Submitter : Dr. Ole Peloso **Date:** 10/06/2006

Organization : Vein Center of New Mexico

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,

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

Impact

Impact

See comments below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See comments below

Submitter :

Organization : **Radiology Associates of Ocala, P.A.**

Category : **Physician**

Date: **10/06/2006**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

We are 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.

We 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:
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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.

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a. 2006: 51.5
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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).

We 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.

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

Respectfully submitted,

Mark A. Yap, M.D.
David A. McKay, M.D.
Caleb Rivera, M.D.
Rolando Prieto, M.D.
Kerry B. Raduns, M.D.
Lance P. Trigg, M.D.
Scott R. Kerns, M.D.

Submitter : Dr. Mark Taylor

Organization : Gateway Dermatology

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

GENERAL

GENERAL

Currently enovenous laser and radiofrequency ablation of diseased varicose veins as a simple in-office outpatient procedure saves medicare millions of dollars annulally and makes it possible for many sufferers of painful varicose veins to receive treatment. It is expensive for physicians to buy the necessary equipment and provide and train staff and facilities to provide this service. The procedure is a win-win for medicare and the physician. Reducing the reimbursement, may make it impossible for physician to office the simple inexpensive alternative to inpatient surgery for varicose veins. Please do not reduce the reimbursement.
Sincerely,
Mark B. Taylor, MD

Submitter :

Organization : **Radiology Associates of Ocala, P.A.**

Category : **Physician**

Date: **10/06/2006**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

We are 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.

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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.

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We 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.

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

Respectfully submitted,

Mark R.V.Willard, M.D.
Fredric Wollett, M..
John M. Cain, M.D.
D. Mark Allen, M.D.
Wendie K. Moore, M.D.
Ralf R. Barckhausen, M.D.
Malcolm E. Williamson, M.D.
Edson G. Cortes, M.D.
John D. Boon, M.D.

Submitter : Dr. Danny Huntley

Organization : Vein Clinics of America

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

Background

Background

To make these provisions as they are proposed will certainly impact negatively the Medicare population'access to quality health care. The reductions in reimbursement rates will ultimately limit access to physician providers who perform these procedures

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:

RVUs have consistently been reduced from 2005 levels:
a. 2006: 46.91
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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.

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

Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
d. 2006: 51.5
e. 2007: 47.77
f. 2008: 44.52

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

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

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

Respectfully submitted,

Danny E. Huntley, MD
Atlanta, Georgia
bkheadmd@yahoo.com

Impact

Impact

See comments below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see general comments below

Submitter : Dr. David Rollins

Organization : Dr. David Rollins

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

Background

Background

The proposed revisions will negatively impact the Medicare patients' acess to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform thest treatments.

GENERAL

GENERAL

I am responding to the CMS proposal of 8/8/06 regarding proposed changes in the physician fee schedule for CPT 36475, 36476,35478 AND 36479, Endovenous Radiofrequency and Laser ablation.

The vast majority of these procedures are now being performed by physicians in the OFFICE SETTING. With the steady increase in practice expenses (6%/year) it is becoming more difficult to provide these necessary services. Additionally,in order to comply with CMS guidelines, the physician must employ a Registered Vascular Technologist (RVT) to provide imaging services at an annual cost of $70,000-80,000 per year. Given the limited number of procedures that the average physicians performs, it is not possible to be within CMS guidelines if the RVU's continue to be decreased.

Current/Proposed RVU adjustments for the procedures are noted below.

year	36478/36479	36475/36476
2006	46.91	51.5
2007	43.53	47.77
2008	40.84	44.52

The radiofrequency ablation(36475/76) and the Laser ablation(36478/79) technologies are comparable. The initial cost of the Laser technology is about $40,000 compared to $25,000 for the radiofrequency equipment. As you know the per patient disposable supplies for each case (eg Sterile Drapes and gowns, anesthetic solutions, IV bags, tubing, sutures and dressings)are a significant added cost. The difference in RVU's is based upon the cost of the radiofrequency procedure kit(750) compared to 400/kit for the laser. However, the radiofrequency kit cost has decreased recently making the costs per case similar. The cost of the laser technology (36478) has increased and radiofrequency technology (36475) decreased making the physician's cost of delivering the services about the same.

Thus, I believe the procedures should be reimbursed at similar rates and request THAT THE FULLY IMPLEMENTED, NON-FACILITY PRACTICE EXPENSE RVU REMAIN AT THE 2006 RATE OF 51.5 AND THAT THE RVU FOR 36478 BE INCREASED TO THE SAME LEVEL IN ORDER TO ALLOW CONTINUED AVAILABILITY OF THESE PROCEDURES TO THE MEDICARE BENEFICIARIES.

Quite simply, physician practice expenses are increasing over 6%/year and the proposed cuts in the non-facility practice fee coupled with the proposed 5.1% across the board Medicare Physician Fee Schedule and the 10-20% proposed cuts for vascular ultrasound reimbursement make delivery of venous health care to Medicare patients by the physician unfeasible and will result in limited access to physicians who perform these treatments.

Thank you ror your attention to this matter

Respectfully submitted

David Rollins MD FACS
Willoughby, Ohio
dlrmd@safier.com

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Impact

see attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see attachment

Submitter : Dr. Brad Uricchio

Organization : Reveal Vein Center

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

Background

Background

Making these revisions as proposed will impact negatively on the Medicare populations access to quality health care. Why? The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments since the costs to providers are only increasing. And as you well know, private insurance often follows the example of Medicare, so the negative impact on access to care goes well beyond those covered by Medicare alone.

GENERAL

GENERAL

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.

Respectfully submitted,

Brad Uricchio, MD
Reveal Vein Center
235 E. Princeton St, Ste 100
Orlando, FL 32804

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below.

Submitter : Dr. Robert Ellison, Jr

Organization : Dr. Robert Ellison, Jr

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

GENERAL

GENERAL

CMS-1321-P

Please be advised that 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 & 36479 and find several issues of great concern:

1) RVUs have consistently been reduced from 2005 levels:
   * 2006: 46.91
   * 2007: 43.53
   * 2008: 40.84

While practice expenses consistently rise (salaries,utilities,rent, etc) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure require that the physician employ a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. 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 in 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 reimbursment for endovenous laser treatment.

3. Values for codes 36475 & 36476, radiofrequency vein ablation have been consistently higher than those for laser ablations.

   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 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,

Robert G. Ellison, Jr., MD
Jacksonville, FL
dre@ellisonvein.com

Submitter : **Dr. John Koziarski** **Date: 10/06/2006**

Organization : **Family Surgical, PC**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

I am responding to the CMS proposal of 8/8/2006 regarding the proposed changes in the physician fee schedule for CPT 36478 and 36479 Endovenous laser ablation.

I have reviewed the proposed 2007 RVU changes for these codes and I am greatly concerned that the economics of the procedures will cause many physicians to be unable to continue to provide these services to Medicare beneficiaries.

There has been a gradual reduction in RVU's from 2005 levels:
2006- 46.91
2007- 45.53
2008- 40.84

This is in sharp contrast to the marked rise in the expenses necessary to provide the services to Medicare beneficiaries. In order to comply with CMS guidelines, the ultrasound component of the procedures requires that the physician employ a Registered Vascular Technologist (RVT) to provide the imaging services. These highly skilled technologists are in very short supply and command very high salaries in excess of $70,000 per year plus benefits.

The ultrasound/imaging portion of the procedure has already been bundled into the code 36478, thus no additional reimbursement is obtained to help offset these rising expenses.

In order for the technologist to provide the imaging during the procedure it is necessary to have an ultrasound machine. Doppler ultrasound machines are very expensive ($50,000-$300,000). Technology changes so rapidily in the imaging field that frequent upgrades are necessary in order to continue to provide high quality service to the Medicare beneficiaries.

In order to perform the procedure it is also necessary to purchase a laser ($40,000-$70,000). In order to be sure that the laser operating within its specifications (and safely) frequent calibration and inpection is necessary. These technicians are also in short supply and command very high fees for their services ($8,000-$10,000/yr).

The supply cost for the procedures are also rising, now up to $360 per procedure.

As you can see there are significant, rising costs associated with this procedure. There are the acquisition costs for the technology (laser and ultrasound)as well as the ongoing, per-case costs (Ultrasound technologist, laser calibration, disposable supplies including a fiber optic laser probe).

There is another issue sorrounding the fact that CPT 36475 (Radiofrequency ablation) reimburses at a high level than 36478 (Laser ablation). There does not seem to be a good reason for this. Even though the per-case supply costs are higher with the radiofrequency procedure, the initial capital acquisition costs and ongoing calibration costs are much higher with the laser procedure. The technical performance of the procedures is almost identical.

I would request that the fully implemented, non-facility practice expense RVU for 36478 (laser ablation) be brought up to the same as 36475 (radiofrequency ablation) of 51.5 and both kept at their 2006 level.

Thank you for your consideration in this matter.

John Koziarski, MD FACS

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below.

Submitter : Dr. Hormoz Mansouri

Date: 10/06/2006

Organization : Long Island Laser Center for Vein Treatment

Category : Physician

Issue Areas/Comments

Background

Background

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:

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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.

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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,

Hormoz Mansouri, M.D., F.A.C.S.
Syosset. New York.

Submitter : Dr. frank ferrier

Date: 10/06/2006

Organization : Vein Clinics of America

Category : Physician

Issue Areas/Comments

Background

Background

Reduction of payment to physicians for EVLS is absolutely untenable considering the amount of time involved in the procedures, cost of equipment, and ideal results to date. Medicine will not survive if reimbursement continues to evaporate. No physicians some day; Is that what we want in this country?

GENERAL

GENERAL

Please refer to the above comments; In U.S.A, like no where else in the civilized and un civilized worlds, our brand of medicine and patient care is second to none. It will be lost like so many mistakes the Feds continue to impose on us. Plese stop this before you have no quality physicians. Thank you.

Impact

Impact

Reimbursement should be fair; Medicare reimbursement is not.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I have been in medicine for 34 years and have watched reimbursement reduced year after year. When will the feds realize that we cannot work for charity?

Submitter : Dr. Bradley R Prestidge

Organization : Texas Cancer Clinic

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-491-Attach-1.TXT

CMS-1321-P-491-Attach-2.DOC

Attachment 491

October 4, 2006

Reference file code: CMS-1321-P

Submitted electronically via Word document attachment
http://www.cms.hhs.gov./eRulemaking

We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

Image-guided robotic stereotactic radiosurgery (r-SRS) is both an alternative to surgery and an adjunct to radiotherapy involving a defined set of clinical resources to deliver effective treatment. Image-guided robotic stereotactic radiosurgery is not radiotherapy, as it is intended to ablate identifiable lesions, while preserving normal tissue adjacent to the target volume, rather than treat microscopic disease. The CyberKnife® is a complex image-guided robotic stereotactic radiosurgery system (r-SRS), delivering radiosurgical precision throughout the body, for as many treatments (fractions) as the clinician deems necessary for a given situation. CMS currently allows for up to five fractionated image-guided robotic stereotactic radiosurgery treatments and our data indicate that treatments average 3 fractions per course of treatment. Clinicians and patients have recognized the benefits of radiosurgery, which include no incisions, no anesthesia, lower risk of complications, and, therefore, improved patient quality of life.

Image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of linac-based systems. It was for this reason that CMS created separate HCPCS codes to distinguish these technologies. Further, it is clear that the resources required for image-guided robotic stereotactic radiosurgery treatment are the same regardless of whether the treatment is performed in the first or a subsequent session.

Image-guided robotic stereotactic radiosurgery is a capital intensive technology, and, due to the relatively small number of patients for whom it is clinically appropriate (as compared with, for example, conventional external beam technology), it is not necessarily cost-efficient for a single hospital to provide these services by itself. Robotic stereotactic radiosurgery facilities that are associated with a particular hospital are typically available for use only by physicians on staff at that hospital, thus restricting their ability to serve the larger community and limiting access. Allowing carriers to pay for the technology when provided in freestanding centers would facilitate cost sharing among a number of hospitals (and others) to provide these services, improving device access to a more diverse population of patients in a given geographic region.

Comment:

A number of temporary codes have been established to enable hospitals to report the technical component c osts o f i mage-guided r obotic s tereotactic r adiosurgery (r-SRS) t reatment (HCPCS

Codes G0339 and G0340). The proposed Rule regarding the Physician Fee Schedule for 2007 designates codes G0339 and G0340 as "C – Carriers price the code."

This is consistent with the technical component radiation oncology services of all kinds that are reimbursed under the Physician Fee Schedule, and have been since the inception of the Physician Fee Schedule methodology.

Recommendation:

The CyberKnife Coalition respectfully recommends and encourages CMS to:

- *Adopt the proposed change to include HCPCS Level II codes G0339 and G0340 on the CY 2007 PFS, classifying the codes with the modifier "C" to indicate that they may be carrier priced.*

We support this modification that would clearly establish carrier authority to cover image-guided robotic stereotactic radiosurgery in freestanding settings, subject to their establishment of appropriate quality assurance measures to ensure patient safety and regulatory compliance, to the satisfaction of the carrier.

We appreciate your consideration of our comment.

Sincerely,

Bradley R. Prestidge, MD
Medical Director
Texas Cancer Clinic

Submitter : Dr. Charles Mok

Organization : Dr. Charles Mok

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

GENERAL

GENERAL

There is a significant practice expense to offer endovenous laser ablation for the treatment of superficial venous disease. The individual practice cost of staffing, equipment, supplies, and professional training are quite high. The current reimbursement rate offsets those costs adequately. A reduction in reimbursement would lead to contraction of practice expenditures that are required to offer high quality care.

Attachment 493

SOUTH CAROLINA HEART CENTER

M. Todd Alderson, M.D.
John T. Beard, M.D.
Myron Bell, M.D.
Lee O. Butterfield, M.D.
Himadri Dasgupta, M.D.
Robert E. Delphia, Jr., M.D.
Charlie W. Devlin, M.D.
Richard A. Edelson, M.D., PhD.
William B. Epps, Jr., M.D.
Michael C. Foster, M.D.
Venk K. Gottipaty, M.D., PhD.
Terry A. Grainger, M.D.
Patrick A. X. Hall, M.D.
Rodney V. Harrison, M.D.
Christie B. Hopkins, M.D.
Leon J. Khoury, Jr., M.D.
Norma M. Khoury, M.D.
Robert G. Kiger, M.D.
Lanneau D. Lide, M.D.
Bashir A. Lone, M.D.
Himaxi M. Maysuria, M.D.
Mark L. Orlandini, M.D.
Vaibhav V. Patel, M.D.
Ram G. Penmetsa, M.D.
J. Huger Richardson, M.D.
W. Lawrence Schoolmeester, M.D.
Paul A. Zimmermann, M.D.

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803 749-1360
Fax 803-749-5428

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

On behalf of the South Carolina Heart Center, 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 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,

Richard W. Davenport MS, CMPE
Chief Executive Officer

Submitter : Eric Chappell

Organization : Urology Associates, PC

Category : Physician

Date: 10/06/2006

Issue Areas/Comments

Background

Background

Another concern that CMS has raised is the locations of the labs in reference to the group practice. Our protocols are the same for our lab as they were with Dianon (lab Corp.). We would package up the biopsy and ship it out of state to the reference lab on the east coast. Dianon sets up their lab back east where the Medicare reimbursement was significantly higher than in Colorado. Many labs use Connecticut or Michigan where the reimbursement is almost 20% higher than our lab in Florida. So our lab is actually saving the Medicare system anywhere from $10 to $20 per specimen.

The large reference labs such as Quest and Lab Corp have lobbied CMS and congress to stop group practices from opening and operating their own pathology lab. They obviously are only concerned that group practices will cut into their profit margins. The Federal Reserve Chairman this week made comments that the aging population in the United States was going to be a major concern to the government s budgets for decades to come. With Medicare reimbursements set to decline as much as five to six percent per year over the next four to five years, if these cuts do take place, many if not most of the physicians in private practice will not be able to maintain a practice and accept Medicare patients. Malpractice insurance will be increasing at a minimum of seven percent a year, salaries for employee s are climbing at two to three percent a year. Our overhead is not decreasing by four to five percent a year. So why shouldn t CMS embrace ideas and allow new concepts such as the Uropath pod model that allows for physician groups to provide the best care at a least amount of overhead to the groups and ultimately to medicare. If CMS does not allow business to think of new ways to provide good care at a reasonable cost, no physician, group, or business will participate with Medicare in the very near future. If you doubt that doctors will not participate in a bad paying Medicare system, look at the Medicaid system today and look at how few physicians are now accepting new patients or any patients at all. Most Medicaid patients are unable to get good care in a timely manner, so they use the emergency rooms as primary care givers which in turn costs the Medicaid system more, and more. The same will be true with the Medicare population, but the cost to the government will be significant more than the cost involved with the Medicaid system.

This country and economy is based on business ingenuity and product improvement. That is what separates the United States far apart from the rest of the world. Why shouldn t CMS follow the lead of the business community and look for new and better ways to provide great care that is cost efficient to the groups as well as the government

GENERAL

GENERAL

Now that we have established a basis for our practice and our experience over the past 20 years, its time to discuss the proposed changes to diagnostic pathology testing. Urology Associates opened our pathology lab in August 2005 after about 8 months of planning, searching for the best pathologists, and building of our suite.

Our physician s and administrator spent a significant amount of time looking into and talking with many different pathology models. After looking into the legal and business models for each of these labs, our office choose to go with a model that was developed with Uropath, LLC. Our lab is located in Sarasota, Florida along with 15 our urology groups that all have formed completely separate labs in a single building. Our lab consists of our own purchased equipment, medical and office supplies, microscope, and computer equipment. We also rent a specific suite within the building that is only used for our patients and no one is allowed to process any other offices specimen s in our lab.
This is what separates the Uropath model from the rest of the pod concepts. We in no way share any equipment or information with the other pathology labs within the building. We doe share the staff of the lab which consist of a histology technician, lab manager, and some administrative staff.

The process to recruit a pathologist was very extensive and very specific. Our group recruited, interviewed, and offered an employment contract to provide the necessary director duties for our lab. We required the pathologist to obtain a medical license in both the State of Florida where our lab is located, and also holds a medical license in the State of Colorado to ensure he is providing the best care required by both states. He specifically is trained and has experience in uropathology. So we are providing the best care available to ensure that the pathology reads are correct. Also with the ability to utilize one pathologist, there is consistency with the reads. An example of this is a pathologist s opinion of high grade pin of the prostate can vary from another pathologist s opinion. Our group in the past has had difficult times with consistency and accuracy of the prostate reads from large labs such as Dianon. The other advantage we have is we can talk with our pathologist at any point, if they need to discuss the results of a patient. Prior to our own lab, it was impossible to get the pathologist on the phone to discuss what the results were.

CMS s has expressed concern that the potential for fraud and abuse will result if more group practices own ancillary services like radiology and pathology. While the potential exists for fraud and abuse with any care that is provided, including radiological or pathology services; our group follows the established American Urological Association guidelines for clinical indications on when and where to provide a prostate biopsy. While the number of prostate biopsies is expected to increase over the coming years, the reason is not from fraud, bur rather improved PSA indications and follow up care for men, and an aging population of baby boomers. The risk for fraud and abuse within a urology practice is very minimal compared with the risk of a CT machine or x-ray being performed in a group setting where a CT machine costs a half million dollars. CMS over the years has chosen to stay out of turf war battles between groups and/ or specialties. This includes the explosion of radiology centers by physician groups located through out the country. So why has a CMS accepted comment from large reference labs to change policies against smaller group practices?

Our group has performed almost the same amount of prostate biopsies this year as compared to previous years. On average, our physicians perform 8 to 12 core biopsies per patient that are sent to the lab. This number of biopsies has remained constant depending on the indicati

Impact

Impact

Reassignment and Physician Self Referral Rule

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I would like to start out by giving you a little history about Urology Associates and our practice as it stands today. Dr. Stanley Galansky started Urology Associates in 1987 after being in private practice for 4 years prior with another small group. Over the years, Dr. Galansky and his partners have continued to grow to where our office stands today. Currently, Urology Associates consists of six urology physicians, 1 pathologist, 3 physician assistants, and 3 locations through out the Denver Metro area. Our office employs 40 men and woman. We also take pride in our employees by providing excellent benefits and very good salaries.

Submitter : Mr. Christian Downs

Date: 10/06/2006

Organization : Association of Community Cancer Centers

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-495-Attach-1.PDF

Attachment 44

The premier education and advocacy organization for the oncology team

ACCC

Association of Community Cancer Centers

October 10, 2006

BY ELECTRONIC FILING

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:

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

published in the Federal Register on August 22, 2006 (the "Proposed Rule").[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

Medicare beneficiaries depend upon advanced drugs[2] to fight cancer, but their physicians only can provide these drugs if Medicare's payment rates adequately cover physicians' expenses for providing them. Since CMS began implementing the payment reforms required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), ACCC has been deeply concerned that reimbursement for cancer therapies, drug administration, and other necessary support services, might not be sufficient to cover physicians' costs. We have been pleased with the steps CMS has taken so far to protect access to care, including introducing new codes for drug administration services, implementing the supplying fees for oral anticancer and anti-emetic drugs, and creating the demonstration projects in 2005 and 2006 to improve the quality of care provided patients undergoing chemotherapy, but we remain concerned.

In 2007, we anticipate that physician offices will be under greater pressure than ever to provide care to a growing number of beneficiaries, yet also face greater uncertainty about Medicare reimbursement for these services. CMS predicts that changes in the fee schedule, including the predicted 5.1 percent reduction in payments for all physician fee schedule services, implementation of certain provisions of the Deficit Reduction Act of 2005 (DRA), and other changes will reduce Medicare payments for hematology and oncology services by 5.6 percent.[3] Physicians cannot sustain their current levels of services under these payment cuts. We urge CMS to take whatever steps are necessary to ensure that physicians are adequately reimbursed for providing advanced cancer care and to protect Medicare beneficiaries' access to life-saving and life-extending treatments.

With these general concerns in mind, we recommend that CMS make the following specific revisions under the physician fee schedule for 2007:

- Work with Congress and all interested parties to make changes to the Sustainable Growth Rate (SGR) or take other action to permanently stabilize

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1 71 Fed. Reg. 48982 (Aug. 22, 2006).
2 Throughout our comments, we use "drugs" to refer to both drugs and biologicals.
3 71 Fed. Reg. at 49070.

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

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

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

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

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

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

We discuss these recommendations below.

I. Background

A. Sustainable Growth Rate

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

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

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

B. Practice Expense Issues and Drug Administration

As set forth in more detail in ACCC's comments on CMS' proposed changes regarding the work relative value units ("RVUs") under the physician fee schedule and proposed changes to the practice expense ("PE") methodology, published in the Federal Register on June 29th, 2006, we have serious concerns about these proposed changes and their effect on beneficiary access to cancer care, particularly when they are considered in conjunction with other payment reductions set forth in this Proposed Rule.[1] As proposed, these PE RVU changes would result in 0.5 to 8.4 percent cuts in many drug administration codes in the first year, and once fully phased in, the payments for these codes would be reduced by 0.5 to 25 percent, before any changes in the conversion factor are applied.

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

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

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

C. Preadministration-Related Services for Standard and Specialty IVIG

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

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

D. Radiation Oncology

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

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

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

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

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

III. DRA Proposals – Payment for Imaging Services

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

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

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

IV. ASP Issues

A. Substitution of WAMP or AMP for ASP

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

B. Payment for Compounding of Drugs

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

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

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

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

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

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

V. Conclusion

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

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

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

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

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

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

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

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

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

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

* * *

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

Respectfully submitted,

Christian G. Downs

Christian G. Downs
Executive Director