Submitter : Dr. Bruce Quinn **Date:** 10/06/2006

Organization : NHIC Medicare Part B California

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

D MISCELLENEOUS CODING ISSUES

D, Section 3, AAA Ultrasound Screening
The DRA amends the statute to allow ultrasound screening services (for aortic aneurysm), one-time only, with certain limitations such as men who once smoked 100 cigarettes. Part of the requirements will be placed in the CFR and others will follow through an NCD.
1. If I interpret the syntax correctly, the patient must be referred based on an initial preventive physical (SSA 1861(ww)(1). This is inappropriate because many patients will be 68, 70, 72, and may not have had the IPP during their first year in Medicare. Referral via the IPP should be *one* option for the test.
2. CMS should have safeguards against duplicative testing with abdominal or retroperitoneal ultrasound using existing CPT codes. Otherwise, abusive providers will perform the statutory screening ultrasound at 1 pm and perform the abdominal ultrasound at 1:30 pm (with a diagnosis such as abdominal pain), or the next day, or vice versa. In California, we observed a select group of IDTFs and general practicioners always performing abdominal and retroperitoneal ultrasound on the same day, a practice that was unknown outside these select providers. While we dealt with that via an LCD, we cannot have an LCD on the screening ultrasound because it will be an entitlement. Nor can we effectively prove that not all patients passing through the clinic had a true checkmark box for 5 packs of lifetime smoking. Other screening benefits (such as PAP smear or colonscopy) are either not expensive or are performed by highly trained specialists. This will not be the case for IDTFs performing duplicative screening benefit and diagnostic ultrasound under different codes at the same time or adjacent days.

Submitter : **Dr. bruce quinn** **Date: 10/06/2006**

Organization : **nhic medicare california part b**

Category : **Health Care Industry**

Issue Areas/Comments

Impact

Impact

L. INDEPENDENT DIAGNOSTIC TESTING FACILITY ISSUES
I support all of the regulations proposed for Independent Diagnostic Testing Facilities. However, I believe CMS has an excellent opportunity to clarify several points in issuing these regulations and in later crafting the Program Manual implementation of these new regulations.
-----1. Bonding of IDTFs for $300,000. It is unclear whether the bonding is against e.g. malpractice or personal injury claims or whether the $300,000 would be available to CMS in the event of a postpay recoupment activity. The latter case is extremely important and should be clarified.
-----2. IDTFs subject to state regulation. This is a principle of IDTF regulation, but can be extremely difficult to enforce. CMS OGC will not interpret state regulations. Medicare contractors have no legal staff to write briefs on the meaning of state regulations. Where the contractor in at least one state (California) has requested to not enroll IDTFs that appear to violate plain-English state regulations, permission cannot be granted because CMS/OGC cannot rule on state regulations. CMS must clarify a specific process through which contractors, regional offices, or CMS central office can consistently and correctly reach a determination on how to implement state regulations, even if such a determination (as any decision) can be contested at the hearing officer or ALJ or DAB level.
------3. Who must be an IDTF. The program manual contains very clear language that an entity (even physician owned) which provides only diagnostic testing on referred patients must enroll as an IDTF. (There are safe harbors for radiologists, etc). This part of the regulation is not changing, but it is extremely weak in implementation. In California numberous extremely active practices were seen in 2004/2005 which billed exactly like IDTFs (performing numerous unrelated expensive tests on non-treated patients) but billing under one or another physician PIN. The manual says such a center must enroll as an IDTF. However, must is meaningless because the carrier has no action whatsoever to require them to enroll as an IDTF. Thus, the clinics escape IDTF LCDs which may require neurologic tests to be supervised by an IDTF neurologist, ultrasound by a radiologist, and so on, and they will escape the 2007 proposed rules. Either the CFR or the manual must contain clear instructions as to how to proceed when an IDTF-like entity declines to enroll as an IDTF in order to escape the IDTF regulations. This problem will escalate with the new rules. Again, the manual is clear they must enroll as an IDTF but there is no penalty for not doing so, thus, the manual is vulnerable to being flaunted without penalty.
-----4. Clarification of allowable tests. G0248/G0249 is INR testing which is a physician service, although it involves a lab test (like a clinical lab service) and involves equipment (like DME). Because it is on the PFS, an IDTF has asserted the right to enroll with one provider but serve all 30 million national beneficiaries, claiming the location of service was the IDTF s mailbox in California. G0248/G0249 should be reclassed as DME, or otherwise the IDTF rules should be clarified.

Submitter : **Dr. bruce quinn** **Date: 10/06/2006**

Organization : **NHIC - CA Medicare Pt B**

Category : **Health Care Industry**

Issue Areas/Comments

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L. INDEPENDENT DIAGNOSTIC TESTING FACILITY ISSUES

-----5. Under the existing and the proposed rules, the supervising physician has enumerated responsibilties for the IDTF. A cross-reference to 42 CFR 432 has been deleted, this was helpful, because it implied the responsibilities of the IDTF physician were the same as for diagnostic tests in a physician office. The cross-reference should be restored, along with the new text. However, the manual gives no instructions or penalties when an IDTF and supervising physician grossly flaunt the supervision rules. Can they be suspended? Disenrolled? Put on a probationary period? These rules are critical to the safety of patients in IDTFs, which are usually under no state regulation, unlike e.g. an ASC or nursing home. There needs to be a clear pathway for specifically dealing with IDTFs which flaunt the supervision rules, for example, hypothetically, asserting that one phone call in 10 years is adequate supervision in the judgment of the IDTF and MD. Exactly state what the carrier may do next.

----6. I fully support the restriction to supervising 3 IDTFs. In California, we observed a direct correlation between thinly supervised IDTFs (e.g. 1 MD and 20 or more IDTFs) and increased beneficiary complaints to fraud hotlines and PSC investigations. Assuming the physician is well-intentioned, this suggests it is not usually possible to supervise large numbers of IDTFs with adequate control.

----7. Not discussed in the proposed rule is an operational abuse which is specific to IDTFs. I have been told of IDTFs renting the space their technician stands on when going mobile to a doctor s office; one California IDTF actually published such a brochure emphasizing this was not a kickback because it is a fee-for-service transaction, as is paying the doctor a high fee for one minute of his time to consult with the IDTF technician on site. . I have been told of IDTFs paying high fees to rent a ramp between a physician office and a mobile radiology van, again, under the guise of a fee-for-service transaction rather than a kickback. These situations appear absurd but regulatory or manualized language could reduce the risk of abuse, or at least the claim, that the abuse is innocent of possible kickbacks

Submitter : Dr. bruce quinn **Date:** 10/06/2006

Organization : NHIC - CA Medicare Pt B

Category : Health Care Industry

Issue Areas/Comments

Impact

Impact

N. PUBLIC CONSULTATION FOR MEDICARE PAYMENT OF CLINICAL DX LAB TESTS
N.2 (d) Gapfilling
I concur that the existing process for crosswalked codes is appropriately implemented in practice and need merely be codified in regulation to satisfy the statute. However, I believe CMS fails to fulfill the Congressional intent to specify gapfilling rules for carriers. CMS proposes to insert the existing manual language into the CFR to fulfill this instruction at new 414.408. The change regarding the lower of carrier amount or national limitation amount, to be converted in 2007 to national limitation amount, is somewhat confusing since the carrier amount in the first gap-filled year is used to create the NLA. The instructions are too broad and vague to be consistently implemented by carriers. For example, one bullet point may yield a price of $10, the next $20, the next $30, and so on. There is no process to resolve a single price from this confusion. While this could be acceptable in itself, it is unacceptable in view of Congress s clearly worded requirement that a clear process will be specified by CMS for carriers.

Date: 10/06/2006

Submitter : Dr. bruce quinn

Organization : NHIC - CA Medicare Pt B

Category : Health Care Industry

Issue Areas/Comments

Impact

Impact

N. PUBLIC CONSULTATION FOR MEDICARE PAYMENT OF CLINICAL DX LAB TESTS
N.3 (a) Blood glucose in SNF. CMS should be aware that locally, extremely high rates of abuse by single providers occur in the home health setting. For example, using DME-supplied patient devices and DME-supplied patient strips, a home health agency co-enrolled as a laboratory and billed some $1M for $4 portable glucose tests, using the nurse already in place to aid the patient with the device as a home health benefit. The contractor reasoned this violated the fact that the DME had already paid for the device and strips, thus, the whole service was not being performed. Or in the alternative, it was inappropriate for the physician to not order the DME equipment while ordering millions of dollars of one-off portable glucose tests. The language for SNF could be manualized for Home Health as well.
[http://www.medicarenhic.com/cal_prov/articles/hhglucosemonitor_0806.htm] CMS Contractor Article A41022.
However, the contractor had to craft this without legal advice and manualized instruction would be helpful.

Date: 10/06/2006

Submitter : Ms. Debra Ness

Organization : National Partnership for Women & Families

Category : Consumer Group

Issue Areas/Comments

Background

Background

please see attached

GENERAL

GENERAL

please see attached

Impact

Impact

please see attached

Provisions of the Proposed Rule

Provisions of the Proposed Rule

please see attached

CMS-1321-P-561-Attach-1.PDF

National Partnership
for Women & Families

October 6, 2006

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

RE:

Physician Fee Schedule: [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 and

Hospital Outpatient Prospective Payment System (OPPS): [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

On behalf of the National Partnership for Women & Families, I am writing to urge CMS to reconsider proposed reductions to Medicare reimbursement for partial breast irradiation, also referred to as breast brachytherapy, for the treatment of early-stage breast cancer. For more than 35 years, the National Partnership for Women & Families has worked to promote better health care for women and families. One of our main goals is to ensure that women have access to high quality health care and a full range of treatment options.

The National Partnership is concerned that the steep Medicare reimbursement cuts to breast brachytherapy proposed in the physician fee schedule and OPPS rules will likely reduce women's access to this more patient and family-friendly treatment approach. In contrast to the required 5-6 week course of therapy with whole beam external radiation, partial breast irradiation can be completed within 5 days, allowing women to get back to their lives. Clinical studies of brachytherapy as a follow-up to lumpectomy show comparable five-year local recurrence rates to whole beam external radiation, making brachytherapy an attractive option for women who deem 5-6 weeks of radiation treatment too onerous.

We understand that the CMS proposal will result in decreased reimbursement:

- for a complete course of breast brachytherapy in a free-standing radiation oncology center or physician office by 15% in 2007 and 54% by 2010; and

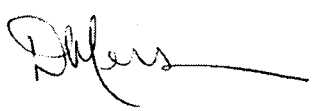
- for the procedures to implant the device into the breast for brachytherapy following lumpectomy by 23-37% in the hospital outpatient department. The newly proposed level of OPPS reimbursement will not even cover the cost of the brachytherapy device.

At the same time, more invasive procedures and therapies – mastectomies and whole beam external radiation therapy – are slated for increased reimbursement.

The National Partnership for Women & Families recognizes that breast brachytherapy is not the right course of therapy for every woman. Both the American Society of Breast Surgeons and the American Brachytherapy Society have published guidelines for selecting patients who are appropriate for this procedure.

We know that CMS shares our commitment to quality health care for women, including access to safe, effective, and patient-friendly treatments. Given the size of the proposed Medicare reimbursement cuts – and the importance of preserving the availability of this less invasive breast cancer treatment option – we ask CMS to carefully reexamine the potential impact of these reductions on Medicare beneficiaries' access to the breast brachytherapy procedure. We fear that these severe cuts are likely to drive medical decisions based on the most favorable reimbursement levels, rather than what is necessarily the best treatment option for the patient.

Sincerely,



Debra L. Ness
President

Cc: Leslie Norwalk, Deputy Administrator, CMS
Herb Kuhn, Director, Center for Medicare Management, CMS
Kathleen Harrington, Director of External Affairs, CMS

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

Organization : **American Venous Forum, American College of Phlebol**

Category : **Physician**

Issue Areas/Comments

Background

Background

The proposed action will probably result in reduced access of Medicare beneficiaries to treatment for chronic venous insufficiency.

GENERAL

GENERAL

To date, Medicare reimbursement for enovenous ablation procedures has been barely satisfactory, but adequate enough that I continue to participate in Medicare because I want to serve that population. Of course, most third-party insurance reimbursement is based on Medicare rates making the treatment of those patients barely financially responsible for a surgical practice. I have resigned all but one of my PPO/HMO contracts because of this. The ugly truth is I need to be paid enough to remain solvent so I can provide care for these patients. I don't have an excessive income considering the extent of my training and the responsibility I take in being a surgeon. I drive a small Toyota, I don't own a second home, at age 52 my retirement is far from funded, my kids don't go to private schools, etc.

In the Medicare age bracket, many of the patients have neglected disease, and they have more advanced complications of chronic venous insufficiency. These patients require more time and sophistication than their younger counterparts with the disease.

The advent of endovenous procedures has resulted in a greatly heightened sophistication on the part of treating physicians compared to just a decade ago. Continuing education to properly perform these procedures requires more sophisticated education in anatomy, physiology, technology, and treatment than for updating one's education in almost any other area of general and vascular surgery. In short, the disease is being treated better because the doctors providing treatment are much better trained. Considering a reduction in reimbursement for these procedures sounds like the idea of someone who is not in the field. I suggest you poll the leadership in The American Venous Forum and the American College of Phlebology, and not rely on the assessments of those not specializing in the treatment of venous disease. At a time when responsible treatment of these patients is finally finding its place in the medical system, making the care financially disagreeable will only serve to reduce convenient access for Medicare patients. This does not seem to be a strategy that serves them well. Also, if reduction of health care costs is your goal, reducing physician fees is not, and never has been, the most effective way of doing so, since the vast majority of costs go to adminstration of hospitals and healthcare plans. The percentage of the cost of healthcare that goes to physician fees is tiny compared to many other areas (though reducing physician fees is certainly the more politically expedient). A strategy to reduce healthcare costs that focuses on a tiny slice of the pie seems ill-conceived, and irresponsible.

Since performing these procedures requires not only a sophisticated knowledge of the disease, but also increased technologic and ultrasound (radiologic) skills, the reimbursement should take that into account. It seems politically attractive to reduce reimbursement for treating venous disease because, after all, it really isn't a life-threatening disease. Reducing reimbursement for cancer care would bring down the roof. There is much documentation on diminshed quality of life and work-hours lost because of this disease that shows that it is not just a cosmetic issue, but a significant health problem. Reducing reimbursement for the hightly specialized physician who treats this disease is unjust to the physician and the patients, irresponsible to Medicare beneficiaries, ineffective financial strategy, and without sound medical or economic basis. Please reconsider these proposals, and, if anything, increase reimbursement for these procedures commensurate with the increase in physician skill and sophistication, as well as office costs (including the purchase of a good ultrasound unit and power generator) required in performing them.

Sincerely,
Daniel L. Monahan, MD

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Endovenous ablation techniques have greatly improved the treatment of chronic venous insufficiency of the lower extremities and its complications, including symptomatic varicose veins, chronic venous stasis, and venous ulceration. I have performed over 600 radiofrequency ablation procedures, belong to both major venous disease oriented organizations, have published research relative to the procedures, and have spoken at national meetings of both organizations. My surgical practice now is entirely composed of treating venous disease. While being much less invasive than vein stripping, it is much more technology-intensive, and requires sophisticated knowledge of the disease, more sophisticated diagnostic evaluation, and both surgical and radiologic skills to perform the procedures well. Especially since the procedure can be done in an office-based procedure room, time and cost savings in terms of facility and personnel are quite significant. Nonetheless, the skills required by the practitioner are significantly greater than vein stripping. In addition, the technology and equipment costs are all on the surgeon's practice.

Submitter : **Dr. Khalil Fattahi** **Date: 10/06/2006**

Organization : **Vein Specialty Medical Clinic, Inc**

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. Our overhead costs in the area we practice, will not allow to offer these services for less than current medicare rates.

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,
Khalil Fattahi, MD
Campbell, CA 95008
vsmclinic@aol.com

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See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : **Dr. Bruce Fearon** **Date: 10/07/2006**

Organization : **Summit Skin and Vein Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I read the proposed medicare fee changes for CPT 36478 and 36479 and believe that you show reconsider this- the costs for these procedures has risen --- not declined. I think you should know that the costs for buying a laser device to perform this procedure is $40,000 and this device is not useful for any other procedure. Buying an Ultrasound machine to use for these procedures is at least another $100,000 and may even be as high as $250,000 depending on the quality of machine you're using. Maintenance contracts for these devices as you can imagine is about $2000/month. Laser fiber costs vary depending on which machine you use- mine cost me $130 per use (and thats using the re usable fibers) and in order to use a reusable fiber you must purchase a sterilizer ($4000)and have people who are trained to use it. The costs for acquiring and maintaining properly trained Ultrasound technicians $36/hr ($74,880/year)is the rate I have to pay. I also have to have a nurse who's knowledgeable in this field --- $24/hr ($49,920)and a float --- $15/hour ($31,200). All of these costs are incurred and paid for before I pay myself one penny. By the way, I forgot to include the costs of my Billing and collection department (combined $30/hr--- $62,400)which I have to spend in order to "remind or fight everyone" for the money that is owed to me for doing a procedure that Medicare and the Insurance Companies said was OK to do in the first place. My costs which include benefits and costs of living increases, malpractice premiums, utilities, etc is going up, not down. Please reconsider your Reimbursement Cuts. Bruce Fearon MD

Submitter : **James Bekeny** **Date: 10/07/2006**

Organization : **James Bekeny**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for 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,

James R. Bekeny MD

Westlake, Ohio 44145

Email JBekeny@lkwh.org

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see commente below please

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see comment below please

Submitter : **Dr. Karl Chiang** **Date: 10/07/2006**

Organization : **Eastern Radiologists, Inc.**

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. Medicare patients that need venous treatment are not cosmetic and are usually the most symptomatic and usually suffer the most with ulcers. The population of medicare patients that I see and treat is far fewer than the younger population, and yet are the ones who need endovenous treatment the most. I think it would be a great disservice to single out medicare patients for this cutback and force many to not get the proper medical care for their crippling venous disease.

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 ($35,000 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).

At our facility, we no longer perform Radiofrequency Ablation even though it reimburses better because we noticed a significantly higher recurrence rate than endovenous laser ablation on retrospect studies of our patients. Our own scientific data allowed us to make the medical decision to perform only laser in spite of its lower reimbursement rate.

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(laser) be increased to this same level.

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

Respectfully submitted,

Karl S. Chiang, MD

Medical Director
Eastern Interventional Radiology Clinic
#8 Doctors Park
Greenville, NC 27834
252-754-5253
chiang@easternrad.com

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See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : Dr. James Altizer **Date:** 10/07/2006

Organization : Vein Center of Charlotte

Category : Physician

Issue Areas/Comments

Background

Background

The proposed revisions to physician's fees will continue and worsen the trend towards limiting elderly patients' access to quality medical care. As MY costs are going up, not down, I will be forced to either limit the number of Medicare patients I can care for or opt out of Medicare altogether, leaving these elderly patients without access to my care, which is probably the best in the entire region for this particular medical problem, which is treatment of varicose vein disease.

GENERAL

GENERAL

CMS-1321-P Recisions to Payment Policies Under the Physician Fee Schedule for the calendar year 2007. I have reviewed the proposed 2007 fully implemented, nonfacility practice expense RVE's for CPT codes 36478 and 36479 and find several issues of great concern: 1. RVU's have consistently been reduced from 2005 levels and those levels are going to be reduced according to these new guidelines from 46.91 now to 40.84 in 2008. While practice expenses consistently rise (salaries, utilities, malpractice insurance , etc,) it has become increasinly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasolund component of the procedure requires that the physician employ a Registered Vascular Technologist to provide imaging services. These technologists are in drastic shortage and are therefore in high demand and command extrememly high salaries in exccess of 70K per year plus benefits. Given the limited number of these procedures that I can perform per year, it is going to be increasingly difficult if not impossible for me to comply with these guidelines if my reimbursement for these procedures continues to drop. Medicare's 2007 Physician fee schedule is already scheduled for a 5% across the board cut, not even including the cuts for ultrasound imaging. I cannot continue to perform these procedures at a loss just out of the goodness of my heart. I have expenses to pay. I do not run a free clinic, but that is precisely what Medicare is beginning to expect of me. What will YOUR MOTHER say to you when I tell her I cannot do her vein surgery because I will not make enough money to pay my expenses? THIS HAS TO STOP!!!! You cannot expect American physicians to continue to provide care for next to nothing. What will Congress do when no physicians accept Medicare anymore?
In addition, the codes 36475 and 36476, radiofrequency vein ablation codes, have consistently been reimbursed at higher rates than for laser ablation. These 2 procedures, laser ablation and radiofrequency ablation are essentially identical. They both use catheters to deliver heat inside a varicose vein to close it permanently. In fact, 5 year data now suggests that laser catheters are superior to radiofrequency, and in view of this data, we stopped using radiofrequency catheters over a year ago.

As a physician who cares about our nation's elderly, I DEMAND that the fully implemented, nonfacility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be incread to this same level. Not to do this may save Medicare some money in the short term, but in the not too distant future, many hundreds of thousands of elderly American citizens will be without access to these necessary procedures. REMEMBER, YOUR PARENTS WILL SUFFER FOR THIS.

Impact

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See below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See below.

Submitter : Dr. Thomas Elliott **Date:** 10/07/2006

Organization : Thomas R. Elliott, M.D. Vascular Surgery

Category : Physician

Issue Areas/Comments

Background

Background

These downward revisions in reimbursement for these procedures will significantly reduce Medicare patient access to these procedures, and ultimately all managed care insured patients. This will result in a significant degradation of the quality of care for these patients, and an associated degradation in quality of life. Also, by limiting access to these procedures (which are procedures that serve ultimately to avoid later severe complications of these conditions when not treated early) more severe and much more costly complications will present later which will mandate care at that time and cost much more in terms of patient pain, long term disability, and cost to the health care system.

GENERAL

GENERAL

I have been a practicing Vascular Surgeon for 22 years and I believe this technology is truly one of the significant advances to occur in that time in terms of allowing a notoriously undertreated and poorly treated disease process to be effectively managed. These procedures are not done, and are never approved, for cosmetic reasons. Although varicose veins are the visible outward manifestation of the disease process, the treatment is done for the indications of unrelenting pain, swelling, skin breakdown, ulceration, blood clotting, progressive inability to stand for long periods leading to loss of employment, and potentially loss of the involved limb. The unavoidable and very real dollar costs to the treating physician are substantial, and with continually rising practice expenses (not only rising liability insurance rates but also salaries and general costs), further reduction in the reimbursement for these procedures will likely make them unfeasable for many or most physicians. This will simply render a very treatable and essentially curable disease process once again untreated. The treating physician simply cannot absorb further reduction in reimbursement in the face of the high fixed costs. The general public is quite aware of the availability of these treatments and I doubt they will accept being denied access to them. Thank you for your consideration in this matter.

Impact

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Reductions in reimbursement for codes 36478 and 36479 specifically targets a relatively new and very effective technology that has allowed for very low risk, very reliable, and almost painless treatment for disorders that previously were vastly undertreated due to the pain and marginal results of treatment methods previuosly available. These reductions are in addition to blanket Medicare reductions already proposed.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Codes 36478 and 36479 relate to treatment of venous insufficiency of the lower extremities, a condition in which return of blood to the heart is hindered by damaged veins. These conditions are associated with potentially very severe limitations of function for the patients and in extreme untreated cases can lead to loss of the limb. The availability of these new technologies has allowed for early treatment of these conditions, and I am convinced that the overall cost burden to the health care system is reduced long term by avoiding the eventual complications of untreated venous insufficiency that predictably occur, typically in the Medicare age group. Unfortunately, new technologies are associated with unavoidable costs for equipment and disposable supplies which the treating physician or hospital must completely absorb. The current reimbursement levels are already reduced to a point of very marginal profitability for the practitionar doing these procedures, and further reductions will lead to the elimination of access for patients to these procedures. The expenses involved for the physician performing these procedures includes at least the following: 1) extensive time and course expenses for training to perform these procedures effectively (there is significant training involved) 2) capital expenditures for the equipment used for the treatment itself ($25,000 - $40,000) 3) capital expenditures for the ultrasound equipment which is a mandatory part of the process ($35,000 - $100,000) 4) training for physician and office staff in use of the ultrasound equipment 5) expenses and salaries associated with hiring registered vascular technicians to operate the ultrasound equipment necessary for each procedure 6) costs required for each and every case for cathters, equipment, and other disposables ($900 - $1000 per procedure) 7) costs for properly equiping and staffing the procedure room where these are performed, etc.

Submitter : **Dr. Phillip Hertzman** **Date: 10/07/2006**

Organization : **Los Alamos Family Practice**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for 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

2. While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. The ultrasound component of the procedure either requires a high level of ultrasound skill by the physician or employing 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.
3. In addition, it is important to note that both of these procedures are minimally invasive as compared to the alternative surgical procedure of vein stripping. Both of these procedures are significantly more successful and significantly less expensive than the surgical alternative which must be performed in the hospital surgical suite.
4. 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.
5. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

6. 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,

Phillip Hertzman MD, FACP, FAAFP
Los Alamos Medical Center
Suite 130
3917 West Road
Los Alamos, NM 87544
Phertz1@aol.com

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See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below.

CMS-1321-P-569-Attach-1.DOC

Attach #
5569

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.

Provisions of the Proposed Rule

See General Comment below.

Background

See General Comment Below

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

2. While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. The ultrasound component of the procedure either requires a high level of ultrasound skill by the physician or employing 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.
3. In addition, it is important to note that both of these procedures are minimally invasive as compared to the alternative surgical procedure of vein stripping. Both of these procedures are significantly more successful and significantly less expensive than the surgical alternative which must be performed in the hospital surgical suite.
4. 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.
5. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

6. 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,

Phillip Hertzman MD, FACP, FAAFP
Los Alamos Medical Center
Suite 130
3917 West Road
Los Alamos, NM 87544
Phertz1@aol.com

Submitter : **Dr. Aatif Husain** **Date: 10/07/2006**

Organization : **American Board of Registration of EEG and EP Techs**

Category : **Physician**

Issue Areas/Comments

Background

Background

The American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) offers the credentials R. EEG T., R. EP T. and CNIM and are dedicated to assessing the competency and quality of technologists performing studies for Independent Diagnostic Testing Facilities (IDTFs) and hospitals.

GENERAL

GENERAL

See Attachment from ABRET

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Established standards for diagnostic testing in Independent Diagnostic Testing Facilities.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The American Board of Registration of Electroenephalographic and Evoked Potential Technologists (ABRET) has a process in place for assessing the competency of EEG, Evoked Potential and Neurophysiologic Intraoperative Monitoring Technologists through a national examination. ABRET has been credentialing technologists for over 40 years.

CMS-1321-P-570-Attach-1.TXT

HHSM
570

A B R E T

October 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, Maryland
Electronic address: http://www.cms.hhs.gov/eRulemaking

Re: CMS-1321-P
IDTF issues

Dear Sirs:

In your notice of proposed rulemaking, you asked for public comments about proposed performance standards for Independent Diagnostic Testing Facilities (IDTFs). You asked about any organizations that have current established standards for diagnostic testing.

The American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) is a national credentialing board for EEG, Evoked Potential and Neurophysiologic Intraoperative Monitoring Technologists, awarding the credentials R. EEG T., R. EP T., and CNIM. ABRET has been focused on the competency and evaluation of technologists serving the neurology community and patients for over 40 years.

The testing procedures performed by ABRET credentialed technologists pertain to electroencephalography, evoked potentials, and neurophysiologic intraoperative monitoring. Such procedures use the CPT codes 95805 through 95829, and 95920 through 95930, and 95950 through 95967.

ABRET would like to take this opportunity to encourage the enforcement of Section 410.32(b) of the Code of Federal Regulation, as adopted in the Medicare physician fee schedule final rule of October 31, 1997, requiring that each non-physician who performs diagnostic tests must be state licensed or certified by a recognized national credentialing body.

ABRET is dedicated to providing an independent evaluation of competency of technologists performing studies, using the Guidelines established by the American Clinical Neurophysiology Society (ACNS). We support your position of evaluating whether of not technologists are qualified to perform the diagnostic test within the

purview of an IDTF and would like to encourage enforcement of this ruling. ABRET credentials may be verified on our website, www.abret.org.

Additional information on our credentialing process is available for review at: http://www.abret.org

The ACNS Guidelines we follow are available at: http://www.acns.org/

If ABRET can be of assistance to you in helping assure quality electroneurodiagnostic testing, please feel free to contact me, or our executive director, Janice Walbert.

Respectfully,

Aatif M. Husain, M.D.
ABRET President
Duke University Medical Center
Box 3678, 202 Bell Building
Durham, NC 27710

Janice Walbert
ABRET Executive Office
1904 Croydon Drive
Springfield IL 62703
217-553-3758
fax: 217-585-6663

Submitter : Mrs. Cindy Saiter **Date:** 10/07/2006

Organization : Interventional Radiology Consultants

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that reimbursement for greater saphenous vein ablation is under review to be reduced. Venous Insufficiency can be very debilitating for some patients and even leading to amputation. My patients have extreme pain due to their venous insufficiency and I feel very strongly that reducing reimbursement will prevent many patients from seeking this treatment. This is not a cosmetic procedure!

Submitter : **Dr. james albert** **Date: 10/07/2006**

Organization : **Dr. james albert**

Category : **Physician**

Issue Areas/Comments

Background

Background

Revisions in CPT code 36479 will megatively impact Medicare patients. Medicare reimbursement is the lowest of all payers and because of fixed facility fee cost for supplies, and ultrasound technicians we may be unable to provide services to medicare patients. It simply will not be cost effective.

GENERAL

GENERAL

I am responding to the CMS proposal regarding proposed changes for CPT codes 36478 and 36479. RVU' s have been proposed to be reduced from 46.9 to 40.8 from 2006 to 2008. Hoever pratice expenses continue to rise. 2007 Medicare physician fee schedule is scheduled to decrease 5.1% in addition there are proposed cuts for non-invasiv vascular imaging. These cuts will make it impossible for physicians to provide these extremely needed services to medicare patients.
Inappropriately, codes for 36475 and 36476 have been hiher than endovenous laser ablation codes that is currantly a better procedure.
My initial laser expense was over $46,000 as compared to radio-frequency ($25,000)
I request that the fully implemented nonfacility practice expense RVU remain at 2006 rate for 36475 of 51.5 and the RVU for 36478 be increased to the same level.

I would be happy to discuss these issues with members of the committee at any time.

Sincerely

James Albert, M.D.
Albert Vein Institute
9475 Briar Village Point 235
Co Springs, CO 8020
719-550-8346

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See General Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Commensts

Submitter : **Dr. Deborah Manjoney** **Date: 10/07/2006**

Organization : **Wisconsin Vein Center and MediSpa**

Category : **Physician**

Issue Areas/Comments

Background

Background

See General Comments

GENERAL

GENERAL

I would like to respond to the proposed 2007 revised physician payment schedule for CPT 36478 and CPT 36479, Endovenous Laser Ablation. I have reviewed the 2007 fully implemented, non-facility practice expense(PE) RVUs for the above codes and I disagree with the assignment of value on several counts.

1. RVUs have been reduced from the 2005 levels as follows:
   2006: 46.91,
   2007: 43.53,
   2008: 40.84,
   Fully implemented: 33.79.

These calculations fail to take into account the consistent rise in overhead (salaries, rent, utilities, etc.) of office-based procedures. Performance of office-based procedures requires more skilled employees than offices not performing procedures. Nurses or physician assistants are essential for monitoring patients and assisting at the procedures. The Endovenous Laser procedures, by CMS guidelines, require the physician to employ a Registered Vascular Technologist(RVT) to provide imaging services. These highly skilled personnel are in short supply, and command high salaries, currently in excess of $70,000 per year. Physicians are in competition with hospitals for these employees, and are likely not going to be able to afford continuing salary demand escalation if reimbursement continues to drop. Compliance with guidelines to employ RVTs for these procedures will become impossible as their salaries rise despite falling reimbursement.
The overall cost to Medicare for Endovenous Laser procedures performed in the office is a fraction of traditional treatment of venous insufficiency, i.e. vein stripping, performed in a hospital under general anesthesia. In-office procedures should be encouraged as a sensible way to cut expenses for Medicare patients.
The 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. There are, additionally, proposed cuts for non-invasive vascular imaging(vascular ultrasound). These cuts will strictly limit the ability of physicians to perform an extremely important procedure, ultimately resulting in a loss of access to superior modern care for Medicare beneficiaries.

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

3.Endovenous Laser Ablation codes have consistently been lower than Radiofrequency Ablation codes 36475 and 36476.
   2006: 51.5,
   2007: 47.77,
   2008: 44.52.
Both endovenous technologies are comparable, with laser treatment possibly having more applicability and somewhat improved longterm outcomes. Initial capital cost of acquistion is higher for the laser than for the radiofrequency device($35,000 to $65,000 for laser, and $25,000 for RF). Patient supply costs are somewhat less for the laser vs the RF($360 for laser and $750 for the RF)for procedure kits and catheters, but disposable sterile supplies such as drapes, gowns, bandage supplies are the same. The overall cost to the physician is significantly higher to aquire the device, thereby equating the costs of the two procedures.
The reimbursement rates for both procedures should be the same. I request that the fully implemented RVU remain at the same 2006 rate for 36475, and that 36478 should be increased to the same level.

Impact

Impact

The proposed revisions will have a negative impact on the Medicare populations' access to quality health care. The reduction in reimbursemet rates will ultimately limit access to physicians who perform technologically advanced treatments.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comments