient care is most nearly consistent with the underlying CMS methodology. Therefore, I believe that the figures in the rightmost column ($213.07 total) would be the correct weighted average to use in the CMS practice expense

calculations, given this basic approach of taking a weighted average of the hospital and non-hospital values.

Table 3: Re-computing Weighted Average Practice Expenses					
			Weighted Average		
	Hospital-based	Non-Hospital Based	Lewin Study	Using Table 1 Data, 2004 proportion of physicians	Using Table 2 data, 2004 proportion of physician time
Memo: Proportion hospital-based			0.75	0.64	0.62
Memo: Proportion non-hospital-based			0.25	0.36	0.38
Direct PE per hour					
Clinical Payroll	$ 9.93	$ 153.24	$ 45.47	$ 61.52	$ 64.39
Medical Equipment	$ 3.64	$ 91.04	$ 25.32	$ 35.10	$ 36.85
Medical Supplies	$ 1.56	$ 13.11	$ 4.42	$ 5.72	$ 5.95
Indirect PE Per Hour					
Office Expense	$ 19.31	$ 87.88	$ 36.32	$ 44.00	$ 45.37
Clerical Payroll	$ 12.04	$ 59.56	$ 23.82	$ 29.15	$ 30.10
Other Expense	$ 16.92	$ 52.43	$ 25.73	$ 29.70	$ 30.41
Total PE Per hour	$ 63.40	$ 457.26	$ 161.08	$ 205.19	$ 213.07

Source: Lewin study (cited in text), analysis of 2004 5 percent sample SAF data (Table 1, physician counts), and 2004 100% summary file data (Table 2, physician time).
Notes: The Lewin weighted average is as-published in the Lewin report, and appears to reflect slightly less than 75.0% in hospital-based settings.

Submitter : **Dr. Andrew Douglass** **Date: 10/06/2006**

Organization : **East Tennessee Vein Clinic, P.C.**

Category : **Physician**

Issue Areas/Comments

Background

Background

30% of female and 15% of male Medicare age patients suffer from painful varicose veins and venous insufficiency. Until the advent of new miminimally invasive procedures these patients were not treated because the sole option, surgical stripping, had an rate of recurrence and risk of complications that was unacceptable to physicians and patients alike. Now that treatment is available which can safely and effectively relieve the burden of suffering the loss of adequate reimbursement will reduce availability of the procedure to patients.

GENERAL

GENERAL

1. Now that effective treatment is available for painful venous insufficiency, essentially Medicare is proposing to remove the treatment from being available by not paying for it.
2. The proposed reduction of allowance for the procedures 36478 and 36479 is countered against the requirement of a costly laser, $25,000 as well as the consumable items of approximately $400 a case and the cost of an ultrasound technologist whose salaries are in the range of $65,000 plus a year.
3. The alternative of vein stripping is much more costly in terms of patient risk of complications as well as the procedure and anesthesia itself.
4. The ultimate result is to reduce the availability of the procedure.

Impact

Impact

See general comment.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See general comment.

Submitter : Mr. Michael Mawby **Date:** 10/06/2006

Organization : Novo Nordisk Inc.

Category : Drug Industry

Issue Areas/Comments

Impact

Impact

Novo Nordisk Inc. supports CMS decision to establish work relative values for the Medical Nutrition Therapy (MNT) procedure codes, which are used by registered dietitians in providing MNT to qualifying beneficiaries who have diabetes mellitus and non-dialysis chronic renal disease.

With the broadest diabetes product portfolio, including the most advanced products within the area of insulin delivery, Novo Nordisk is a world leader with an 80-year history of innovation and achievement. In the United States, Novo Nordisk s ambition in nothing less than Changing Diabetes (tm). Accordingly, we have launched a National Changing Diabetes Program to work as a catalyst to improve diabetes treatment and care. In addition, the government affairs department has the mandate to work to implement public policies, laws, and regulations that will improve diabetes prevention, treatment, and access to care. Overall, Novo Nordisk s business is driven by the Triple Bottom Line: a commitment to economic success, environmental soundness, and social responsibility to employees and customers.

Novo Nordisk s support for CMS to establish relative values for MNT procedure codes is consistent with our corporate commitment to improve care for people with diabetes.

Specifically, Novo Nordisk supports CMS decision to establish work values for MNT codes and the MNT G HCPCS codes (97802, 97803, 97804, G0270 and G0271). This decision corrects the previously undervalued code relative values. It also precludes the large reductions that would have occurred using the new bottom-up methodologies suggested in the proposed rules, if work continued tonot be recognized for the MNT codes.

Novo Nordisk believes the recommendations to establish work RVUs for MNT and MNT G HCPCS codes will have two positive impacts: it will improve beneficiary access to MNT services, and provide an incentive for registered dietitians to continue participation in the Medicare Part B program.

Establishing work values for the MNT codes also supports the intent of the original MNT legislation where Congress recognized work effort in the legislative language, e.g. registered dietitians should be paid 85% of the amount for the same services if provided by a physician.
Novo Nordisk encourages CMS to carefully review the work values established for the MNT and the MNT G HCPCS codes. The work values should reflect the detailed, complex cognitive and behavioral therapy components inherent in MNT services.

In addition, Novo Nordisk urges CMS to update and expand the current MNT coverage policies so as to extend this coverage to people with pre-diabetes. CMS currently appropriately covers screening for asymptomatic individuals presenting to a Medicare provider with diabetic risk factors. The screening is authorized to take place once a year and for those whose blood sugar values fall in the medically-recognized pre-diabetes range testing is authorized every six months. Yet, MNT is not covered until the individual tests within the diagnosed diabetes range.

Novo Nordisk appreciates the opportunity to offer these comments in support of the agency s establishment of equitable work relative values that reflect professional work provided by registered dietitians for MNT services. Novo Nordisk also urges CMS to better inform and promote this vital service that has historically been underutilized, thereby jeopardizing optimal self-management by beneficiaries. Finally, we hope that CMS will extend MNT coverage to the pre-diabetic population and undertake a public-private campaign to diagnose and treat this population. Novo Nordisk and a host of other organizations stand ready to participate in such an initiative.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

While the current coverage is critically important for people with diabetes, it also makes sense for CMS to extend the MNT coverage to the pre-diabetic population as a preventive measure. The seminal Diabetes Prevention Program, an NIH-sponsored clinical trial ended a year early due to overwhelming evidence, found that with moderate diet modification and exercise, the progression to diabetes in high-risk individuals could be prevented in 58 percent of the cases. More importantly for CMS, the progression to diabetes was prevented in 71 percent of the cases for people 60 years of age and older. This study tells us that with an appropriate emphasis, CMS could save lives and save money with a focus on finding and treating the 14 million Medicare beneficiaries with pre-diabetes.

Submitter : Stephen Torpy **Date:** 10/06/2006

Organization : General & Vascular Surgery PC

Category : Physician

Issue Areas/Comments

Background

Background

I believe that making the revisions as proposed will substantially limit Medicare patients' access to a innovative and clearly superior method of treatment for varicose vein problems.

GENERAL

GENERAL

CMS-1321-P Medicare Program: Revisions to Payment Policies Under teh Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the Physician fee schedule fpr 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 issue of great concern:
1. RVUs have been consistently reduced since 2005 levels while practice expense continue to rise. Practice expenses continue to rise, particularly the cost of Registered Vascular Technologist salaries that are necessary to comply with CMS guidelines. The combination of cuts in Physician Fee Schedule and non-invasive vascular imaging will limit the ability of our practice to continue to provide care for Medicare beneficiaries.
2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further reducing reimbursement for endovenous ablation therapy.
3. I have participated in Medicare since 1979 and have never to this point considered non-participation. However, when reductions in reimbursement are such that payment essentially covers only my minimum cost in providing the service I end up working for nothing. Obviously the business of medicine makes this an impossibility. My only recourse will be to become a non-participating physician--certainly not my preference.

I would request that the fully implemented, non-facility practice expense RVU for endovenous therapy remain at the 2006 level.

I would be happy to discuss the above with members of your committee.

Respectfully submitted,

Stephen D Torpy MD
Omaha, NE 68130
storpy6012@aol.com

Impact

Impact

refer to general comment below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

refer to general comment below

Submitter : **Dr. kenneth todd** **Date: 10/06/2006**

Organization : **Southeast vein and laser center**

Category : **Physician**

Issue Areas/Comments

Background

Background

reducing payment for this procedure will limit the number of physicians who perform the procdure and limit access to healthcare for patients.It will also drive physicians to perform strippings which cost medicare $7,000 to $10,000 due to hospidtal and anesthesia costs instead of $2,000 for EVLT.This procedure has a 98% success rate confirmed at least 6 years. Radiofrequency and stripping have a 1% rate of DVT which then requires costly hospitalization and long term coumadin therapy with its inherent cost of lab testing and long term follow-up care. If these cost are added in to the cost to medicare then , clearly, EVLT is under-reimbersed.Any further cuts in reimbursement, on top of the across the board cuts already planned, will force me to limit the number of medicare patients that I see. This procedure takes 1 1/2 hours to perform and requires expensive technology which I have to pay for in addition to the disposables on a per case basis. I feel that medicare, and the nation at large have asked physicians to deliver technology which provides better safer healthcare. Now that this procedure delivers this goal, Medicare does not want to pay for it. this will stifle future efforts to develope high quality, lower cost, alternative technology.

GENERAL

GENERAL

In an environment where lack of funds is a major problem why would medicare pay less for a procedure performed in an office where research has proven less wound infections and complications occur than in a hospital whrer complications are much more common.

Impact

Impact

see below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see below

Submitter : **Dr. Fazal Bari** **Date: 10/06/2006**

Organization : **Dr. Fazal Bari**

Category : **Physician**

Issue Areas/Comments

Background

Background

As the head of a busy 6 physician practice, I find the current proposal regarding the use of red cell stimulating agents extremely limiting and disruptive in allowing me to offer the best individualized care to my patients. As you know, we make decisions based on clinical parameters, and to tie in the use of a drug to a contract would severely restrict its use in situations where patients would benefit. The current Amgen contract actually gives me the flexibility of more choices, not less.

Submitter : Ms. Lisa Mekenas **Date:** 10/06/2006

Organization : Sharp Hospital/Vein Institute

Category : Hospital

Issue Areas/Comments

Background

Background

People will have less access to the better treatment to venous insufficiency, which can be linked to days off work missed as well as disability. Treatment now is not done because HMO do not provide for qualified care. This will set it back even further.

GENERAL

GENERAL

We have begun to find better ways of treating this life disabling and very painful disease. Please do not cut funding now, it should be expanding to cover ablation, and accompanying sclerotherapies. We have found the old surgical techniques actually increased neovascularization--research from European trials for 20 yrs is available. Please don't let this send American medicine back! This is a true and painful,disabling disease that affects many americans who have been denied treatment because the primary care HMO MD has said"there are just varicose veins, they are just cosmetic". I can tell you how many MD's I have seen that have changed thier minds when they were affected or a family member!

Impact

Impact

Should be payment to providers who have proven phlebology experience, vascular physicians and others who are qualified in the field. Should include payments for ultrasound investigations.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Vascular Sonographer in the field for 15 yrs and worked with venous research.

Submitter : **Dr. Daniel Green** **Date: 10/06/2006**

Organization : **Univ. of Tennessee Medical Center-Knoxville**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-511-Attach-1.DOC

Attachment 511

October 6, 2006

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

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

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

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

- The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for robotic SRS procedures.

- We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement.
- Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004).

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

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

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

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

Sincerely,

Daniel M. Green M.D.
Medical Director- University of Tennessee Medical Center- Knoxville
1924 Alcoa Highway
Knoxville, TN 37920
865 544-9040
dgreen@utk.edu

Submitter : **Dr. eric lester** **Date: 10/06/2006**

Organization : **oncology care associates**

Category : **Physician**

Issue Areas/Comments

Impact

Impact

Re Asp issues: It is frustrating that reimbursement issues consume so much of the providers time. It is frustrating that reimbursement changes and pending changes are constantly needing our attention. While it has been beneficial for some manufacturers to provide additional discounts for bulk purchases,etc. we choose a drug based on it being the right drug for the right patient for a specific clinical problem. Often competing contracts give us more choice and flexibility when planning our drug purchases--this is greatly appreciated.,i.e, the Amgen and Orthobiotech products. However, you must take strong measures to insure that changes in the Asp system will reflect actual discounts that are available. A "smoke and mirrors" approach to "discounts" erodes our confidence and undermines the true value of such concepts. Providers need to have simple, basic facts that are easy to interpret when confronted with drug contract choices and prices. I urge you to leave the door open for "healthy" competition between groups such as Orthobiotech and Amgen on the growth factor products and let providers decide which drug is right for which patient. Thank you.

In addition to what we have said above, I think it is important and only fair to say that the approach CMS has taken to the cuts in payment for oncology drugs in the last few years has been damaging to our practice and to the care of our patients. It has been a profoundly demoralizing nightmare for our practice to try to determine what we will be paid next quarter- can we afford to hire the nurses and social workers we need, etc. When can we expect a stable business (reimbursement) environment and a reliable partner in CMS?? Why do we have to be at the receiving end of someone else's political agenda? I would like to say thanks for listening.