CMS-1321-P
534

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09/26/2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8017

Re: CMS 1321-P

Dear Dr. McClellan:

As an interventional pain physician (CMS designation -09), I am writing to urge you to alleviate the impact of the proposed reduction of 12% to 38% in reimbursement for interventional pain services, as proposed in the Proposed Rule on the Medicare Physician Fee Schedule for Calendar Year 2007.

I am deeply concerned that the combined effect of all the proposed changes in reimbursement, along with an anticipated negative conversion factor of 5.1%, will make it economically impossible for me and my colleagues to continue to provide interventional pain procedures to our Medicare patients. At these reduced reimbursement rates, we will not be adequately reimbursed for the interventional pain services that we provide to our Medicare patients. Not only will the reduced reimbursement rates affect my and my colleague's interventional pain practices today, we are facing drastic reductions in Medicare reimbursement over the next four years.

Given the impact on interventional pain physician practices and our ability to continue to provide services to Medicare patients, we ask that CMS impose a moratorium for at least one year so that the impact of the various changes in the physician fee schedule can be assessed. Unless a moratorium is imposed, interventional pain physicians will be in a financial situation that makes it impossible for them to continue to offer Medicare patients interventional pain services. Like CMS has done in the past to moderate the effect of payment changes for certain services that would have a negative impact on beneficiary access, we urge CMS to impose a moratorium to ensure that Medicare patients will have continued access to interventional pain services.

Thank you for your consideration.

Sincerely,

Nicholas DeAngelo, D.O.

11921 Rockville Pike, Ste. 505
Rockville, MD 20852
301-881-PAIN (7246) • Fax 301-881-2449

3901 Greenspring Ave., Ste. 304
Baltimore, MD 21211
410-383-7443 • Fax 410-383-8397

305 Hospital Drive, Ste. 304
Glen Burnie, MD 21061
410-553-8255 • Fax 410-553-8264

1150 Professional Court, Ste. P
Hagerstown, MD 21740
301-665-9696 • Fax 240-420-5715

75 Thomas Johnson Drive, Ste. C
Frederick, MD 21702
301-620-0012 • Fax 301-620-9687

92-1

September 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8010
Baltimore, MD 21244-8010

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 – **"DRA Proposals."**

Dear Dr. McClellan:

As a vascular surgeon who practices in Ohio and as a member of the Society for Vascular Surgery (SVS), I am writing in response to the publication of 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, specifically the section regarding implementation of Section 5102 (b) (1) of the Deficit Reduction Act (DRA) and the list of imaging services that the Centers for Medicare and Medicaid Services (CMS) has included within the scope of "imaging services" defined by the DRA provision.

I am concerned that CMS has proposed to include non-invasive vascular diagnostic studies, CPT codes 93875 – 93990 and G-code 0365, in the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies contain no imaging or are predominately non-imaging in nature. Given the inclusion criteria that CMS has proposed, there are numerous reasons that these studies should not be listed in Addendum F.

The CPT manual is very clear that non-invasive physiologic studies are performed using equipment that is separate and distinct from the duplex scanner. In a vascular surgeon's practice, we perform physiologic studies on Medicare patients where there are signs and symptoms of peripheral arterial disease and we use physiologic vascular studies, CPT codes 93922, 93923 and 93924 to confirm presence of disease, assess the severity, allow accurate delineation of prognosis and provide a measure of effectiveness of treatments including exercise programs, percutaneous intervention and bypass surgery. Because these codes **do not contain imaging**, CMS should remove them from the list of services included under the imaging provisions of the DRA in the Final Rule, just as it has done in the proposed rule for nuclear medicine services that are "non-imaging diagnostic services" and radiation oncology services that are "not imaging services".

CMS should also exclude duplex scans of arteries (CPT codes 93880, 93883, 93925, 93926, 93930, 93931 and 93990) from DRA because the most important component of these procedures is collection of Doppler velocity data, **a non-imaging ultrasound modality**. For example, CPT 93880 is a non-invasive duplex scan of extracranial arteries; a complete bilateral study. B-mode imaging ultrasound is used to find the arteries in the neck, but non-imaging Doppler-based blood flow velocities are the most important data collected during the exam. Non-imaging Doppler-based blood flow velocities are the most important elements on which arterial stenosis measurements are based, and the stenosis determination is the criterion on which clinical treatment decisions are made. In summary, the single main reason for "imaging" in the carotid duplex scan is to find the correct location to obtain Doppler velocity measurements.

In addition, I believe there is confusion regarding the term "Doppler" and the information that this modality provides to a vascular surgeon for use in diagnosing vascular disease. There are several forms of Doppler ultrasound used in non-invasive vascular diagnosis (continuous-wave Doppler, pulsed-wave Doppler, color-flow Doppler velocity mapping), but all Doppler modalities have one thing in common – they measure blood flow. In the absence of blood flow, the Doppler measures nothing: there is no audible sound, velocity determination or flow mapping. The Doppler does not provide images of body parts. Thus, **Doppler techniques do not meet CMS's definition for inclusion, as these services do not provide "visual" information.** Duplex scans should be excluded from the DRA provisions in the Final Rule because the most important information provided by these tests is based on Doppler.

I recently participated in a survey conducted by the SVS of its members with office-based vascular labs regarding the impact of cuts on non-invasive vascular diagnostic studies, if they are erroneously included under DRA. The dramatic results demonstrate that Medicare beneficiaries' access to these services would be severely affected: 54 percent of vascular surgeons with office-based vascular labs would no longer provide or would reduce vascular laboratory services to Medicare beneficiaries and 24 percent would close the lab entirely or reduce services; 35 percent estimate that Medicare beneficiaries would wait three to four weeks to receive services if they had to go elsewhere and 22 percent estimate that patients would have to travel more than 20 miles to receive suitably high-quality vascular lab studies.

Given this level of impact and the fact that non-invasive vascular diagnostic studies do not meet CMS's proposed criteria for inclusion under DRA and instead meet the criteria CMS is proposing to exclude certain diagnostic services, I respectfully request that CMS remove these codes from Addendum F – Proposed CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA.

I greatly appreciate this opportunity to provide CMS with information and I would be happy to answer any questions. Please do not hesitate to contact me at 440-243-0100.

Sincerely,

Vincent J. Bertin, M.D., F.A.C.S.

FYI - Rag Staff

DHHPC (recon) #: 93

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August 9, 2006

AUG 29 2006
11:30 A.M.

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Room 314-G
Washington, D.C. 20201

Re: CMS-1512-PN, RIN 0938-A012, Medicare Program; Five-Year Review of Work Relative Value Unites Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

Dear Dr. McClellan:

It has come to our attention that CMS recently issued a proposed rule to make substantial reductions in Medicare reimbursements for technologies used in screening for osteoporosis and breast cancer. If left undetected, osteoporosis and breast cancer can have devastating consequences, particularly for older women. As the nation's leading non-profit organization for the support of medical discoveries to improve the experience of aging, we urge you to reconsider the proposed cuts to these vital services.

As you know, more than 10 million Americans have been diagnosed with osteoporosis and another 45 million are at risk. Expenditures related to hip fractures exceed $18 billion each year, however the human cost is much greater. Fractures suffered by elderly Americans often result in severe disability, loss of independence, and death. Over the past decade, tremendous strides have been made in the development of technologies and treatments to decrease the effects of bone loss. Foremost among them is dual-energy x-ray absorptiometry (DXA).

DXA is a non-invasive test that is proven to be the most accurate method for measuring bone density. DXA is the only osteoporosis screening method recognized by experts in the field of bone densitometry and currently 75% of all screening exams are preformed using this method. Further proliferation of this method would serve to benefit the thousands of Medicare beneficiaries who do not receive proper screening each year, yet CMS is looking to decrease reimbursement rates by 75%.

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T 202.293.2856 | F 202.785.8574

CMS is also proposing cuts to similarly sophisticated and minimally invasive methods for breast cancer screening. Although we are often struck by the tragedy of young women developing breast cancer, this disease is actually more common in older women. In fact, 22% of women diagnosed with breast cancer in the U.S. are over age 75. Breast cancer is a leading cause of death among women, second only to lung cancer. The proposed rule would significantly reduce reimbursement for services utilizing Computer Aided Detection (CAD) and stereotactic breast biopsy. These services are key to detecting the early presence of breast cancer.

We commend CMS for the steps it has taken to increase access to preventative care services but feel strongly that this current proposal will undermine the progress that has been made. We hope that instead of limiting access to these critical services, CMS will withdraw its proposal and continue to focus on ways to ensure the health and well-being of all Medicare beneficiaries.

Thank you for your consideration.

Sincerely,

Deborah H. Zeldow
Senior Director, Strategies & Programs

Alliance
FOR AGING RESEARCH

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Room 314-G
Washington, D.C. 20201

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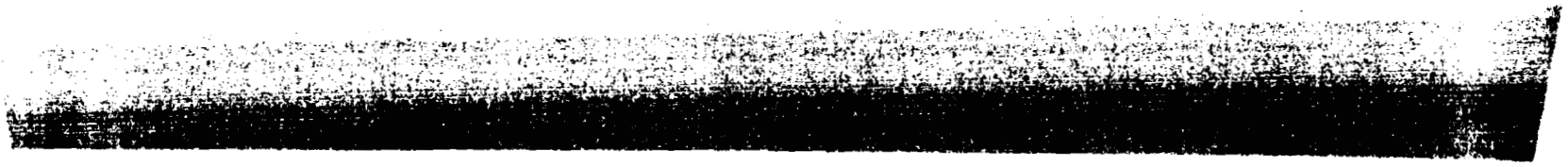

Department of Health and Human Services
Attention: CMS- 1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore. MD 21244-1850

To Whom It May Concern:

I am responding to your proposed changes in the reimbursement schedule regarding BMD-DEXA testing. To open, I strongly object to the changes that have been outlined.

Osteoporosis is a disease which is reaching epidemic proportions and carries with it tremendous physical, mental, and emotional burdens for the individual as well as financial burdens for our society. In my practice as a gynecologist I deal with a large percentage of patients who suffer from this malady or are at a high risk of developing this disease in the imminent future. The old adage that an ounce of prevention is worth many pounds of cure certainly aptly applies to this disease process.

Providing this service to my patient population certainly enables us to hopefully prevent the vast sequelae of this disease process and, in the long run, save money for our society. To cut reimbursements based upon faulty assumptions is severely problematic.

Firstly, the new methodology should not be based on a trial and error policy or philosophy. Secondly, there is a significant difference between pencil beam and fan beam technology and this data needs to be applied appropriately in order to obtain meaningful information. Your use of incorrect data invalidates your results simply based on logic. What you have done is analogous to comparing apples and oranges! Incidentally, for your information, the majority of the systems sold today are fan beam, not pencil beam. Thirdly, my equipment is not used 50 per cent of the time. Rather, it is used only 10 per cent of the time for testing, but it still is in my office incurring expenses due to space occupancy and rent, electricity, labor and salaries related to its proper daily care and evaluation, licenses, registrations, monthly lease payments and maintenance costs, paper and other supplies, as well as my time in the oversight of the machine and its functionality.

The actual report that is produced by my GE Lunar BMD-DEXA is an elaborate one consisting of several pages of vital information that enables the practitioner to confront the burdensome disease of osteoporosis with proper armamentarium so as to properly treat the patient in order to prevent the sequelae from occurring and , in the long run, save money for all involved parties, since this is what appears to be your main focus.

As time evolves, the CPI and inflation continue to rise and the cost of doing business becomes more and more burdensome. It has reached the point where it simply will not be cost effective to offer the service and it will not be offered by most providers. The outcome will be egregious and you will forever regret your rather myopic, flawed decision. The long-range expenses regarding treating the disease will far outweigh the current costs of diagnosis and disease management. This will be a decision that you will long regret and for which you will be held responsible.

Kindly indulge me and other members of the healthcare profession by informing me about which other industries are there in society that are not raising their charges due

to the increasing costs of operating expenses and inflation and, of course, the ever-increasing CPI. On an almost daily basis, or so it seems, we receive correspondence from contractors, etc, that state that they are forced to increase their charges due to increasing expenses which they have no control over. Yet, here we stand in the medical community attempting to provide a bonafide service to patients in our communities, which will benefit their quality of life and help save society money in the long-run, and we are being forced to accept cuts that make operating this service unfathomable and utterly impossible.

We are not even requesting a cost of living remuneration raise. Simply, leave the reimbursement rate where it is and we will absorb the losses due to inflation. This, we will find palatable and be able to continue to provide this much needed service to our patient populations.

Incidentally, DEXA was recently added as a preventive service and these cuts will serve to undermine your own initiative by decreasing utilization and it will disengage your "Healthy People 2010" initiative, for which I felt you were to be commended.

If you have any questions, please feel free to contact me. Closing, I remain,

Sincerely,

Alan Wayne Black M.D., FACOG

Alan Wayne Black, M.D., FACOG
5800 Colonial Drive
Suite 308
Margate, FL 33063
954-968-5000(Phone)
954-968-8335(Fax)

Note : This is regarding CMS-1321-P Proposed 2007 Physician Fee Schedule

DHPPC

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F4I - Ress 95

#598856

RICHARD J. GIMPELSON, M.D., P.C.

F.A.C.O.G.

222 S. WOODS MILL ROAD, SUITE 400

CHESTERFIELD, MISSOURI 63017

OFFICE: (314) 878-1866

FAX: (314) 878-7661

EXCHANGE: (314) 869-7900

August 22, 2006

AUG 28 2006

1:30 P.M.

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Comments to the HOPPS Proposed Rule – Payment Increase Needed for Magnetic Resonance Guided Focused Ultrasound Technology

Dear Dr. McClellan:

I am writing to call your attention to the need for increased payment under the Medicare hospital outpatient prospective payment system ("HOPPS") for an exciting technology that is available at Exablate of St. Louis and other facilities that could benefit hundreds of thousands of American women that require treatment for uterine fibroids.

The technology, Magnetic Resonance Guided Focused Ultrasound (MRgFUS) integrates magnetic resonance imaging with focused ultrasound energy to create a non-invasive technology that destroys tumors and fibroids without invasive surgery. Using the precise visualization provided by the MRgFUS images, an ultrasound beam can be aimed at tumors and non-cancerous tissue growths such as fibroids, without burning or harming healthy tissue. MRgFUS offers a significant clinical improvement to women suffering from uterine fibroids and it is an important treatment option alternative for many women facing possible hysterectomies of other invasive procedures. Unfortunately, however, patient access for MRgFUS is currently threatened due to inadequate payment for the procedure. While most women who need treatment for fibroids are not Medicare beneficiaries, Medicare payment is the benchmark that private insurers use in settling payment rates. Therefore, we need CMS to assign MRgFUS procedures appropriate payment to preserve access to this technology.

In the most recent proposed rule updating HOPPS payment rates for 2007, CMS is silent on this payment issue although I understand some of my colleagues met with CMS staff earlier this spring and submitted hospital cost data demonstrating that the average costs for MRgFUS ranges from over $7,000 to about $9,500. As proposed, the CPT codes related to MRgFUS (0071T and 0072T) will remain in Ambulatory Payment Classifications (APCs) 195 and 202 Female Reproductive Procedures where they will be significantly under paid at $1,770 and $2,640, respectively. APCs 195 and 202 are comprised of far simpler procedures when compared to MRgFUS ablation.

MRgFUS is much more complex and is furnished in a very sophisticated, MR suite similar to other stereotactic radiosurgery procedures, which precisely target a narrow therapeutic beam of energy to treat tumors and lesions. For this reason, I urge CMS to assign MFgFUS to APC 127 Stereotactic Radiosurgery at least on an interim basis.

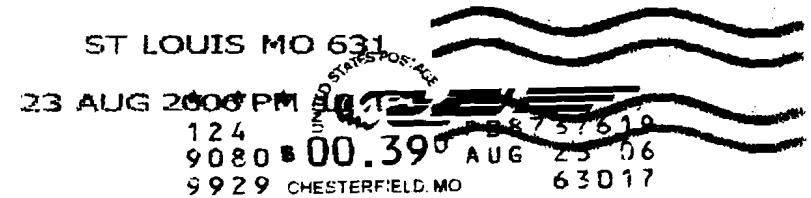
When, as with MRgFUS, facilities are under-reimbursed because a CPT code has been incorrectly assigned, there is financial pressure not to perform the procedure. Payment for APC 127, in the range of $7,800, more closely matches the reasonable costs a facility incurs when performing MRgFUS. I encourage CMS to reassign the MRgFUS procedure to APC 127 on an interim basis (or to a new APC providing reimbursement that more closely reflects the true costs of the procedures) in order to make this treatment more widely available to the any women in my area who could benefit from this exciting alternative treatment.

Thank you for your consideration of this important matter.

Sincerely,

Richard J. Gimpelson, M.D.

Richard J. Gimpelson, M.D., P.C.
222 S. Woods Mill Rd. Ste. 400
Chesterfield, MO 63017-3425



Mark B. McClellan, M.D., Ph.D.
Adm., Ctrs for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

21244+1843

96-1

Seven Hills Women's Health Centers

5049 Crookshank Road
Suite 102
Cincinnati, OH 45238

10506 Montgomery Road
Suite 201
Cincinnati, OH 45242

Michael Karram, M.D. • Gerard P. Reilly, M.D. • M. Kathryn Jabin, M.D. • John M. Samol, M.D.

(513) 922-0009 • FAX (513) 922-2931

(513) 791-6268 • FAX (513) 791-2138

October 4, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8010

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, Specifically **"Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007."**

Dear Dr. McClellan:

As a obstetrician/gynecologist practicing in Cincinnati, OH, I am writing in response to the publication of CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, specifically "Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007." I am particularly concerned with the negative effect of these changes on the practice expense RVUs for CPT code 58565 – Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants, by CY 2010.

I understand that major changes to the PE methodology for CY 2007 were discussed in the June 29, 2006 proposed notice. However, I am concerned that the specific, proposed practice expense RVUs published in this regulation for CPT codes 58565 by the end of the transition period in CY 2010 will negatively impact access to this procedure when performed in a physician's office.

I am concerned that CMS' proposed method uses budget neutrality adjustors in three separate steps. I cannot continue to absorb these under-valuations, especially as my practice faces 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. For example, the impact of the budget neutrality adjuster on the direct expenses means over $350 of the direct costs for CPT code 58565 are not included as part of the practice expense valuations for this code under the new methodology. Given that many private insurance companies and Medicaid programs use the Medicare physician fee schedule to set their payment rates, the impact of CMS not accounting for all the costs of the procedure are magnified with each additional payer.

Seven Hills Women's Health Centers

5049 Crookshank Road
Suite 102
Cincinnati, OH 45238

10506 Montgomery Road
Suite 201
Cincinnati, OH 45242

Michael Karram, M.D. • Gerard P. Reilly, M.D. • M. Kathryn Jabin, M.D. • John M. Samol, M.D.

(513) 922-0009 • FAX (513) 922-2931

(513) 791-6268 • FAX (513) 791-2138

Also, I understand that as CMS calculates the service level allocators for the indirect PEs, which happen to be the direct PE RVUs and the work RVUs, they are using direct PE RVUs or work RVUs that have been adjusted for budget neutrality. Indirect costs for a service need to allocate using all of the costs associated with the inputs for a service.

It is important that Medicare payment levels are appropriate such that access to permanent birth control that is non-incisional does not become constrained for women of child-bearing age. In my practice, I have treated over 75 women with the Essure® micro-insert system and their outcomes have been excellent, with less risk and complications versus an open, surgical tubal ligation procedure. Therefore, CMS needs to be sure that the direct costs for this procedure used in its calculations are accurate and totally accounted for in the PE RVUs. It would be unfortunate if access to this non-incisional, permanent birth control for women with Medicaid or commercial insurance was no longer a viable option for me to offer my patients because of the practice expense formula used to calculate Medicare payments starting in 2007 and beyond.

Please do not hesitate to contact me at 513-922-0009 if I may be of help with regard to providing additional information or answering any questions you or your staff may have.

Sincerely,

MD MKarram MD

97-0
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P. V. Ross, M.D., F.A.C.C.
G. E. De Gent, M.D., F.A.C.C.
M. W. Pulsipher, M.D., F.A.C.C.
S. G. McDowell, M.D.
W. E. Downey, M.D.
J. M. Hardin, M.D.

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D. R. Patterson, M.D., F.A.C.G.
D. M. Brodie, M.D.
M. T. Stark, Jr., M.D., F.A.C.G.
J. N. Perry, Jr., M.D.
R. D. Kaplan, M.D., F.A.C.G.
C. E. Gessner, M.D., F.A.C.G.

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M. B. Wert, M.D., F.C.C.P.
P. E. Wright, M.D., F.C.C.P.
K. M. Clance, M.D., F.C.C.P.
D. B. Simonds, M.D.
C. L. González, M.D.

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S. F. LeBauer, M.D. (1905-1989)
W. F. Hopper, M.D., F.C.C.P.
M. E. Norins, M.P.H., M.D.
J. E. Jenkins, M.D.
S. A. Ellison, M.D.
A. V. Plotnikov, M.D.
J. W. John, M.D.
B. H. Swords, M.D.
P. F. Kwiatkowski, M.D.
V. A. Leschber, M.D.
J. E. Paz, M.D.

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R. N. Schaller, M.D.
P. A. Shevlin, M.D.
R. L. Dough, Jr., M.D.
M. D. P. Irwin, M.D.
A. M. Kulik, M.D.
M. A. Tower, M.D.
S. A. Fry, M.D.
Y. R. Lowne, D.O.

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W. K. Panosh, M.D.

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D. L. Gutterman, Ph.D.

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A. S. Esterwood, P.A.C.
M. M. Lenze, P.A.C.
W. S. Minor, Jr., A.C.N.P.

Vice President/Executive Director
R. L. Goldstein, FACMPE

September 28, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Dr. McClellan:

I am a practicing gastroenterologist in Greensboro, NC with LeBauer HealthCare. I am writing to express my deep concern over Medicare's proposed rule to change the payment system for ambulatory surgery centers.

I use an ASC and perform about 1,000 endoscopic procedures every year, including many to screen for colorectal cancer. About 30 percent of my patients are Medicare beneficiaries. My practice, LeBauer HealthCare, has 55 physicians and 8 of them are Gastoenterologists who actively use our ASC called LeBauer Endoscopy Center. We serve patients primarily in Guilford County but we see many patients from Rockingham County, Randolph County, Forsyth County and Alamance County.

Medicare is proposing to reduce its ASC payment for endoscopy more than 25% by 2008. The rates Medicare is suggesting are below the costs of performing these endoscopic procedures, including screening for cancer. Our practice will lose money on every Medicare patient that comes to our ASC. Our only choice will be to treat Medicare beneficiaries at the hospital, which is considerably more expensive. It will also cost our patients more in out of pocket expenses and will probably delay their care because our hospital does not have the capacity to handle this additional caseload on a timely basis.

This is unfair to our patients and a needless expense for Medicare. Medicare says that it has to set rates this low because Congress requires that the new payment system be budget neutral and many new procedures are going to be added to the ASC list of covered services in 2008. In order to pay for these new services, reimbursement for endoscopy and many other surgical procedures will have to be cut.

The ASC is a safe, economic site for these services and is very popular with our elderly patients because of its convenience. It would be a disservice to these beneficiaries to adopt Medicare's proposal.

Congress needs to change its instructions on budget neutrality to avoid this result. I know we can continue to provide services to Medicare patients in the ASC and save Medicare money if the reimbursement rules make sense. This proposal, however, does not pass that test.

Thank you for your careful consideration of this request. I urge you to convey these concerns to the leadership of the Committees that handle Medicare and to encourage action this year to correct this problem.

Sincerely,

Dora M. Brodie, MD
LeBauer HealthCare

FYI Reg Staff

✓ OSORA reg comment 98

2006 AUG 28 AM 8:52

August 18, 2006

The Honorable Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd., CA-26-05
Baltimore, MD 21244

Dear Sir,

I am writing to express my concern regarding the CMS proposal to apply a 10% negative physician work RVU adjuster to all codes with physician work. As a Neonatologist in a group that provides intensive care to our sickest newborns (more than 40,000 annual patient days), the majority of my patients are underprivileged and do not have private health insurance. Our 14 member physician group experiences > 60% Medicaid payer mix. The proposed RVU adjuster will disproportionately hurt hospital-based physicians who serve all patients regardless of their ability to pay.

The current work E&M changes have been well thought out and should be implemented without destroying the relative weight of the physician work amounts against the malpractice values and practice expense components of the physician total relative value.

As you know, states periodically update their rates using Medicare RVUs. Physician practices that serve our neediest patients will be further underpaid by lowering Medicaid payments. I fear that states with even lower Medicaid rates from the 2007 Medicare changes will put physician access for our most underprivileged at even greater risk - recall the Oklahoma example where federal courts ruled that that states with low Medicaid reimbursement create a sham program with functionally insufficient Medicaid access to provider physicians. Even the lay press has recently noted the effect of lower Medicare payments limiting access for patients utilizing our government payer system. In an August 2006 article, the *Wall Street Journal* states: "Some doctors are leaving towns like Santa Cruz because of the relatively low payments they get from Medicare...where government payments to physicians haven't necessary kept up with rising, living costs."

Furthermore, the proposed arbitrary, artificial reduction in the physician work RVUs would create inaccurate physician work and total RVUs that would be expected to subsequently lower private sector reimbursements that use a factor of "current Medicare" as a payment methodology. Financially this would be a double whammy to my practice and many physician groups such as ours.

I request that CMS understand the harm of the proposed reduction in the physician work as a RVU component and not require budget neutrality in this way. Congress should understand the anticipated impact on its providers for America's underserved and the danger of even further reduction in provider access. I ask that Congress grant a 2007 increase to fund the physician work E&M changes without budget neutrality.

Respectfully yours,

Michael J Stevener, MD
Medical Director, Neonatology Group Fort Worth/Arlington/ Mid-Cities
1301 Pennsylvania Ave
Fort Worth, TX 76104

Hospitals served:
Cook Children's Medical Center
Harris Methodist Fort Worth
Harris Methodist HEB
Harris Methodist Southwest
Medical Center of Arlington
North Hills Community Hospital
Huguley Memorial Hospital
Presbyterian Hospital of Denton

PEDIATRIX
MEDICAL GROUP OF TEXAS

Neonatal Office
1301 Pennsylvania Ave.
Fort Worth, TX 76104
817-250-2892

FACSMILE

DATE: August 18, 2006

TO: The Honorable Mark McClellan, MD
Administrator
FAX: 202-690-6262

FROM: Michael Stevener, M.D.
Medical Director, Neonatology
FAX: 817-250-5335

RE: RVU Reduction

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Message:

Attached please find my concerns regarding the CMS proposal regarding RVUs.

99

NICHOLAS G. BAMBINO, M.D.
10 Elm Street
Cornwall, NY 12518

Diplomate of the American Board of Internal Medicine
Diplomate of the American Board of Gastroenterology
Associate of the American College of Gastroenterology

Telephone (845)534-7080
Fax (845)534-4171

September 15, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1512-PN & CMS-1321-PN
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Dr McClellan,

It has come to our attention that the CMS is proposing for the cuts in our reimbursement not only for our personal services but also for the ambulatory surgical centers that have been coming up. I have been practicing Internal Medicine and Gastroenterology in a small upstate New York community now for 33 years and can tell you that my fee schedule that I have at present is less than what I had initially. I had no problem in 1974 with charging 150 dollars for an upper endoscopy and 250 dollars for a colonoscopy and had no complaints from the patients for that charge. I came to that number based on what would be fair and equitable for me as well as for my specialty and probably was on the low end of charges. Since we've had further cuts obviously those numbers have gone and I think that the people who are making the decisions in Washington should realize how far those cuts have taken us.

I am no longer able to fund a 401K and actually have not had one for the last 5 years nor do I offer it to my employees. I can also no longer afford healthcare for my 3 employees and thank goodness they are all covered under there husband's plans. The last time I was able to give my staff a raise was 3 years ago as my income has plummeted at least 50% from the good old days to the present time.

I see no hope for the future, I certainly don't see myself working any harder as I am in my mid 60s now and really keep the office open basically because it is the love of my life and I really enjoy taking care of my patients. If I had any other attitude I would probably retire and live on my savings which should be more than enough to keep me happy for the rest of my years. I see no way that we are going to be able to continue this process as far as physician reimbursement. We are the only profession that has had to make due with less and really at the bewilderment of all of my colleagues. My dentist is well aware of our situation, my personal attorney can't believe things have gotten so far and my banker friends have also been quite astonished to see how far things have come.

The only hope for the future is that we have to come up with another method of reimbursement. I don't think that the government should be expected to pay all of our fees and I certainly think the public has to shoulder some responsibility. By giving everybody the same price there is really no incentive for people to go into our specialty and most seem to be going to higher paid specialties such as orthopedic medicine, radiology, plastic surgery and dermatology. We are loosing quite a few good young physicians to those high paying fields and very few qualified people are going into primary care. The only answer to this problem is that since the fee schedule can not be changed and raising it a few percentage points is really an insult to us as professional people but I think we should be allowed to either increase the co-pay that the patients pay or to raise our prices and reimburse the patients what ever you feel the government is able to do. Anything short of that is going to result in the end of primary care medicine as we see it and also into gastroenterology as we practice it. I also think the current practice of trying to cover people from the cradle to the grave based on what the federal government is able to raise through taxes is not the answer and we have to look to another means of support.

Yours truly,

Nicholas Bambino, MD
NB/ks

100

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014
7500 Security Boulevard
Baltimore, MD 21244–8014

RE: Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Notice

Dear Doctor McClellan:

I am a practicing gastroenterologist in Sun City, Arizona and have been a Medicare participating provider since 1986. Thank you for the opportunity to comment regarding the proposed changes to the Physician Fee Schedule for 2007.

I am pleased that CMS has agreed with the recommendations of the RUC, as part of the five-year review process, to maintain the current work values for the following procedures commonly performed by gastroenterologists: 43235 (esophagogastroduodenoscopy); 43246 (upper gastrointestinal endoscopy, with directed placement of percutaneous gastronomy tube); 45330 (flexible sigmoidoscopy) and 45378 (colonoscopy). I support the recommendation to implement these work values in the 2007 final rule.

I am also supportive of the increases proposed to the physician work values for the evaluation and management codes. However, I am concerned about the constraints caused by budget neutrality and a flawed sustainable growth rate formula, and hope that Congress can allocate additional money to prevent cuts in reimbursement for other services. Given that our practice overhead continues to increase, and employees are dealing with higher commuting costs, it is unconscionable for CMS to recommend a reduction in fees when Medicare payments fail to cover our costs for providing services to Medicare beneficiaries. In addition, we have had a payment freeze or slight increase in Medicare payments for the past several years.

In the Proposed Rule, CMS is proposing to change the practice expense methodology and incorporate the supplemental practice data for gastroenterology and several other specialties. Unfortunately, CMS did not implement this data in 2006 after its acceptance in the 2006 Proposed Rule. I request that CMS implement this supplemental practice expense data in the Final Rule for 2007 and future years.

I am extremely concerned about the projected 4.7% cut to the conversion factor for 2007. This will have a serious and adverse impact to my practice, and will negatively impact beneficiary access to medical care. I hope that CMS will work with Congress to avert this payment cut for 2007, and work to provide a permanent solution remedying the flawed sustainable growth rate

(SGR) formula. I support the recommendation that CMS should remove expenditures for drugs from the SGR formula on a retrospective basis, and rectify this situation as soon as possible.

Thank you for your consideration of my comments.

Sincerely,

Frederick J. Kogan, Ph.D.,M.D.
Arizona Medical Clinic
13640 N Plaza Del Rio Blvd
Peoria, Arizona 85381

Paul E. McLaughlin, M.D.

Mount Sterling Medical Center
250 Foxglove Drive Suite #8
Mount Sterling, Kentucky 40353
Office: (859) 498-3098 and Fax: (859) 498-3035

September 18, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS 1512-PN
P.O. Box #8014
Baltimore, MD 21244-8014

Re: Revisions to Payment Policies Under the Physician Fee Schedule

To Whom It May Concern:

Unless Congress and the Administration act before October 10, the physician payment rate under Medicare will be cut by 5.1 percent effective January 1, 2007. Moreover, cuts of similar size are projected for several years into the future. Physicians', like myself, are asking you to stand up for America's seniors and the physicians who serve them by taking action this year to stop these drastic cuts.

Medicare cut the physician payment rate in 2002 by 5.4 percent. Additional cuts in 2003, 2004, and 2005 were averted by the passage of legislation that provided TEMPORARY relief. Physicians greatly appreciated this intervention by Congress and the Administration. But because the fundamental problems with the SGR formula were not addressed, repeated cuts in reimbursement are forecast for the foreseeable future.

My practice is located in a rural area of Kentucky. It's a small business that operates on a slim margin of profit. As a solo practitioner with ever increasing costs I do not have the resources to absorb sustained losses or steep payment cuts that are resulting from the SGR formula. I do however, have numerous patients that will suffer or will no longer have a family physician if I am forced to close my practice due to the growing costs and reimbursement cuts. Moreover, I can not be expected to continue taking an economic loss and still be able to keep my practice doors open.

It needs to be pointed out that only physicians are subject to these deep payment rate cuts triggered by the SGR. Hospitals, Medicare Advantage plans, skilled nursing facilities, and home health agencies are all subject to rate setting that is based on market basket indices. These plans and providers have regularly received and will continue to receive annual INCREASES based on the measure of medical inflation. Data from CMS and MedPAC confirm that between 2006 and 2013, inpatient hospital payments are projected to rise over 30 percent while payments to physicians will plummet by the same amount.

I urge you to repeal the sustainable growth rate formula and replace it with a fair and predictable payment system. Doing so will bring much needed stability to the Medicare program and give America's seniors the confidence that their physicians' doors will remain open to them. Thank you for your immediate attention to this matter.

Sincerely Yours,

Paul E. McLaughlin, M.D.

102-C
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GASTROINTESTINAL ASSOCIATES, P.A.

BARBARA J. MACCOLLUM, M.D.
PAUL J. BERGGREEN, M.D.
BRENDA DENNERT, M.D.
JOSEPH DAVID, M.D.

September 20, 2006

Marc McClellan, M.D.
Centers for Medicare and Medicade Services
Department of Health and Human Services
Attention CMS-1506-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: MEDICARE PROGRAM AMBULATORY SURGICAL CENTER PPS PROPOSED RULE

Dear Dr. McClellan:

I am a private practice gastroenterologist in Phoenix. I am writing to express my concerns with the CMS proposal to change the way your agency pays ambulatory surgical centers regarding their facility fee payments.

The proposed rule change as I see it will be of significant detriment to Medicare patients by institutionalizing a higher payment for hospital outpatient departments for the same procedure that we perform more efficiently and at lower cost in an outpatient endoscopy center. This will only serve to lower access to Medicare beneficiaries for colorectal cancer screening.

Additionally, by penalizing ambulatory surgical centers for providing access to Medicare beneficiaries for a screening colonoscopy, you are actually initiating a system which will cost more money for Medicare in the long run, and at the same time, decrease access to screening colonoscopy for Medicare beneficiaries. This is obviously bad for the budget as well as bad for screening colonoscopy, a concept which has been proven to dramatically decrease rates of colon cancer.

Therefore, I am respectfully requesting that this issue be reviewed and modified to be less punitive towards ambulatory surgical centers. This will avoid the closure of gastroenterology ASCs and

BOARD CERTIFIED IN INTERNAL MEDICINE AND
GASTROENTEROLOGY

1300 NORTH 12TH STREET • SUITE 608
PHOENIX, ARIZONA 85006 • 602/254-5321

a reduction in access in colorectal cancer screening rates and ultimately prevent an increase in the number of GI procedures performed in a more costly hospital outpatient department setting.

Your attention to this matter is appreciated.

Respectfully,

Joseph David, M.D.

JD/CMT/jeb

September 25, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
7500 Security Boulevard, C4-26-05
Baltimore, MD 21244-1850
Subject: Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Notice

Dear Doctor McClellan:

As practicing anesthesiologist, in Columbus OH, who has taken care of Medicare patients for over 20 years I would like to take this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the Five-Year Review of the Work Relative Value Units (RVUs) under the Physician Payment Schedule, as well as the proposed update to the Practice Expense methodology, published in the Federal Register on June 29, 2006.

I'm sure that you are giving the formal comments provided to you on August 21,2006 by the American Society of Anesthesiologist, the serious consideration that they deserve. As a member of the Society of Anesthesiologists, I strongly support the arguments set forth by them concerning these issues.

The proposed adjustments in Medicare payments appear to amount to a 10% decrease in payments to anesthesiologist over the next several years. This decrease will have a serious economic impact on many anesthesiologists and will increase the difficulty in attracting anesthesiologists to work in practice settings that have a high percentage of Medicare patients. There is a huge disparity between what anesthesiologist are paid by all other payers compared to Medicare. This disparity already makes it very difficult to attract anesthesiologists to work in practices that have a high percentage of Medicare patients.

I have always felt that the Medicare fee schedule grossly underestimates the value of anesthesiologist's "work", compared to other physicians and I am hoping that you take this opportunity to correct these long standing disparities.

Thank you for you time.

Sincerely,

Scott K. Henderson, MD
400 Braemer Court
Gahanna, OH 43230

104-0
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Nancy E. Kleber, FACMPE
105 Bally Shannon Way
Apex, NC 27539

October 4, 2006

Department of Health and Human Services
Attention: CMS-1321-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing concerning the significant consequences of the scheduled 5.1 percent reduction in Medicare reimbursement for physician services as a result of the flawed Sustainable Growth Rate (SGR) formula. As a medical practice administrator, I remain concerned about the future of Medicare reimbursement to physician practices.

If the flawed Medicare reimbursement formula is not eliminated, physician reimbursement rates in 2007 will fall below their 2001 levels. In fact, Medicare's reimbursement formula for physicians is so irreparably broken that the Centers for Medicare & Medicaid Services estimates that physicians will receive reductions of this magnitude until at least 2015, with a total projected reduction in reimbursement of 34 percent.

Please reconsider the projected 5.1 percent cut for 2007 and to provide physicians with an annual update that keeps pace with increasing overhead costs as estimated by the Medicare Economic Index (MEI). The Medicare Payment Advisory Commission recommended to Congress that Medicare physician reimbursement for 2007 be increased by 2.8 percent, consistent with the growth in the MEI. But the current flawed SGR formula responds by further reducing reimbursement.

You should also be aware that most physician group practices have contracts with private payers linking their payment rates to the Medicare fee schedule. A drop in Medicare payments in 2007 will mean a commensurate drop in reimbursement from numerous other payers, damaging our ability to provide medical care in Cary, NC.

Today, fifty three percent of my practice is devoted to the care of Medicare beneficiaries. To keep serving these patients, we must be able to meet the expenses we incur in providing their medical care.

The Medical Group Management Association (MGMA), of which I am a member, has conducted extensive practice cost surveys for more than 50 years. MGMA data indicates that the cost of operating a group practice rose by 30 percent over the past five years. However, Medicare reimbursement for physician services has actually fallen over the same time period. Therefore, it is critical to replace the failed SGR formula and link Medicare physician reimbursement updates to the MEI, or some other method that more accurately measures increases in the cost of providing care.

Sincerely,

Nancy E. Kleber

Nancy E. Kleber, FACMPE

PEDIATRIX
MEDICAL GROUP

105-0
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August 18, 2006

The Honorable Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd., CA-26-05
Baltimore, MD 21244

Sir:

The CMS review of Evaluation and Management services for updates on physician work RVUs is currently appropriate, as there is common agreement that physician work in E&M services has been undervalued. Any increases must be budget neutral under current law. The CMS proposal to apply a 10% negative physician work RVU adjuster to all codes with physician work in an effort to achieve budget neutrality for the increases is particularly unfair to those providers who work in high indigent areas or who provide intensive care services to our most valuable natural resource, our children.

A 10% reduction across the board will damage the integrity of physician work within the RVU system. The physician work E&M changes are logical and they should be implemented without destroying the relative weight of the physician work amounts against the practice expense and malpractice values, the other two components of physician total relative value.

Physician work will be relatively devalued (the -10% reduction) against the unchanged malpractice and overhead amounts, particularly for those physicians who practice in high acuity situations.

In my opinion, if budget neutrality is desired, it should be factored into the 2007 conversion factor, without changing the components that comprise total physician Medicare payments. This will keep the balance between the three components relatively logical and intact.

Virtually all states periodically update their rates using Medicare RVUs. The proposed artificial reduction in the physician work RVUs would create inaccurate, undervalued physician work and total RVUs that will deflate Medicaid payments.
States with even lower Medicaid rates from the 2007 Medicare changes will be without adequate physician access and may be in possible violation of federal law, as their physician compensation shifts downward. Oklahoma is the best example where the federal courts determined that the low Medicaid rates and lack of physician

5414 Fredericksburg Road, Suite 100, San Antonio, TX 78229
210.541.8281 877.636.7374 Fax: 210.541.9123

access resulted in a sham program with insufficient Medicaid beneficiary access to care. Other states including mine in Texas are facing similar challenges.

The impact is particularly damaging on hospital based physicians who have a high [redacted]icaid payor mix and must serve all patients who arrive at the hospital.

Private sector health insurance plans have historically maintained their own custom fee schedule with unique payment methods. While providers can sometimes negotiate the applicable conversion factor in their payor/provider contract, the RVUs are fixed as payors rely on the process that results in the CMS RVUs. Private payors regularly update their rates using the latest Medicare RVUs. The artificial reduction in the physician work RVUs creates inaccurate physician work and total RVUs that will deflate private sector reimbursement. Rates will deflate based on existing contracts that use a factor of "current Medicare" as a payment method.

I believe that CMS should develop an analysis to understand how the changes in physician work may be implemented without budget neutrality and provide this information to the United States Congress. Given the lack of an increase in the Medicare conversion factor in 2005/2006, Congress should grant a 2007 increase to fund the physician work E&M changes without budget neutrality.

Sincerely:

Amil Ortiz, MD
Neonatologist,
Methodist Children's Hospital
Pediatrix Medical Group of Texas
San Antonio, TX 78229
amil_ortiz@pediatrix.com
210-541-8281

106

MIDCOAST RHEUMATOLOGY, Inc.
DEIRDRE A. GRAMAS, M.D., M.P.H.
P.O. Box 146
Glen Cove, Maine 04846
Telephone: (207) 594-3281
Fax: (207) 594-3326

Dear Dr. McClellan:

We are writing to call your attention to a proposed rule, recently issued by CMS, which would make substantial reductions in reimbursement for technologies used to screen for osteoporosis and breast cancer. (CMS-1512-PN, RIN 0938-AO12, Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology)

These cuts to basic preventive services, described more fully below, seem at odds with your commitment to disease prevention, and the "Welcome to Medicare" physical exam which you instituted. In fact, the physical is described in part as "a great way to get up-to-date on important screenings".

We are hoping that you will review these proposed cuts in light of the public health mission of your agency, and withdraw them

Osteoporosis

The "gold standard" for bone mineral density testing is central DXA (axial dual-energy x-ray absorptiometry), the only method recognized by the International Society for Clinical Densitometry and the International Osteoporosis Foundation for the diagnosis of osteoporosis. At least 75% of all bone densitometry screening exams are performed using central DXA.

Despite the fact that screening rates for the Medicare population remain below 25%, CMS proposes to cut reimbursement for central DXA by 75%.

Breast Cancer

To address the problem of missed cancers, academic and industry research groups worked to develop sophisticated computer algorithms to identify features on mammograms that are suspicious for breast cancer. The result was CAD (Computer Aided Detection), which has lead to dramatic increases in the number of cancers detected, and detected at an earlier stage of the disease. Women enjoy improved likelihood of survival and less aggressive treatment options.

Despite the benefits CAD offers women in screening and diagnosis, the proposed rule would cut Medicare reimbursement for CAD by 54%.

Finally, the proposed rule cuts reimbursement for stereotactic guided breast biopsy, a minimally invasive alternative to open surgical biopsies.

Minimally invasive biopsies generally require some form of image guidance, either ultrasound, or stereotactic (x-ray based). Stereotactic is the predominant guidance technology used with vacuum assisted breast biopsy devices, due to device maneuverability and patient positioning requirements. In addition, stereotactic imaging, unlike ultrasound, makes it possible to see micro-calcifications -- sub-centimeter tissue abnormalities -- critical in determining the early presence of breast cancer.

The proposed rule would cut stereotactic guided biopsy by 80%.

We think you will agree that cuts of this magnitude to basic preventive services, as well as a minimally invasive form of breast biopsy, would have the effect of limiting access to critical, life-saving technologies to the women most at risk for osteoporosis and breast cancer. Thank you for your attention to this matter. We look forward to hearing from you.

Sincerely,

Midcoast Rheumatology, Inc.
Deirdre A. Gramas, M.D., M.P.H.
P.O. Box 146
Glen Cove, Maine 04846
Phone: (207) 594-3261
Fax: (207) 594-3326

Fact Sheet

Osteoporosis

More than 10 million Americans, mostly women, have been diagnosed with osteoporosis, and another 45 million are at risk. The human cost is incalculable. Within one year of suffering a hip fracture, 20% of seniors die, and another 20% enter a nursing home. Annual expenditures related to hip fractures alone exceed $18 billion.

Fortunately, within the last 10–15 years, we have seen the advent of screening technologies that can detect and monitor this "silent" disease, and more recently, the availability of drugs that can stop or even reverse the effects of bone loss. As a result, the U.S. Preventive Services Task Force recommended in 2002 that women aged 65 and older be screened routinely for osteoporosis. Two years later, the Surgeon General warned that, unless immediate action was taken, half of all Americans older than 50 would be at risk for fractures from osteoporosis and low bone mass by 2020.

The "gold standard" for bone mineral density testing is central DXA (axial dual-energy x-ray absorptiometry), the only method recognized by the International Society for Clinical Densitometry and the International Osteoporosis Foundation for the diagnosis of osteoporosis. At least 75% of all bone densitometry screening exams are performed using central DXA.

Despite the fact that screening rates for the Medicare population remain below 25%, CMS proposes to cut reimbursement for central DXA by 75%.

Breast Cancer

For the year 2004, except for non-melanoma skin cancers, breast cancer was the most common cancer among women, and the second leading cause of death after lung cancer. Mammography is the best screening procedure currently available for the detection of breast cancer, though far from perfect. Due to large caseloads, fatigue, the complex structure of the breast and the subtlety of early disease, radiologists fail to detect some 20% of breast cancers that are visible on the mammogram.

To address the problem of missed cancers, academic and industry research groups worked to develop sophisticated computer algorithms to identify features on mammograms that are suspicious for breast cancer. The result was ***CAD (Computer Aided Detection***), which has lead to dramatic increases in the number of cancers detected, and detected at

an earlier stage of the disease. Women enjoy improved likelihood of survival and less aggressive treatment options.

CAD has been endorsed by the Blue Cross/Blue Shield TEC, the American Cancer Society and the American College of Radiology. It is now the standard of care at state-of-the-art facilities like Washington Radiology; Susan Komen Breast Cancer Center in Dallas; the Elizabeth Wende Breast Center in Rochester, NY; Stanford University; Brigham and Women's at Harvard; and the Mayo Clinic.

Despite the benefits CAD offers women in screening and diagnosis, the proposed rule would cut Medicare reimbursement for CAD by 54%.

Finally, the proposed rule cuts reimbursement for ***stereotactic guided breast biopsy***, a minimally invasive alternative to open surgical biopsies. Minimally invasive biopsies are performed as outpatient procedures, requiring only a local anesthesia, and can be completed in 30 to 40 minutes. Over the last 12-15 years, they have displaced more conventional surgery as the preferred approach.

Minimally invasive biopsies generally require some form of image guidance, either ultrasound, or stereotactic (x-ray based). Stereotactic is the predominant guidance technology used with vacuum assisted breast biopsy devices, due to device maneuverability and patient positioning requirements. In addition, stereotactic imaging, unlike ultrasound, makes it possible to see micro-calcifications -- sub-centimeter tissue abnormalities -- critical in determining the early presence of breast cancer.

The proposed rule would cut stereotactic guided biopsy by 80%.

107

Middletown Anesthesia Consultants, Inc.
105 McKnight Drive
Middletown, Ohio 45044-4898
937-297-6072 (FAX) 937-293-0960

September 29, 2006

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

I am writing to express my concern as an anesthesiologist over upcoming changes to the physician fee schedule. I've been advised that the proposed practice expense methodology and changes in work values will result in a 10 percent cut in payments to anesthesiologists over the next 4 years. This only compounds the problems with the standard growth rate formula, adversely affecting all Medicare Part B physicians. Experts are projecting an alarming 34 percent reduction in reimbursement over the next 10 years based on the proposed 4.6 percent reduction to the fee schedule in 2007.

These cuts stand to have a dire impact on access to vital medical care for America's seniors. Medicare's failure to keep pace with the cost of delivering patient care is disturbing. Costs continue to increase while reimbursements decrease at an alarming rate. This is particularly troubling because the proposed practice expense methodology changes stand to adversely affect anesthesiologists more than any other specialty.

I am urging both CMS and Congress to address this issue immediately and make significant changes to the current methodology used to reimburse providers. I feel it would be in CMS' best interest to take advantage of the American Society of Anesthesiologists and other physician organizations' offer to financially support a comprehensive, multi-specialty practice expense survey. By collecting and using new practice expense data, CMS can take major steps towards improving the basis and accuracy of practice expense payments for all providers. Likewise, Congress needs to take action by supporting legislation that eliminates the unrealistic sustainable growth rate formula and replaces it with a more market-sensitive system based on positive changes to the Medicare Economic Index.

The ever-increasing gap between physician reimbursement and the costs incurred to provide care cannot be allowed to continue. My concern is that our nation's most vulnerable populations face a shortage of anesthesia care in operating rooms, pain clinics and critical care facilities throughout the country, unless action is taken. I greatly appreciate your time and consideration in this matter.

Sincerely,

Howard A. Seitzman, M.D.

Cc: Senator Mike DeWine
Senator George Voinovich
Congressman Michael G. Oxley

Ronald P. Spencer, M.D., P.A.

108

September 25, 2006

Department of Health and Human Services
ATTENTION: CMS-1502-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Gentlemen/Madam:

I am writing regarding my concerns about proposed changes for Medicare reimbursement for coverage of bone mass measurement (BMM) test.

I am a gynecologist working part time. I try to provide preventative care for menopausal women with an emphasis on osteoporosis related fracture reduction. If you have ever had a relative who has suffered a hip fracture in old age, you will probably appreciate the importance of trying to prevent this particularly cruel injury.

I rented my bone densitometer with the intention of being able to break even regarding rent for this service. As it turns out with the proposed changes in methodology result in a decreased payment of 18%.

Please be advised that DEXA bone testing was recently added as a preventative service.

If the proposed decreased fees for this service become enacted, I will not longer be able to provide this test for my patients. I will give up my lease on the bone density machine. Most of these patients will not go to another facility to obtain a bone density. Many of them, as a consequence, will be not be preemptively treated to reduce their risks of painful, crippling fractures in later life.

Please act carefully and consider the many other practices where DEXA is compliantly offered. Many of these will no longer be able to provide this service as well. I respectively request that the Deficit Reduction Act regarding this subject be delayed until a more thorough analysis can be conducted using cost figures based on appropriate technology. I appeal to Congress to intervene and stop the reduction of the conversion factor as well. I hope this will occur before the October adjournment.

Very truly yours,

Ronald P. Spencer, M.D.
RPS/clh

McQ
McQueary Bros.
WHOLESALE DRUG COMPANY

109-0
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2006 OCT -5 PM 3:37

October 4, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P.
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: CMS-1321-P (ASP Issues)

Dear Dr. McClellan:

On behalf of McQueary Brothers Drug Co., I would like to take this opportunity to provide our comments on the Proposed Rule CMS-1321-P, *"Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B"* (the "Proposed Rule"). This rule was published in the *Federal Register on August 22, 2006.*[1]

McQueary Brothers Drug Co. is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. McQueary Brothers Drug Co. fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on two items addressed in the HDMA comment letter regarding Average Sales Price (ASP) Issues. First, McQueary Brothers Drug Co. especially encourages CMS to reconsider its opinion that prompt pay discounts should continue as a type of price concession that manufacturers must include in their ASP calculation. We urge CMS to reverse its position, and inform manufacturers that customary prompt pay discounts should not be applied to wholesalers when they calculate ASP. We believe that manufacturers could continue to deduct any prompt pay discounts extended directly to end customers on sales that do not go through a wholesaler, but those that are not passed along to the customer are not appropriately included in the ASP. This revision is consistent with recent congressional directives that prompt pay discounts should be excluded from the Average Manufacturer's Price (AMP) calculation.

4727 East Kearney P.O.Box 5955 Springfield, MO 65801 1-800-747-2577 Phone (417) 869-2577 FAX (417) 831-5207

McQ
McQueary Bros.
WHOLESALE DRUG COMPANY

Secondly, McQueary Brothers Drug Co. strongly endorses CMS' proposal to codify the definition of bona fide services, to treat fees paid to wholesalers the same as fees paid to third party logistics providers, and not to deduct those bona fide service fees when ASP is determined.

Thank you for this opportunity to provide our comments on Proposed Rule CMS-1321-P, and to endorse the comments of the HDMA as written. We hope these comments are constructive in your deliberation of developing an Average Sales Price calculation that represents an equitable and reasonable approach to reimbursement for the products that we distribute.

Sincerely,

Rick McQueary
President
McQueary Brothers Drug Co.

RM:arm

4727 East Kearney P.O.Box 5955 Springfield, MO 65801 1-800-747-2577 Phone (417) 869-2577 FAX (417) 831-5207

110

5404 N Canyon Rise
Tucson, AZ 85749
9/26/06

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Dept of Health nd Human Svcs
CMS – 1321-P
PO Box 8015
Baltimore, MD 21244-8017

RE: CMS 1321-P

Dr McClellan:

I am an Interventional Pain Physician (CMS designation -09). I am writing to ask you to reconsider the proposed reduction of 12% to 38% in reimbursement for interventional pain services as proposed in the 2007 fee schedule.

I am concerned the effect of the changes plus the anticipated negative conversion factor of 5.1% will make it economically impossible for me and my colleagues to continue to provide interventional pain care for Medicare patients. I am also concerned these changes will be exacerbated over the next four years.

I ask you impose a moratorium for at least one year so that the impact of changes in the physician fee schedule can be analyzed. Without proper analysis, a course of denying Medicare patients access to interventional pain services might be embarked upon.

William L Roberts, MD

111-D
(2)

TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER
School *of* Medicine™
Department of Anesthesiology

Gabor B. Racz, MD, DABPM, FIPP
Co-Director Pain Services
Department of Anesthesiology
3601 4th Street - MS 8182
Lubbock, Texas 79430
(806) 743-3112
FAX (806) 743-3965

September 26, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1321-P
P.O. Box 801
Baltimore, MD 21244-8015

Dear Sir:

I am a pain management physician (09.) with a full-time pain practice at Texas Tech University Health Sciences Center. As a physician who takes care of Medicare beneficiaries and other patients, I write to urge you to take steps to prevent the scheduled 5.1% decrease to Medicare reimbursement for physicians in 2007. The impending physician payment cuts would be extremely detrimental to my practice and the patients I treat.

Currently, physician payment updates are driven by a flawed formula called the Sustainable Growth Rate (SGR). Instead of the SGR, payment updates should be based on increases in practice costs. If Congress does not pass legislation this year, Medicare payments to physicians will be cut by 5.1%. Some physicians may face cuts as high as 38% as CMS is using bottom-up methodology in calculating practice expense and improving reimbursement for evaluation and management services.

For years physicians have operated under a Medicare reimbursement system that does not keep track with inflation. While we support higher payment for evaluation and management services, substantial cuts in other areas are not acceptable. Physicians cannot continue to operate in an environment of such uncertainty, and as a result more and more doctors are electing to stop taking on additional Medicare patients, and an even more threatening issue, all other payers follow Medicare.

Congress must deal with this critical issue before it recesses for the elections. It is extremely frustrating to fight this battle each and every year. Please replace the 5.1% cut with a positive update that reflects increases in practice costs and stabilize Medicare physician payments.

Please take action to prevent these scheduled cuts to Medicare reimbursement for physicians and protect beneficiary access to healthcare.

Yours sincerely,

Gabor B. Racz, M.D.
Grover Murray Professor
Professor and Chair Emeritus
Co-Director Pain Services and Pain Training Program Director

112

Mr. Michael Patrick Flynn Sr. C.R.N.A.
3783 Byrnes Blvd.
Florence, SC 29506

September 29, 2006

Dr. Mark McClellan, MD PhD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I wish to express my serious concern that the Centers for Medicare & Medicaid Services (CMS) proposed rule making adjustments in Medicare Part B practice expenses and relative work values (71 FR 37170, 29/2006) severely cuts Medicare anesthesia payment without precedent or justification. I request the agency reverse these cuts.

The proposed rule mandates 7-8 percent cuts in anesthesiology and nurse anesthetist reimbursement by 2007, and a 10 percent cut by 2010. With these cuts, the Medicare payment for an average anesthesia service would lie far below its level in 1991, adjusting for inflation. The proposed rule does not change specific anesthesia codes or values in any way that justifies such cuts. In fact, during CMS' previous work value review process that concluded as recently as December 2002, the agency adopted a modest increase in anesthesia work values. Further, Medicare today reimburses for anesthesia services at approximately 37 percent of market rates, while most other physician services are reimbursed at about 80 percent of the market level. The Medicare anesthesia cuts would be in addition to CMS' anticipated "sustainable growth rate" formula-driven cuts on all Part B services effective January 1, 2007, unless Congress acts.

Last, hundreds of services whose relative values and practice expenses have been adjusted by the 5-year review proposed rule have been subject to extensive study and examination. However, the proposed rule indicates no such examination has been made on the effects that 10 percent anesthesia reimbursement cuts would have on peoples' access to healthcare services, and on other aspects of the healthcare system.

For these reasons, I request the agency suspend its proposal to impose such cuts in Medicare anesthesia payment, review the potential impacts of its proposal, and recommend a more feasible and less harmful alternative.

Thank you and I look forward to hearing back from you.

Sincerely,

Michael P. Flynn Sr. C.R.N.A.

J. Michael Rollins, MD, FACOG
Medbrook Medical Office
1370 Johnson Ave.
Bridgeport, WV 26330
304-842-6650

Original plus Two Copies via Priority Mail

28 September, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Deparment of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8010

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, Specifically "Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007."

Dear Dr. McClellan:

I am an Obstetrician/Gynecologist practicing in Clarksburg/Bridgeport, WV. I am writing with regards to concern over proposed changes to the Physician Fee Schedule for CY 2007, specifically "Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007". I am particularly concerned with the negative effect of these changes on the practice expense RVU's for CPT code 58565 – Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants, by CY 2010.

This procedure offers significant advantages to women of childbearing age, especially when performed in the office setting. I have treated over 50 women with the Essure micro-insert system with excellent results and high patient satisfaction. Additionally, the cost of laparoscopic sterililztion performed in the outpatient surgery setting is significantly more, and the risks for the patient are higher because of the need for general anesthesia and abdominal surgery.

I am worried that the proposed changes, which are often adopted by private insurance companies, will reduce reimbursement to the point that physicians can no longer offer these services through their office based practices. CMS needs to review these changes and be certain that direct costs are fully accounted for in its calculations.

Thank you for considering my concerns. I would be happy to talk with you or your staff anytime.

Sincerely,

J. Michael Rollins, MD, FACOG

114

M. E. THURMOND-ANDERLE, M. D., P. A.
6701 Woodward Street • Amarillo, Texas 79106
Phone (806) 379-7732 • Fax (806) 379-6740

September 25, 2006

Department of Health and Human Services
Attention: CMS-1502-P (Document Number 1321-P)
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

Allow me to introduce myself. My name is Margaret E. Thurmond-Anderle, M. D., and I am a rheumatologist practicing in Amarillo, Texas. I am writing to voice my concern about the proposals to the Coverage of Bone Mass Measurement (BMM) Tests (document number 1321-P). As a single practice rheumatologist, it will be very difficult to provide my patients with the highest possible medical care if the proposed budget cuts take effect. The majority of my practice is Medicare, and the proposed Federal cuts would directly affect my practice.

I understand that Medicare believes most bone densitometry machines across the country are idle half the time. This, in my opinion, does not justify Medicare cutting reimbursement costs in half. If the proposed cuts go into effect, many of these machines will never be used. The cost of the maintenance will far outweigh the reimbursement costs. Due to the number of Medicare patients in my practice, I am afraid these individuals will be denied proper medical treatment due to insurance reasons. This consequence is already occurring throughout the country on both Medicare patients and commercial insurance patients.

Recently, CMS added DXA as a perspective service. These proposed cuts go against their own initiative to increase the utilization of these machines. These cuts also diminish the impact of CMS's own "Healthy People 2010" initiative. I thought CMS wanted to reduce the annual costs of hip replacement surgery and the subsequent therapy involved. By allowing these cuts to go through, CMS will defeat their purpose and the annual costs will increase. I do agree the requirements for steroid dosage should be 5.0 mg.

A standard DXA procedure takes about 30 minutes to perform. My technologist reviews the patient's medical history with them to look for indications, risk factors, etc. before performing any testing. Once the testing begins, our standard procedure is an AP Spine, Dual Femur and Forearm which takes about 15 minutes. Based on these results, I then determine the effectiveness of the therapy and what changes may need to occur.

I believe feel an emphasis should be placed on the skill of performing DXA testing. I believe this would increase utilization of these machines, and ensure proper interpretation of the results. Both my technologist and I are certified through the International Society for Clinical Densitometry to perform and read these tests. Many practices, physicians and radiologists using this equipment have not received the proper training to perform and interpret these tests.

I also believe the assumptions used to recalculate the MPFS are inaccurate. The new methodology should not be a trial and error policy. I also believe inaccurate data was used to calculate the bone densitometer. There are many differences and advantages between the pencil beam and the fan beam densitometers. The majority of systems sold today are fan beams, and I personally prefer the fan beam densitometer because it is easier to use on older patients. Our fan beam equipment is used in our office about 75% of the time, not 50% of the time as speculated by various studies.

In addition, I strongly encourage Texas legislators to delay the DRA until a complete and thorough analysis can be conducted using cost figures based on the appropriate technology. I also request congress to intervene and stop the reduction of the conversion factor. I feel strongly Congress should act on this matter before their October adjournment.

I sincerely hope my opinion will be taken into consideration on this matter.

Sincerely,

M. E. Thurmond-Anderle MD

M. E. Thurmond-Anderle, M. D.

Board Certified Rheumatology & Internal Medicine
www.dranderle.com

115

Bruce Reider, M.D.
Director of Sports Medicine
Professor
773-702-6346
Fax: 773-702-3462
breider@surgery.bsd.uchicago.edu

Sherwin S. W. Ho, M.D.
Associate Professor
Fellowship Program Director
773-702-5978
Fax: 773-702-3462
sho@surgery.bsd.uchicago.edu

Michael A. Terry, M.D.
Assistant Professor
773-702-6346
Fax: 773-702-3462
mterry@surgery.bsd.uchicago.edu

THE UNIVERSITY OF CHICAGO
SPORTS MEDICINE
5841 S. Maryland, MC 3079
Chicago, IL 60637-1470

September 5, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-1321-P – CHANGES TO THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2007; -- REQUEST FOR OFFICE PRACTICE EXPENSE RVUS FOR ARTHROSCOPY PROCEDURES

Dear Dr. McClellan:

In response to the above referenced proposed rule which recommends payment policies under the Medicare physician fee schedule for calendar year 2007, [1] I am writing to ask that you establish office-based practice expenses for orthopaedic arthroscopy procedures described by CPT codes 29870, 29805, 29839, 29840, 29860. Making this important revision to the Medicare physician fee schedule would allow orthopaedic physicians such as myself to improve the diagnosis and treatment of joint problems afflicting many Medicare patients by ensuring that we can continue to furnish these services. Thus, I encourage MCS to assign non-facility (office) practice expense relative value units to CPT codes 29870, 29805, 29839, 29840, 29860 in the final 2007 physician fee schedule rule.

As you may be aware, significant refinements in the arthroscopes and instruments used for arthroscopy procedures in the past few years have made it more practical for doctors to furnish arthroscopy procedures in the office setting. Using smaller arthroscopies, we are better able to assess, on a more immediate basis, the etiology of a patient's complaints. Often, this allows us to forego ordering more expensive and time consuming MRI scans. In addition, with development of better instrumentation and surgical techniques, many conditions now can even be treated arthroscopically, resulting in much easier patient recovery that open surgery.

Unfortunately, under the current physician fee schedule physicians are not adequately reimbursed for the significant practice expenses associated with providing arthroscopies in the office setting, While the supplies and devices used for arthroscopy procedures are estimated to cost nearly $1,000 per procedure, the CPT codes associated with providing arthroscopies in the physician office do not include a practice expense component. As a result, doctors often can not afford to provide arthroscopy services in the more efficient office setting.

Duchossois Center for Advanced Medicine
5758 S. Maryland, MC 3079
Chicago, IL 60637
Appt: 773-834-3531
Fax: 773-702-5434

4801 Southwick Drive,
Suite 500
Matteson, IL 60443-2456
708-748-2310
Fax: 708-748-0229

To avoid jeopardizing patient access to this exciting technology, I respectfully request that CMS add **non-facility (office) practice expense relative value units (PE RVUs) to cover physician office expenses for CPT codes 29870, 29805, 29830, 29840, 29900 arthroscopy procedures.** The American Association of Orthopaedic Surgeons (AAOS) requested that CMS assign non-facility PE RVUs to these codes as long ago as 1998.

CMS can easily correct the payment inequity facing doctors who wish to provide arthroscopy procedures in the office setting by establishing non-facility PE RVUs which take into account the costs of the devices and supplies used to provide in-office arthroscopy services falling under CPT codes 29870, 29805, 29830, 29840, 29900. Appropriate payment under the Medicare physician fee schedule will allow physicians to more expeditiously manage our patients' conditions and preserve patient access to vital more efficient, and cost effective in-office arthroscopy procedures.

Thank you for your consideration of this important matter.

Sincerely,

Sherwin Ho, M.D.
Associate Professor of Surgery
Section of Orthopaedics
University of Chicago

SH/hda

[1] Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48981 (August 22, 2006)

Cc: Carolyn Mullen
Gail Daubert

116

MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
James D. Kinard, PhD, M.D.
Justin J. Wu, M.D.
Matthew A. Manning, M.D.
Nancy M. Bednarz, M.D.

September 20, 2006

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

Attention: CMS-1321-P - Rule: Physician Fee Schedule

Dear Administrator,

Thank you for allowing me the opportunity to provide comments on file #CMS-1321-P for the CY 2007 / 2008 CMS proposed Physician Fee Schedule Rule. I have some serious concerns regarding your proposed changes.

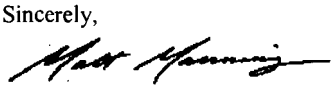
Under the proposed rule, professional reimbursement (work RVU) is slated to be significantly reduced for Radiation Oncologists treating with brachytherapy services in the OP Hospital Setting (2006 work RVU = 0.53 -- 2007 work RVU cut proposed = 0.33). The work RVU is very important to treating Physicians because it makes up the greatest portion (52%) of the RBRVS system. The work RVU comprises the Physician's time to perform a service, technical skill & physical effort, mental effort & judgment, as well as psychological stress associated with the Physician's concern about iatrogenic risk to the patient. CMS must preserve the work RVU on the professional side for Medicare patients to continue to keep brachytherapy services available.

Other anticipated reductions include CPT Code 77781 (proposed to reduce approximately 26%) and a proposed conversion factor reduction slated to decrease by 5.1%. These reductions will be a significant problem for remote afterloading high intensity brachytherapy; 1-4 source positions or catheters.

Brachytherapy is an important procedure offered to Medicare beneficiaries diagnosed with early stage breast cancer. Radiation Oncologists want to continue offering brachytherapy to the Medicare beneficiaries but many will not be able to continue offering this service if payment is reduced.

Medicare patients deserve the right to have access to brachytherapy services. CMS should set a goal to preserve the 2006 work RVU on the professional side and prevent any reductions on CPT code 77781. Thank you for heeding these recommendations. We would like to continue servicing your Medicare beneficiaries.

Sincerely,



Matthew Manning, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

New Horizons
Dr. David H Johnson
LISW, FAPA, DAC
Individual, Couples, & Family Counseling

2600 Fairview Ave
Farmington, NM 87401

505-327-2532
Fax 505-327-1939

September 13, 2006

To Whom It May Concern:

I am a Clinical Social Worker in private practice for over 30 years. I now make per hour of service to your enrollees what my local mechanic makes for repairing my car. A reduction in the fee schedule we now have will mean I will be making less than my mechanic. People are more important than car repairs and education should be respected and paid for accordingly.

Do not reduce the rates. You will loose many more providers and create a service vacuum that will cost us more in the long run and create a great deal of suffering in the interim.

Sincerely,

Dr. David H Johnson
LISW, FAPA
New Horizons

cw

Chairperson, Board of Directors, Four Corners Chapter, NASW
Board of Directors, State Chapter of NASW
Diplomat of the American Psychotherapy Association
National Board of Cognitive & Behavioral Therapists - Certified Cognitive Therapist
National Academy of Brief Therapists, Certified Brief Therapist
National Board of Addicitions Examiners - Doctoral Addictions Counselor

118

HEIDI M. McNANEY-FLINT MD, PA
ERIKA CIURSO R.N.C., M.S.N., A.R.N.P.
863 S.E. Monterey Commons Blvd / Stuart, Florida 34996
phone 772.781.3815
fax 772.781.3817

September 21, 2006

Department of Health & Human Services
ATTENTION: CMS-1502-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear HHS:

RE: DOCUMENT #1321-P

I am writing this to comment on the coverage of bone mass measurement tests that you address in CMS-1512-PN. The proposal appears to make changes to:

1) The five year work review,
2) To practice expense methodology change,
3) The deficit reduction Act,
4) The conversion factor,
5) Bone mass measurement tests.

I am a gynecologist practicing in Florida. I am performing bone density testing. I am against the proposed changes.

DEXA scanning was recently added as a preventative service, and these cuts go against your own initiative to increase utilization. These cuts will diminished the impact of the "healthy people 2010 initiative." Of all of the changes mentioned, the only one I can agree with is the requirement for steroid dosage at 5.0.

I think that you are underestimating the work component including physician time, intensity and skill detail. I think you are underestimating the technical component including the methodology for calculation of practice expenses.

It is hard to believe that you are reducing the current value of 3.0 to a value of 2.57. This is a decease of 18%. Under the DRA guidelines, you will reduce this further to 2.53% as this is the lower amount of the physician fee schedule versus the hospital outpatient rate.

The time, skill, and intensity involved in these tests are more than you are giving us credit for. Many patients have problems even just getting up on the table. Positioning patients can be problematic. Putting them in proper positions is sometimes uncomfortable and they have a tendency to move.

Continued

The scan is started, the few lines of image are evaluated, and the scan is stopped and the patient has to be repositioned appropriately. There is then the repositioning between doing the spine and both hips. The patient is totally repositioned from the spine DEXA to one hip and then the other. As you know, only one hip has to be scanned but most us feel that both hips are necessary. We are already scanning the second hip "for free", despite the fact that it takes additional time and positioning. This will impact patients in that only one hip will be scanned for the most part.

It appears that the assumptions used to recalculate the MPFS are inaccurate. It almost appears as if this is just a trial and error type policy. It is also my understanding that inaccurate data was used to calculate bone densitometer. My understanding is that you depended on pencil being information when most of us use a fan beam and the majority of systems sold use the fan beam.

In addition, some adjustment was made because equipment was not utilized 50% of the time and this is just not true.

I think that you need to delay the DRA until a complete and thorough analysis can be conducted using true cost figures based on the appropriate technology.

Your immediate attention in this matter will be greatly appreciated.

Respectfully,

HEIDI M. McNANEY-FLINT, M.D.

HMCF/pb

New line provider of DEXA services for now.

P.S. If the reimbursement falls below a critical value, which are changes will cause it to do, then many of us will not be able to provide the services and patients will go without necessary evaluation and management.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS – 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

On August 22, 2006, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2007 (the "**Proposed Rule**"). The Proposed Rule includes at Section II.I. two rules related to diagnostic tests that are of particular importance to Uropath: (i) proposed changes to existing Medicare reassignment rules (the "**Reassignment Rule**"); and (ii) proposed changes to existing physician self-referral regulations (the "**Self-Referral Rule**"). The Reassignment Rule and Self-Referral Rule and the preamble language discussing them make clear that CMS views small centralized pathology laboratories as significant fraud and abuse risks, though the basis for this conclusion is unknown.

Uropath has prepared this letter to share with its client group practices Uropath's perspective on the potential impact of the Reassignment Rule and Self-Referral Rule on Uropath's business model, to advise group practices of what Uropath believes to be the bases for CMS' contention that these pathology laboratories present fraud and abuse risks, and to voice Uropath's concerns with respect to the suppositions CMS relies on in reaching its determinations with respect to these pathology laboratories. **The analysis, discussion and legal reasoning contained herein are designed to serve only as a structural framework for the consideration of these issues by attorneys or other persons that you retain to review and analyze these issues on your behalf, and on whose opinion you may be entitled to rely. The issues discussed herein are by no means, and are not intended to be, exhaustive of the legal issues that may present themselves in connection with the Proposed Rule. This letter is not, and should not be construed as legal or regulatory advice.**

CMS states that the Reassignment Rule and Self-Referral Rule are designed to address two separate but related concerns. First, recent changes to Medicare rules on reassignment have led to confusion as to whether existing

RICHARD J. DEAN, M.D. • RALPH J. DEVITO, M.D. • DAVID G. HESSE, M.D. • STANTON C. HONIG, M.D. • THOMAS V. MARTIN, M.D.
ARNOLD M. BASKIN, M.D., FOUNDER, EMERITUS

THE UROLOGY CENTER P.C., 330 ORCHARD STREET, SUITE 164, NEW HAVEN, CT 06511 • 203-789-2222 FAX: 203-624-3697
EAST SHORE MEDICAL CENTER, 6 WOODLAND ROAD, MADISON, CT 06443 • 203-245-8824
MEDICAL CENTER OF ORANGE, 339 BOSTON POST ROAD, ORANGE, CT 06477 • 203-795-6380
SPRING GLEN MEDICAL CENTER, 2200 WHITNEY AVENUE, HAMDEN CT 06518 • 203-288-3526

Medicare anti-markup rules apply to situations in which a reassignment has occurred pursuant to a contractual arrangement. Second, CMS believes certain business arrangements that are proliferating are not within the intended purpose of physician self-referral laws, which permit physician group practices to bill for services furnished by a contractor physician in a "centralized building." CMS specifically identified remotely located centralized pathology laboratories, or "pod labs" as such an arrangement. It is for these reasons CMS proposed the changes discussed below.

I. THE REASSIGNMENT RULE

A. The Rule

CMS is proposing the Reassignment Rule to clarify how purchased test and purchased test interpretation rules apply in the context of a contractual reassignment. Apparently, some providers are using the more flexible reassignment provisions to avoid application of the anti-markup provisions to the billing of "purchased" tests. CMS is proposing to incorporate into its reassignment regulations provisions similar to those that currently appear in its regulations and in the Medicare Reimbursement Manual relating to the billing of purchased diagnostic tests.

Current law provides that if the technical component (the "**TC**") of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of the costs charged by the performing supplier to the billing physician, or the performing supplier's reasonable charge. This is known as the "**Anti-Markup Provision**." The Anti-Markup Provision definitively applies to situations in which a group practice purchases a TC from an independent supplier and then bills the payor as though the group practice actually performed the service. The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate.

The Social Security Act also generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This provision has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. Prior to 2003, a physician could reassign his or her rights to bill and receive Medicare payment under a contractual arrangement (as opposed to an employee-employer relationship) only if the services being paid for were performed on the premises of the assignee. Section 952 of the Medicare Modernization Act of 2003 ("**MMA**"), however, extended this general reassignment exception to any contractual arrangement regardless of whether the services were being performed on the premises of the billing entity. CMS believes that the broadening of the reassignment exception has allowed the proliferation of pod labs, which CMS has concluded without identifiable evidence are subject to fraud, waste and abuse.

First, to address perceived abuses, the Reassignment Rule provides that any reassignment made pursuant to the MMA is subject to roughly the same rules that apply to the billing of purchased diagnostic tests under the Anti-Mark Provision. Specifically, CMS proposes to amend the reassignment regulations to provide that if the TC of a diagnostic test is billed by a physician or medical group under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity may not exceed the lower of the physician's net charge, the billing physician's actual charge, or the physician fee schedule amount under Medicare regulations. The Reassignment Rule would also require that in order to bill for the TC of a diagnostic test, the billing entity must also perform the professional interpretation of the test (the "**PC**").

Second, CMS is considering, but is not proposing in the Proposed Rule, the imposition of additional conditions governing when a physician or medical group can bill for a reassigned PC. These conditions would include:

(i) the test must be ordered by a physician that is financially independent of the person or entity performing the TC and also of the physician or medical group performing the PC;

(ii) the physician or medical group performing the PC does not see the patient; and

(iii) the physician or medical group billing for the PC must have performed the TC.

Finally, in additional to the proposed amendments and considered amendments, CMS is seeking specific comment on the following issues:

1. Whether radiology and imaging services should be excepted from the proposed reassignment provisions;

2. Whether the proposed reassignment rules should apply to only pathology services;

3. Whether the reassignment rules should apply to services performed on the premises of the billing entity and if so how to define such premises appropriately;

4. Appropriate wording of a rule imposing limitations on billing for the PC of a test; and

5. Whether the Anti-Markup Provision elements should be made applicable to a reassigned PC of a diagnostic test performed under a contractual arrangement.

B. Analysis

The Reassignment Rule is principally an amendment of 42 CFR § 424.80(d)(3). In pertinent part it would provide that certain billing limitations exist if "a physician or medical group bills for the [TC] of a diagnostic test . . . following a reassignment involving a contractual arrangement with the physician or other supplier who performed the [TC]." While it is clear that CMS intends with this and other proposed regulations to make it infeasible for pod labs to continue to exist, Uropath does not believe the Reassignment Rule will affect that manner in which Uropath-managed labs currently provide and bill for the TC of pathology services.

The billing limitations in the Reassignment Rule apply only in the case of a reassignment involving a "physician or other supplier who *performed*" the TC. The problematic example given by CMS is one in which a supplier itself employs a histotech and pathologist, the employees go from lab to lab providing the TC, and then through a contractual reassignment the group practice bills for services provided by the supplier. This is substantially different from the arrangement utilized by Uropath-managed labs, in which the TC is performed by leased employees of a group practice who are *supervised* by a physician who has a direct contractual relationship with the group practice. Indeed, clarifications made in April, 2004 to the Anti-Markup Provision specifically acknowledge that diagnostic tests provided by leased employees are not "purchased tests" for purposes of the rule.

Counsel for Uropath spoke directly to the designated CMS contact for the Reassignment Rule about this very issue. The CMS contact assured counsel that if the services at issue were not provided by another supplier (and thus not subject to the Anti-Markup Provision), then the services would not now be subject to anti-markup limitations by virtue of the Reassignment Rule. The result of this interpretation is that the Reassignment Rule would not affect the billing practices typically utilized by pod labs managed by Uropath, though they could greatly affect the business model utilized by some of Uropath's competitors, particularly those which bill for the TC while permitting supervising pathologists to bill for the PC of diagnostic tests. While the informal interpretation of a CMS delegate is not binding on CMS, it does represent the interpretation of the regulation in the opinion of the person relied on by CMS for this interpretation and held out by CMS as its agency contact on the issue.

The Reassignment Rule would also require that a group practice "directly perform" the PC of a diagnostic test if it is going to bill for the TC of the same test. It is not absolutely clear what is meant by the phrase "directly perform." Uropath believes it is intended to require that a "physician in the group practice" (as defined in the Stark Law regulations) actually perform the PC and that the group bill for it. It is possible that CMS intends by insertion of this provision to require that an actual owner or employee of a group (as opposed to an independent contractor) provide the PC of diagnostic services if the group intends to bill for the TC of the same service. This is unlikely, however, for a couple of reasons.

First, the Stark Law definition of a "Physician in the Group Practice" assumes that an independent contractor physician may provide services for a group practice, provided they are performed on the group's premises, and in fact requires that the agreement between an independent contractor physician and a group practice comply with the Medicare reassignment regulations. The Physician Services and the In-Office Ancillary Services Exceptions to the Stark Law expressly require that a group practice bill for services provided by such physicians. It would be inconsistent for the Stark Law and Medicare regulations to require or even permit a group practice to bill for services that reassignment regulations suggest are not in fact provided by the group practice through its contracted physicians. Second, this interpretation would prohibit a group practice from utilizing a locum tenens physician to provide the PC of diagnostic tests, since those tests would not be directly provided by the group, and thus would prohibit a group from billing for the TC of the same test.

We believe a more reasoned interpretation of this element is to require that a group billing for the TC of a diagnostic test be the same entity that is providing and billing for the actual interpretation, and that those services must be provided on the group practice's premises. This would eliminate existing arrangements in which a group practice outsources to a supplier the TC of a diagnostic test for which the supplier bills Medicare, and then independently contracts with a physician to provide the PC of the test for which the group practice bills under reassignment for a profit. It would also eliminate arrangements where a group practice contracts with a pathology group to provide technical staff and supervision for the TC of tests in the group's premises and for which the group practice bills, in exchange for the pathologist getting an exclusive contract to provide and bill for the PC in his own name. We believe both of these models are utilized by competitors of Uropath. This new requirement would not implicate a Uropath-managed lab, because group practices globally bill for the TC provided by its leased staff and the PC provided by its independent contractor pathologist.

Uropath-managed lab owners must appreciate, however, that CMS states it is implementing these rules to eliminate pod labs, which it considers an abusive arrangement. CMS is also considering additional provisions which could meaningfully affect the business model employed by Uropath-managed labs, and is in fact seeking suggestions on appropriate ways to do so without jeopardizing business models it does not believe are subject to abuse. For example, CMS is considering, but has not proposed in this rulemaking, amending 42 CFR § 424.80(d) to provide that a group cannot bill for a PC provided by an independent contractor physician under a reassignment unless:

(i) the test is ordered by an entity independent of both the physician and the group contracting with the physician;

(ii) the physician and medical group contracting with the physician do not see the patient; and

(iii) the medical group billing for the PC also performs the TC.

This rule, if adopted, would prohibit a group practice from billing Medicare for the reassigned PC of a test relating to a self-referral, even if the self-referral was expressly permitted under the Stark Law. Further, if a group practice was not able to bill Medicare for the PC due to this rule, it might then no longer be able to bill for the TC of the same test, since the Reassignment Rule provides that a group may only bill for the TC of a diagnostic test if it directly performs the PC of the same service (and if a group cannot bill for the PC it will not perform it). The considered amendments do not appear to have been sufficiently thought through at this point, but they are important in gaining an appreciation of CMS's perspective on pod labs and other diagnostic test business models.

II. THE SELF-REFERRAL RULE

A. The Rule

The "In-Office Ancillary Services Exception" to the Stark Law permits a group practice to provide designated health services (which include anatomic pathology services) for which the group bills and collects if, among other things, the services are provided in a "centralized building" as defined in 42 CFR § 411.351. CMS defines the term "centralized building" as all or part of a building that is owned or leased on a full-time basis by a group practice and is used exclusively by the group practice. CMS has expressed concern in the Proposed Rule that the definition of centralized building in its current form has been exploited to create abusive pathology arrangements that technically comply with the elements of the In-Office Ancillary Services Exception. CMS gives as an example of such an abusive arrangement the proliferation of pod labs.

To address this concern, the Self-Referral Rule proposes to modify the definition of "centralized building" to require a minimum square footage of 350 feet. The minimum area requirement would not apply to space owned or rented in a building in which no more than three group practices both (i) own or lease space in the same building and (ii) share the same "physician in the group practice" (meaning independent contractor physician). CMS flatly states the purpose of this square footage requirement and the related exception is to prevent abusive arrangements such as pod labs, while not disqualifying legitimate, stand-alone physician offices that are unusually small.

Further, CMS would require that the centralized building contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services that are performed on the premises in order to meet the definition of a "centralized building." CMS believes this requirement would prevent pod labs from moving equipment from lab to lab to minimize overhead for a centralized building.

In addition to these proposed revisions, CMS is also considering, but not proposing in the Proposed Rule, the following:

In the event a modification of the centralized building is not possible, a group practice could also comply with the new requirement by contracting with an independent pathologist who contracts with no more than two other pathology laboratories in the same medical office building. This would limit the number of group practices in a single medical office building that a single independent pathologist could contract with. Currently, Uropath is identifying group practices whose labs are smaller than 350 square feet so that Uropath and those group practices can plan for any necessary accommodations.

The Self-Referral Rule also requires that a "centralized building" contain, on a permanent basis, the necessary equipment to perform substantially all of the pathology services that are performed in the space. Uropath-managed pathology labs will have no problem complying with this new requirement. As a threshold matter, CLIA regulations require that certain equipment, materials, and supplies be available in the pathology laboratory in order for it to be licensed to provide pathology service. In addition, Uropath has taken the position that the In-Office Ancillary Services Exception to the Stark Law requires that a group practice's centralized building be independently equipped with all necessary equipment to provide the services it provides. It is for that reason that the compliance policy Uropath provides to all group practices, entitled "Provision of Services at Remote Pathology Labs Under Stark Law" requires at Section IV.B 3 (b) that each lab be independently equipped, and at Section IV.B 3 (d) that under no circumstances should a lab share laboratory equipment necessary for the provision of pathology services. This requirement may adversely affect the business arrangements utilized by pathology provides that are in competition with Uropath.

III. FUTURE CONSIDERATIONS

While the Reassignment Rule and Self-Referral Rule will either have no effect on Uropath-managed pathology labs, or may be accommodated by a Uropath-managed lab with reasonable changes to premises, contractual relationships, or other business mechanics, the more serious long term threat to the Uropath business model is the apparent decision made by CMS that pod labs are by definition abusive arrangements which must be regulated out of business. The following conclusory statements provide insight into CMS's institutional perspective on pod lab arrangements:

1. "We are concerned that allowing physician group practices . . . to . . . contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services . . . ." 71 FedReg 49054 (August 22, 2006).

2. "[C]ommenters stated that pod lab arrangements are subject to fraud, waste, and abuse, including but not limited to . . . medically unnecessary biopsies, kickbacks, fee-splitting, referrals that would otherwise be prohibited under the [Stark Law]. . . . [W]e shared the commenters concerns." 71 FedReg 49055.

HEIDI M. McNANEY-FLINT MD, PA
ERIKA CIURSO R.N.C., M.S.N., A.R.N.P.
863 S.E. Monterey Commons Blvd. / Stuart, Florida 34996
phone 772.781.3815
fax 772.781.3817

September 21, 2006

Department of Health & Human Services
ATTENTION: CMS-1502-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear HHS:

RE: DOCUMENT #1321-P

I am writing this to comment on the coverage of bone mass measurement tests that you address in CMS-1512-PN. The proposal appears to make changes to:

1) The five year work review,
2) To practice expense methodology change,
3) The deficit reduction Act,
4) The conversion factor,
5) Bone mass measurement tests.

I am a gynecologist practicing in Florida. I am performing bone density testing. I am against the proposed changes.

DEXA scanning was recently added as a preventative service, and these cuts go against your own initiative to increase utilization. These cuts will diminished the impact of the "healthy people 2010 initiative." Of all of the changes mentioned, the only one I can agree with is the requirement for steroid dosage at 5.0.

I think that you are underestimating the work component including physician time, intensity and skill detail. I think you are underestimating the technical component including the methodology for calculation of practice expenses.

It is hard to believe that you are reducing the current value of 3.0 to a value of 2.57. This is a decease of 18%. Under the DRA guidelines, you will reduce this further to 2.53% as this is the lower amount of the physician fee schedule versus the hospital outpatient rate.

The time, skill, and intensity involved in these tests are more than you are giving us credit for. Many patients have problems even just getting up on the table. Positioning patients can be problematic. Putting them in proper positions is sometimes uncomfortable and they have a tendency to move.

Continued

The scan is started, the few lines of image are evaluated, and the scan is stopped and the patient has to be repositioned appropriately. There is then the repositioning between doing the spine and both hips. The patient is totally repositioned from the spine DEXA to one hip and then the other. As you know, only one hip has to be scanned but most us feel that both hips are necessary. We are already scanning the second hip "for free", despite the fact that it takes additional time and positioning. This will impact patients in that only one hip will be scanned for the most part.

It appears that the assumptions used to recalculate the MPFS are inaccurate. It almost appears as if this is just a trial and error type policy. It is also my understanding that inaccurate data was used to calculate bone densitometer. My understanding is that you depended on pencil being information when most of us use a fan beam and the majority of systems sold use the fan beam.

In addition, some adjustment was made because equipment was not utilized 50% of the time and this is just not true.

I think that you need to delay the DRA until a complete and thorough analysis can be conducted using true cost figures based on the appropriate technology.

Your immediate attention in this matter will be greatly appreciated.

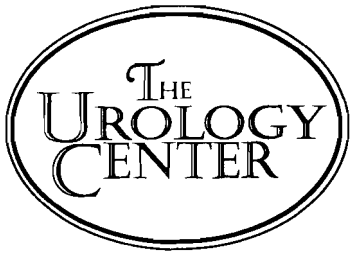
Respectfully,

HEIDI M. McNANEY-FLINT, M.D.

HMCF/pb

New line provider of DEXA services for now.

P.S. If the reimbursement falls below a critical value, which are changes will cause it to do, then many of us will not be able to provide the services and patients will go without necessary evaluation and management.



Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS – 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

On August 22, 2006, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2007 (the "**Proposed Rule**"). The Proposed Rule includes at Section II.I. two rules related to diagnostic tests that are of particular importance to Uropath: (i) proposed changes to existing Medicare reassignment rules (the "**Reassignment Rule**"); and (ii) proposed changes to existing physician self-referral regulations (the "**Self-Referral Rule**"). The Reassignment Rule and Self-Referral Rule and the preamble language discussing them make clear that CMS views small centralized pathology laboratories as significant fraud and abuse risks, though the basis for this conclusion is unknown.

Uropath has prepared this letter to share with its client group practices Uropath's perspective on the potential impact of the Reassignment Rule and Self-Referral Rule on Uropath's business model, to advise group practices of what Uropath believes to be the bases for CMS' contention that these pathology laboratories present fraud and abuse risks, and to voice Uropath's concerns with respect to the suppositions CMS relies on in reaching its determinations with respect to these pathology laboratories. **The analysis, discussion and legal reasoning contained herein are designed to serve only as a structural framework for the consideration of these issues by attorneys or other persons that you retain to review and analyze these issues on your behalf, and on whose opinion you may be entitled to rely. The issues discussed herein are by no means, and are not intended to be, exhaustive of the legal issues that may present themselves in connection with the Proposed Rule. This letter is not, and should not be construed as legal or regulatory advice.**

CMS states that the Reassignment Rule and Self-Referral Rule are designed to address two separate but related concerns. First, recent changes to Medicare rules on reassignment have led to confusion as to whether existing

RICHARD J. DEAN, M.D. • RALPH J. DEVITO, M.D. • DAVID G. HESSE, M.D. • STANTON C. HONIG, M.D. • THOMAS V. MARTIN, M.D.
ARNOLD M. BASKIN, M.D., FOUNDER, EMERITUS

THE UROLOGY CENTER P.C., 330 ORCHARD STREET, SUITE 164, NEW HAVEN, CT 06511 • 203-789-2222 FAX: 203-624-3697
EAST SHORE MEDICAL CENTER, 6 WOODLAND ROAD, MADISON, CT 06443 • 203-245-8824
MEDICAL CENTER OF ORANGE, 339 BOSTON POST ROAD, ORANGE, CT 06477 • 203-795-6380
SPRING GLEN MEDICAL CENTER, 2200 WHITNEY AVENUE, HAMDEN CT 06518 • 203-288-3526

Medicare anti-markup rules apply to situations in which a reassignment has occurred pursuant to a contractual arrangement. Second, CMS believes certain business arrangements that are proliferating are not within the intended purpose of physician self-referral laws, which permit physician group practices to bill for services furnished by a contractor physician in a "centralized building." CMS specifically identified remotely located centralized pathology laboratories, or "pod labs" as such an arrangement. It is for these reasons CMS proposed the changes discussed below.

I. THE REASSIGNMENT RULE

A. The Rule

CMS is proposing the Reassignment Rule to clarify how purchased test and purchased test interpretation rules apply in the context of a contractual reassignment. Apparently, some providers are using the more flexible reassignment provisions to avoid application of the anti-markup provisions to the billing of "purchased" tests. CMS is proposing to incorporate into its reassignment regulations provisions similar to those that currently appear in its regulations and in the Medicare Reimbursement Manual relating to the billing of purchased diagnostic tests.

Current law provides that if the technical component (the "**TC**") of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of the costs charged by the performing supplier to the billing physician, or the performing supplier's reasonable charge. This is known as the "**Anti-Markup Provision**." The Anti-Markup Provision definitively applies to situations in which a group practice purchases a TC from an independent supplier and then bills the payor as though the group practice actually performed the service. The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate.

The Social Security Act also generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This provision has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. Prior to 2003, a physician could reassign his or her rights to bill and receive Medicare payment under a contractual arrangement (as opposed to an employee-employer relationship) only if the services being paid for were performed on the premises of the assignee. Section 952 of the Medicare Modernization Act of 2003 ("**MMA**"), however, extended this general reassignment exception to any contractual arrangement regardless of whether the services were being performed on the premises of the billing entity. CMS believes that the broadening of the reassignment exception has allowed the proliferation of pod labs, which CMS has concluded without identifiable evidence are subject to fraud, waste and abuse.

First, to address perceived abuses, the Reassignment Rule provides that any reassignment made pursuant to the MMA is subject to roughly the same rules that apply to the billing of purchased diagnostic tests under the Anti-Mark Provision. Specifically, CMS proposes to amend the reassignment regulations to provide that if the TC of a diagnostic test is billed by a physician or medical group under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity may not exceed the lower of the physician's net charge, the billing physician's actual charge, or the physician fee schedule amount under Medicare regulations. The Reassignment Rule would also require that in order to bill for the TC of a diagnostic test, the billing entity must also perform the professional interpretation of the test (the "**PC**").

Second, CMS is considering, but is not proposing in the Proposed Rule, the imposition of additional conditions governing when a physician or medical group can bill for a reassigned PC. These conditions would include:

(i) the test must be ordered by a physician that is financially independent of the person or entity performing the TC and also of the physician or medical group performing the PC;

(ii) the physician or medical group performing the PC does not see the patient; and

(iii) the physician or medical group billing for the PC must have performed the TC.

Finally, in additional to the proposed amendments and considered amendments, CMS is seeking specific comment on the following issues:

1. Whether radiology and imaging services should be excepted from the proposed reassignment provisions;

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B. Analysis

The Reassignment Rule is principally an amendment of 42 CFR § 424.80(d)(3). In pertinent part it would provide that certain billing limitations exist if "a physician or medical group bills for the [TC] of a diagnostic test . . . following a reassignment involving a contractual arrangement with the physician or other supplier who performed the [TC]." While it is clear that CMS intends with this and other proposed regulations to make it infeasible for pod labs to continue to exist, Uropath does not believe the Reassignment Rule will affect that manner in which Uropath-managed labs currently provide and bill for the TC of pathology services.

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First, the Stark Law definition of a "Physician in the Group Practice" assumes that an independent contractor physician may provide services for a group practice, provided they are performed on the group's premises, and in fact requires that the agreement between an independent contractor physician and a group practice comply with the Medicare reassignment regulations. The Physician Services and the In-Office Ancillary Services Exceptions to the Stark Law expressly require that a group practice bill for services provided by such physicians. It would be inconsistent for the Stark Law and Medicare regulations to require or even permit a group practice to bill for services that reassignment regulations suggest are not in fact provided by the group practice through its contracted physicians. Second, this interpretation would prohibit a group practice from utilizing a locum tenens physician to provide the PC of diagnostic tests, since those tests would not be directly provided by the group, and thus would prohibit a group from billing for the TC of the same test.

We believe a more reasoned interpretation of this element is to require that a group billing for the TC of a diagnostic test be the same entity that is providing and billing for the actual interpretation, and that those services must be provided on the group practice's premises. This would eliminate existing arrangements in which a group practice outsources to a supplier the TC of a diagnostic test for which the supplier bills Medicare, and then independently contracts with a physician to provide the PC of the test for which the group practice bills under reassignment for a profit. It would also eliminate arrangements where a group practice contracts with a pathology group to provide technical staff and supervision for the TC of tests in the group's premises and for which the group practice bills, in exchange for the pathologist getting an exclusive contract to provide and bill for the PC in his own name. We believe both of these models are utilized by competitors of Uropath. This new requirement would not implicate a Uropath-managed lab, because group practices globally bill for the TC provided by its leased staff and the PC provided by its independent contractor pathologist.

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To address this concern, the Self-Referral Rule proposes to modify the definition of "centralized building" to require a minimum square footage of 350 feet. The minimum area requirement would not apply to space owned or rented in a building in which no more than three group practices both (i) own or lease space in the same building and (ii) share the same "physician in the group practice" (meaning independent contractor physician). CMS flatly states the purpose of this square footage requirement and the related exception is to prevent abusive arrangements such as pod labs, while not disqualifying legitimate, stand-alone physician offices that are unusually small.

Further, CMS would require that the centralized building contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services that are performed on the premises in order to meet the definition of a "centralized building." CMS believes this requirement would prevent pod labs from moving equipment from lab to lab to minimize overhead for a centralized building.

In addition to these proposed revisions, CMS is also considering, but not proposing in the Proposed Rule, the following:

1. Whether to require that, for a space to qualify as a centralized building, the group practice must employ in that space a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours a week; and

2. Whether a group practice should be allowed to maintain a centralized building in a state different than the state(s) in which it has a clinical office, or whether other restrictions on the location of such premises should be implemented.

CMS specifically states that it anticipates the restrictions on marking up the TC of diagnostic tests, the considered limitations on who can bill for the PC of diagnostic tests, and the square footage limits and requirements of having necessary equipment on site in a "centralized building" will make it financially infeasible for pod labs to exist. CMS is even seeking comment on whether its' proposed and considered amendments will be likely to reduce the number of existing pod labs and discourage the development of new ones.

B. Analysis

The Self-Referral Rule amounts to one change to the "centralized building" prong of the In-Office Ancillary Services Exception to the Stark Law: If a group practice contracts with a physician to provide professional services on its behalf in a centralized building, and that physician also contracts with more than two other group practices to provide professional services in the same building, the group practice's centralized building must be larger than 350 square feet. Presumably, CMS chose 350 square feet because it believed that pod labs are larger than that, though it has sought comment on whether the area requirement should be more or less than 350 square feet. If a group practice's lab is larger than 350 square feet, this change is irrelevant, and if a group practice's independent contractor pathologist contracts with fewer than four groups in the same building, the change is irrelevant.

Most Uropath-managed labs are located in medical office buildings that contain as few as five and as many as fifteen other pathology laboratories that Uropath manages. Because CLIA regulations permit a single physician to serve as laboratory director of up to five pathology laboratories, most pathology laboratories contract with an independent pathologist who has also contracted with at least four other laboratories in the same building. In addition, many group practices also contract with a secondary pathologist to provide pathology services in the absence of its primary pathologist, so a single independent contractor pathologist may contract with as many as ten groups in a single medical office building.

Assuming that each pathology laboratory contracts with a pathologist who has also contracted with more than three other groups in the same medical office building, the square footage limitations in the Self-Referral Rule will apply to Uropath-managed pathology labs. Some of the pathology laboratories Uropath manages are smaller than 350 square feet, while some of them are not. It is possible that modifications can be made to existing pathology laboratories so that they exceed the minimum square footage requirement.

In the event a modification of the centralized building is not possible, a group practice could also comply with the new requirement by contracting with an independent pathologist who contracts with no more than two other pathology laboratories in the same medical office building. This would limit the number of group practices in a single medical office building that a single independent pathologist could contract with. Currently, Uropath is identifying group practices whose labs are smaller than 350 square feet so that Uropath and those group practices can plan for any necessary accommodations.

The Self-Referral Rule also requires that a "centralized building" contain, on a permanent basis, the necessary equipment to perform substantially all of the pathology services that are performed in the space. Uropath-managed pathology labs will have no problem complying with this new requirement. As a threshold matter, CLIA regulations require that certain equipment, materials, and supplies be available in the pathology laboratory in order for it to be licensed to provide pathology service. In addition, Uropath has taken the position that the In-Office Ancillary Services Exception to the Stark Law requires that a group practice's centralized building be independently equipped with all necessary equipment to provide the services it provides. It is for that reason that the compliance policy Uropath provides to all group practices, entitled "Provision of Services at Remote Pathology Labs Under Stark Law" requires at Section IV.B 3 (b) that each lab be independently equipped, and at Section IV.B 3 (d) that under no circumstances should a lab share laboratory equipment necessary for the provision of pathology services. This requirement may adversely affect the business arrangements utilized by pathology provides that are in competition with Uropath.

III. FUTURE CONSIDERATIONS

While the Reassignment Rule and Self-Referral Rule will either have no effect on Uropath-managed pathology labs, or may be accommodated by a Uropath-managed lab with reasonable changes to premises, contractual relationships, or other business mechanics, the more serious long term threat to the Uropath business model is the apparent decision made by CMS that pod labs are by definition abusive arrangements which must be regulated out of business. The following conclusory statements provide insight into CMS's institutional perspective on pod lab arrangements:

1. "We are concerned that allowing physician group practices . . . to . . . contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services . . . ." 71 FedReg 49054 (August 22, 2006).

2. "[C]ommenters stated that pod lab arrangements are subject to fraud, waste, and abuse, including but not limited to . . . medically unnecessary biopsies, kickbacks, fee-splitting, referrals that would otherwise be prohibited under the [Stark Law]. . . . [W]e shared the commenters concerns." 71 FedReg 49055.

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3. "[S]everal commenters strongly criticized the centralized building prong of the in-office ancillary services exception. [It] encourages numerous abusive arrangements that are designed solely to permit groups to bill in circumvention of the [Stark Law prohibitions]. Commenters objected to medical groups establishing satellite DHS facilities, sometimes in different states, especially to capture ancillary income. Several commenters identified pod labs that rent space to urology labs as among the types of abusive arrangements that are proliferating." Id.

4. "[T]he purpose of the square foot minimum and the exception is to prevent abusive arrangements such as pod labs . . . ." 71 FedReg 49057.

5. "We believe that the proposed clarification to our reassignment rules, in tandem with our proposed changes to the definition of "centralized building" . . . would prevent abusive arrangements . . . . In particular, we anticipate that [these changes] would not make it financially feasible for pod labs to exist." Id.

CMS appears to have concluded that pod labs are abusive arrangements that are subject to fraud and abuse without providing any evidence supporting that conclusion.[1] The CMS representative with whom Uropath's counsel spoke explained that the primary focus of the Reassignment Rule and the Self-Referral Rule is to eliminate pod labs. Uropath-managed labs may be able to continue to operate after implementation of the Proposed Rule, but unless CMS is persuaded to reexamine its belief that pod labs are inherently abusive, it may simply continue to implement new rules and regulations until it finds one that pod labs can no longer accommodate.

CMS's perspective on the propriety of pod labs has been heavily influenced by comments from special interest groups that have lost business to pod labs. Those comments are premised on the theory that if profit can be realized from the ordering of ancillary services, over-utilization will occur. Many comments appear to have highlighted to CMS structural aspects of pod lab arrangements that appear unusual or peculiar in an attempt to infer that pod labs have engineered an inefficient model for delivering pathology services simply to conform with fraud and abuse laws which were designed to prevent such a model.

Uropath agrees with CMS that additional safeguards regarding business arrangements under which pathology services are delivered are appropriate. For example:

.0[1] This is similar to the specialty hospital moratorium enacted in 2003, in which Congress froze the development of new physician owned hospitals and the growth of current ones while administrative agencies conducted studies to determine whether, in fact, such hospitals compromised care or resulted in increased costs to government health care programs. Neither assertion was validated by interim studies, and the specialty hospital moratorium expired under its own terms in 2005.

A. Uropath agrees with CMS that an independent contractor physician of a group practice should only be able to provide professional or technical services on behalf of the group practice, and for which the group practice bills and collects, if the services are provided on the premises of the group practice. Uropath has always believed the definition of "Physician in the Group Practice" in the Stark Law Regulations requires this. Uropath's draft compliance plan for group practices requires that a pathologist provide his supervision and professional reads on behalf of the group in the group practice's pod lab. This rule would discourage the contractual reassignment of services by providers whose only relationship with the billing entity exists on paper.

2. Uropath agrees that if a group practice intends to bill for the technical component of a diagnostic service, it ought to also perform the professional component of that same service. This is particularly true when the technical component in question is performed under the supervision of the same physician. This rule would eliminate situations in which a pathologist agrees to serve as an independent contractor of a group for purposes of supervision, in exchange for providing and billing for the professional component of the same service in the physician's own name.

3. Uropath strongly agrees that any centralized building used for the provision of designated health services should contain on a permanent basis the necessary equipment to perform substantially all of the services that are performed in the space. Again, Uropath has always contended that this is a requirement of the In Office Ancillary Services Exception and/or existing CLIA regulations. Uropath's draft compliance plan for group practices requires that each laboratory contain all necessary equipment and supplies, and that no pod lab shares equipment or supplies with another.

Other proposed or considered rules, such as the minimum square foot requirement, are intended solely to eliminate pod labs without any justification. There is no evidence that pod labs present fraud and abuse risk to the Medicare program. And more importantly, the Proposed Rule is devoid of any discussion regarding the quality of pathology services that can be delivered by a pod lab as compared with the outsourcing of pathology to an unknown third party. Contrary to what their opponents believe or assert, pod labs actually improve patient care and in some cases reduce costs to the Medicare program.

Uropath is preparing comprehensive, substantive comments to the "Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests" which are set forth in Section II.I of the Proposed Rule, and which can be found beginning at page 49054 of Volume 71 of the Federal Register (August 22, 2006 edition). Uropath expects to submit comments:

(i) in support of proposed and considered rules which it believes will maintain or improve the quality of urological pathology services without exposing the Medicare program to risk of fraud and abuse;

(ii) in opposition to proposed and considered rules which it believes single out remotely located centralized pathology laboratories without any evidence to support the contention that these facilities expose the Medicare program to fraud and abuse;

(iii) articulating the ways in which Uropath-managed pathology laboratories improve the quality of urological pathology;

(iv) articulating the reasons that the purported fears of over-utilization, kickbacks, and the performance of medically unnecessary biopsies which precipitated the Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests either do not exist or have limited application to medical clinical decisions regarding the performance of a prostate biopsy; and

(v) presenting facts which refute allegations made by opponents of "pod labs" that such labs utilize peculiar and/or unorthodox business practices solely to capture ancillary pathology revenue at the expense of the Medicare program.

Uropath encourages all group practices to submit comments to CMS with respect to the Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests. Comments must be delivered to CMS by October 10, 2006, and the acceptable methods for delivering these comments are set forth at page 48982 of the Federal Register. Uropath believes that group practices are in the best position to present to CMS compelling evidence that their internal pathology laboratories provide a superior pathology service to urologists and their patients without additional cost to Medicare. In preparing your comments, you may wish to consider the following points which Uropath has identified and is using as organizational guideposts in preparing its submission to CMS:

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

2. CMS proposes these rules to address perceived program abuse caused by pod labs, but there exists no substantive evidence to support the premise that pod labs have resulted in the over-utilization of services, the provision of unnecessary medical services, kickbacks, fee-splitting, or any other program abuses. Uropath data and group practice data (including data provided to the OIG Office of Audit Services in 2005) confirm no over-utilization or other program abuse is occurring.

3. Unlike radiology turf battles, where physicians in other specialties seek to provide professional radiological services otherwise performed by radiologists, Uropath pod labs utilize licensed and board certified pathologists to provide all supervisory and professional services. Opponents of pod labs are universally non-physician reference lab owners, pathology group practices, or special interest groups composed of those persons, who stand to lose revenue with the in-housing of urological pathology. This is a physician food fight that the government traditionally does not and should not try to legislate.

4. Most clinical indications and other evidence of prostate cancer which give rise to prostate biopsies are not subjective. Unlike the criteria supporting the upcoding of pneumonia, for example, elevated PSA counts, DRE results, [other data], age, prior medical history, are not susceptible to manipulation to support the ordering of medically unnecessary biopsies. The ratio of positive samples to total samples at Uropath-managed laboratories supports this.

5. Several factors other than profit have resulted in increased prostate biopsy services and related pathology, including but not limited to: (i) changes in the number of specimens interpreted by a pathologist for a single patient required by the applicable medical standard of care for prostate biopsy pathology; (ii) a larger and still growing patient population in the age ranges in which prostate cancer is most prevalent; and (iii) alternative prostate cancer treatment methodologies (IMRT, chryotherapy) may require subsequent biopsy procedures to ensure positive outcomes.

6. Elements of pod labs criticized by opponents are often utilized by those same entities to game the Medicare system. For example, commenters criticized that the location of pod labs may be several states from where a group practice's clinical offices are located. But large reference labs locate their national pathology labs in Connecticut and Warren, Michigan, where Medicare reimbursement for the most common prostate biopsy code is almost 20% higher than the reimbursement rate in locations where Uropath managed labs are located. This forum shopping costs Medicare between $10 and $20 per billable code.

7. Uropath ensures that every pathologist that reviews specimens used in the care and treatment of a patient are licensed in both the state where they work and the state where the patient is located. This ensures compliance with state law, a prerequisite for billing Medicare. Large reference laboratories receive specimens from many states across the country, and may employ pathologists licensed in those states, but do not have a procedure for ensuring that every specimen for a given state is actually interpreted by the pathologist licensed in that state.

8. Uropath managed pathology laboratories provide a superior pathology product which results in better patient care. Some examples of this are:

   (i) Utilizing a single pathologist to provide all prostate biopsy pathology work for a group practice provides consistency interpretations;

(ii) Utilizing a single pathologist for the provision of all prostate biopsy pathology services for a single group practice allows the single group practice to prioritize and enjoy more meaningful personal consultation with their pathologist regarding his or her findings;

(iii) By focusing solely on the pathology of prostate biopsies, an individual pathologist becomes more competent and consistent in rendering interpretations related to the detection of prostate cancer;

(iv) Based on the independent contractor relationship between pathologists and group practice, the pathologist has a meaningful opportunity to discuss with the group practice best practices with respect to the removal, storage, and transportation of human tissue from clinical office to pathology laboratory;

(v) By having direct supervisory control over the non professional medical personnel responsible for preparing pathology slides for interpretation, the pathologist is in the best position to influence best practices regarding the preparation of human tissue for pathological interpretation; and

(vi) Uropath typically manages many labs in a single complex, requiring the full time services of two or more pathologists, all of whom are dedicated exclusively to urological pathology. This provides each pathologist with meaningful professional consultation on site at their laboratories with other full time urological pathologists.

Uropath plans to aggressively communicate with CMS and Congressional leaders to present its case on why the labs it manages provide superior urological pathology without any undue risk of program abuse, and will keep you advised of our efforts. We hope this information is helpful to your group practice in understanding the proposed rules and in formulating an appropriate response. Do not hesitate to contact us if we can be of further assistance. Our main phone number is (203) 789-2222, or you can reach us by calling one of our private numbers: (203) 867-4378, (203) 867-4383, (203) 867-4385 of (203) 867-4384. We can also be reached via email at: office@urologycenter.com

Respectfully submitted,

R DeVito, MD

Ralph J. DeVito, M.D.
Managing Partner

The Urology Center, P.C.

120

Radiation Oncology
Mississippi, P.A.

Gregg A. Dickerson, M.D.
Richard B. Friedman, M.D.
S. Albert Johnson, Jr., M.D.
David A. Wahl, M.D.
Steven E. Zachow, M.D.

September 25, 2006

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

Attention: Physician Fee Schedule Rule #CMS-1321-P

Dear CMS Administrator:

I am the President of the Mississippi Radiological Society, a Fellow of the American College of Radiology, and a Diplomate of the American Board of Radiology. I practice at St. Dominics / Jackson Memorial Hospital in Jackson, MS.

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

With the prevalence of breast cancer, I urge CMS to reconsider the proposed Work RVU reduction for Brachytherapy. What CMS is proposing - a 2007 work RVU stated to be 0.33 reduced down to that number from 0.53 in 2006 - is what I consider a drastic cut in the professional component for breast brachytherapy services. The reduction CMS is proposing will have a detrimental impact on my ability to offer the Brachytherapy / Partial Breast Irradiation Therapy treatment to my Medicare patients

Access to Brachytherapy is critical so that women, who cannot undergo 7 weeks of conventional radiation therapy following conservative surgery, have an option other than radical and debilitating surgery. Brachytherapy allows the radiation process to be performed quickly allowing our rural patients to have access to conservative treatment and so that other treatments, such as chemotherapy, can be started in a timely fashion. The preparation and effort for planning & treatment is quite time consuming and proper catheter placement must be confirmed before each fraction is given. The CMS proposed reduction to all Brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for Brachytherapy. I must stress that if the reduction does take place, CMS will be limiting access to Brachytherapy for Medicare patients.

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

Regards,

Gregg Dickerson, M.D., FACR

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee MD, President, American Brachytherapy Society

P.O. Box 4997 / Jackson, Mississippi 39296-4997

Treatment Facilities

Central Mississippi Medical Center
Jackson, Mississippi
601-376-2074

Mississippi Baptist Medical Center
Jackson, Mississippi
601-968-1416

St. Dominic Cancer Center
Jackson, Mississippi
601-200-3070

121-0
4

VASCULAR CENTER OF
NEPHROLOGY ASSOCIATES OF NORTHERN VIRGINIA

BOARD CERTIFIED IN NEPHROLOGY
DAVID L. MAHONEY, M.D.
VARSHASB BROUMAND, M.D.

13135 LEE JACKSON MEMORIAL HWY.
SUITE #145
FAIRFAX, VIRGINIA 22033

September 22, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

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 Dr. McClellan:

I am writing to you as a physician practicing both clinical Nephrology and Interventional Nephrology in the largest private practice Nephrology group in Northern Virginia. Our practice serves over six hundred dialysis patients and is constantly seeking ways to improve both the care we deliver and the cost-effectiveness of that care. In the past year we have opened a vascular access center for management of dialysis accesses and to date have performed approximately five hundred access procedures in the center.

Interventional Nephrology is a new and growing sub-specialty in medicine. As nephrologists deal with vascular access every day in providing dialysis to our patients, it has become evident that we must take a more proactive and "hands-on" role in the management of these accesses, often considered the "Achilles heel" of dialysis. Currently an inordinately high percentage of dialysis expenditure is for vascular access care. Numerous studies have demonstrated that compared to a hospital, a dedicated vascular access center can provide this care at significantly lower cost, with higher procedure success rates, greatly reduced hospitalization rates, and lower complication rates. Equally importantly, patient satisfaction rates are higher, and the outpatient vascular access centers enable prompt return to the outpatient dialysis center, precluding the need for more expensive dialysis treatments in the hospital, which frequently occur with hospital-centered access care.

In light of the clinical and financial record of these dedicated outpatient centers, I am writing to you to express my grave concern regarding the CMS 2007 Update to the PE RVUs for Interventional Radiology CPT codes. The proposed changes reflect drastic cuts to the PE RVUs for interventional radiology, and will affect quite adversely the very

centers which carry the greatest potential to offer to dialysis patients improved outcomes at substantially less cost than traditional hospital-based intervention.

I believe that every physician in practice today understands the need to make difficult budgetary decisions regarding CMS funds. However, the proposed practice expense reductions for interventional radiology may serve as a significant disincentive for nephrologists to consider providing what has proved to be a dramatic source of cost savings in dialysis care. A significant portion of our center's vascular access procedures involve imaging, and the proposed cuts would significantly impact upon our ability to provide these services to our patients. These proposed cuts may result in the return of patients exclusively to hospital-based vascular access care, which is often two to three times the cost of procedures performed in a dedicated vascular access center.

In addition, we are concerned that the reductions did not consider the costs of providing imaging services. For example, a significant driver of costs is tied to the equipment. The current system does not have a specific mechanism for capturing those costs, and they may have been overlooked.

I thank you for your kind consideration of my concerns. I believe that in dialysis care, we must look at "best practice" means of cost savings. In the field of vascular access, nephrologists are finally taking a much more active role in the planning, creation, and maintenance of vascular access. Our goal is to promote the creation of fistulas (as opposed to catheters or synthetic grafts) which have a high rate of primary successful development, are monitored closely for adequate and timely maturation, and are maintained such that function is optimal for long-term dialysis adequacy. Ideally, this will result in fewer access revision surgeries, fewer hospitalizations, fewer unnecessary dialysis catheter placements, and improved patient outcomes. Your support of these goals by reconsidering the funding changes will not only lead to improved outcomes for our patients, but an overall enormous savings to CMS.

Respectfully submitted,

David L. Mahoney MD

September 22, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

RE: Federal Register, Volume 71, No. 162, Page 49065, August 22, 2006, Proposed Rules for Blood Glucose Testing

Dear Sir / Madam:

I would like to bring to your attention an inequity that is being forced upon the Skilled Nursing Home (SNF) industry. The Centers for Medicare & Medicaid Services (CMS) has posted a proposed regulation in the above captioned federal register that materially disadvantages SNFs. I believe the proposed rule for blood glucose testing does not meet the spirit and intent of the Medicare program. The proposed regulation is unduly restrictive and contrary to the Act, the governing regulations, inconsistent with Medicare's National Coverage Decision (Program Memorandum-AB-02-110) and contrary to standards of medical practice.

The NCD (PM-AB-02-110) recognizes that blood glucose testing is necessary for patients with diabetes and other defined medical conditions. The NCD specifically states that testing "using a device approved for home monitoring or by using a laboratory assay system using serum or plasma" is covered. It is also clear that this coverage determination encourages use of devices for home monitoring. The NCD goes on to say that the "convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting (underline added). The NCD does not place any specific limitations on the frequency of testing. In fact the NCD simply states that "frequent home blood glucose testing by diabetic patients should be encouraged."

Thru the above proposed regulation CMS seeks to install unrealistic requirements in order for an SNF to be reimbursed for Medicare Part B blood glucose services. CMS proposes to set aside current standards of medical practice in favor of an unrealistic, burdensome physician notification requirement. CMS is seeking to require an SNF to notify a physician on every blood glucose test performed in order to be paid for the service. CMS proposes to eliminate the physician's standing order system, the current standard of medical practice, which is the system by which a physician cares for a patient in an SNF. The standing order works like this. A physician orders blood glucose testing usually based on a sliding scale for a month at a time. These are explicit instructions to the attending RN to provide X amount of insulin for Y reading with instructions for immediate physician contact on outlier readings (unreasonably high or low readings). The physician reviews the results of these tests on his monthly visit, considering changes in

Ocean Promenade Nursing Center, Inc. • 140 Beach 113th Street • Rockaway Park, New York 11694
Tel: (718) 945-6350 • Fax (718) 945-1206

patient's diet, change of medications that may affect glucose levels, physical or cognitive issues etc. The physician either modifies or renews his testing and insulin orders as a result of his review of the test results achieved. It is ludicrous to expect a physician to be contacted several times a day to transmit test results and it is certainly contrary to current standards of medical practice.

CMS Pub 100-8 Chapter 13.5.1 states that in pertinent part that a service is considered reasonable and necessary when "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition", is "ordered and furnished by qualified personnel" and "meets, but does not exceed, the patient's medical need." In an SNF the accepted standard of medical practice is for the physician to order these glucose tests to treat the patient. Orders are executed by an RN qualified to administer the test, read the results and act on the physician's order to dispense insulin. These procedures are the "accepted standard of medical practice" today. For this proposed regulation to summarily state that a physician's standing order will not be acceptable as reasonable and necessary clearly violates Pub 100-8 Chapter 13.5.1.

It is interesting to note that CMS does not apply the above standard uniformly through out all the covered services paid by Medicare. For example; enteral services are paid under Medicare Part B. The doctor executes a Certificate of Medical Necessity (CMN) for a patient under his care that is in effect for as long as the patient remains on that service. The doctor is not required to constantly update this order. It is a standard medical practice to continue an order for a required service until such time as the service needs to be changed or terminated. Enteral services are required to keep the patient alive. Blood glucose services are needed to ensure that a patient does not go into diabetic shock. Both services are administered by nursing staff authorized and trained to do so. Both are required services to ensure the health and safety of the patient. Yet blood glucose has an unrealistic physician notification requirement.

For the reasons cited above I respectfully request that your office intervene on behalf of the SNF industry to instruct CMS to modify the proposed regulation to conform to the cited authorities and accepted standards of medical practice prevalent in the medical community today. To deny an SNF from availing itself of state of the art medical technologies and techniques to care for their residents in favor of a restrictive, not realistic, draconian approach to patient care effectively shifts the cost of practicing good patient care to the SNF. Instead CMS should be issuing instructions to their Fiscal Intermediaries through regulatory changes and updates to conform to the aforementioned NCD developed under the authority of the Negotiated Rulemaking Act and standard medical practices.

I look forward to your response and help in providing immediate intervention with CMS to eliminate the proposed regulation and ensure that our aged population continues to receive optimal medical care.

Respectfully Yours,

A.Y. Grunewald

Akiva Grunewald
Administrator

collaboratively with the clinical laboratory community on these issues.

b. Blood Glucose Monitoring in SNFs

In response to inquiries regarding our policy on blood glucose monitoring in SNFs, we are taking this opportunity to restate our long-standing policy on coverage of blood glucose monitoring services and to propose to codify physician certification requirements for blood glucose monitoring in SNFs.

Generally, section 1862(a)(1)(A) of the Act requires that a service be reasonable and necessary for diagnosis and treatment in order to be eligible for coverage by Medicare. Our regulations at § 410.32(a) already require that, for any diagnostic test, including a clinical diagnostic laboratory test, to be considered reasonable and necessary, it must be both ordered by the physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

In the context of blood glucose monitoring, we most recently stated this policy in Transmittal AB–00–108, "Glucose Monitoring", which is available on our Web site at *http://www.cms.hhs.gov/transmittals/downloads/ab00108.pdf*. This interpretation of § 410.32 is also the basis for our policy in Chapter 7 of the Medicare Claims Processing Manual ("Skilled Nursing Facility Part B Billing" available on our Web site at *http://www.cms.hhs.gov/manuals/downloads/clm104c07.pdf*.)

In addition, section 1835(a)(2)(B) of the Act provides that, in the case of certain "medical and other health services" (including clinical diagnostic laboratory services), payment may be made for Part B services that are furnished by a provider of services only if a physician certifies—and recertifies where those services are furnished over a period of time, with such frequency, and accompanied by such supporting material, as may be provided by regulation—that those services were medically necessary. The regulations currently implementing this provision at § 424.24 do not specifically address the issue of blood glucose monitoring in SNFs. Therefore, we are proposing to amend § 424.24 to provide that, for each blood glucose test furnished to a resident of a SNF, the physician must certify that the test is medically necessary. We are also proposing to amend § 424.24 to clarify that a physician's standing order is not sufficient to order routine blood glucose monitoring.

c. Other Lab Issues—Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

We are proposing to add a new § 414.410 to address concerns that have been raised regarding the date of service of a clinical diagnostic laboratory test that use a stored (or "archived") specimen. In the final rule of coverage and administrative policies for clinical diagnostic laboratory services that we published on November 23, 2001 (66 FR 58792), we adopted a policy under which the date of service for clinical diagnostic laboratory services genarally is the date the specimen is collected. For laboratory tests that use an archived specimen, however, the date of service is the date the specimen was obtained from the storage. In 2002, we issued Program Memorandum AB–02–134 which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered archived. In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered "archived," in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the Federal Register on February 25, 2005 (70 FR 9355), we defined an "archived" specimen as a specimen that is stored for more than 30 calendar days before testing. The date of service for these archived specimens is the date the specimen was obtained from storage. Specimens stored 30 days or less have a date of service of the date the specimen was collected. The February 25, 2005 final notice also clarified that the date of service for tests when the collection spanned more than two calendar days is the date the collection ended. Instructions that implemented these policies were added to Chapter 16, section 40.8 of the Medicare Claims Processing Manual (Pub. 100–04) with the issuance of Transmittal 800 (CR 4156), on December 30, 2005.

Recently, we have received correspondence that expressed concern that our policies have created some unintended consequences, especially in situations in which a specimen is taken in a hospital setting, but then later used for a test after the patient has left the hospital. Under the current manual instructions, if the specimen used for a test ordered subsequent to the beneficiary's discharge is obtained less than 31 calendar days following the date the specimen was collected, the date of service of the test is the date of collection. The date of service of a test may affect payment because, if the date of service falls during an inpatient stay or on a day on which the beneficiary had an outpatient procedure, payment for the laboratory test usually is bundled with the hospital service. To address these concerns, we are proposing to change our current policy so that the date of service would be the date the specimen is obtained from storage, even if the specimen is obtained less than 31 days from the date it was collected, without violating the unbundling rules as long as the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

These conditions are consistent with the guidance in Chapter 16, sec 40.3 of the Claims Processing Manual, which states that "When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services."

In addition, Chapter 3 of the Program Integrity Manual contains instructions for additional documentation if further development of laboratory claims for pre-or postpay are required. Although we believe these changes will help to maintain beneficiary access to care, we are concerned about the potential for these policy changes creating inappropriate incentives in the development of technology and the implications for the unbundling of services. We solicit comment on the proposed changes and these concerns.

O. Proposal to Establish Criteria for National Certifying Bodies That Certify Advanced Practice Nurses

[If you choose to comment on issues in this section, please include the caption "Criteria for National Certifying Bodies-Advanced Practice Nurses" at the beginning of your comments.]

Federal regulatory qualifications for nurse practitioners (NPs) at 42 CFR 410.75 require that an individual be certified as an NP by a recognized national certifying body that has established standards for NPs. Similarly, Federal regulatory qualifications for clinical nurse specialists (CNSs) at 42

123

Central Kentucky Surgeons, P.S.C.

Practice Limited to General Surgery

John H. Lacy, M.D., F.A.C.S.
Paul P. DeLuca, M.D., F.A.C.S.

130 Daniel Drive • P.O. Box 129 Danville, Kentucky 40423-0129
Telephone: 859-236-2222 Fax: 859-236-2227
e-mail: surgeons@mis.net

September 16, 2006

Centers for Medicare and Medicaid Services
Department for Health & Human Services
Attention: CMS 1512-PN
P. O. Box 8014
Baltimore, MD 21244-8014

RE: Revisions to Payment Policies Under the Physician Fee Schedule

To Whom It May Concern:

This letter is regarding Medicare payment cuts scheduled to take effect on January 1, 2007. I am urging Congress and the Administration to act before October 10, 2006, to avert these cuts.

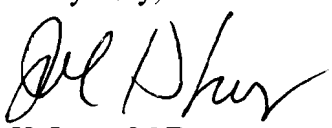
Because of this flawed and outdated formula, Medicare is scheduled to cut the physician payment rate by 5.1%. We already suffered a 5.4% cut in 2002.

Our office operates under a slim margin. Our expenses continue to increase for employees' salaries and benefits. The most striking increase is the increased cost of health insurance. We also need new computer systems and more employees to run our practice. Because of this we cannot tolerate reduction in Medicare payments. At some point we will have to limit the number of Medicare patients we see at our office if payment cuts continue. This is something we do not want to do.

It needs to be pointed out that the only physicians are subject to these deep payment cuts triggered by the sustainable growth rate (SGR). Hospitals, Medicare Advantage plans, home health agencies and skilled nursing facilities are subject to rate setting that is based on market based indices. These plans and providers have regularly received and will continue to receive regular annual increases based on the measure of medical inflation. Physician payment should also be tied into this. We cannot tolerate a 30% payment cut to physicians projected between 2006 and 2013 on this formula.

I urge you to repeal the sustainable growth rate formula and replace it with a fair and more predictable payment system. Doing so will bring much needed stability to the Medicare program.

Yours very truly,



John H. Lacy, M.D.

JHL/sss

cc: Senator Mitch McConnell
361-A Russell Senate Office Building
Washington, DC 20510

Congresswoman Anne Northrup
1004 Longworth Building
Washington, DC 20515

Congressman Hal Rogers
2406 Rayburn HOB
Washington, DC 20515

Senator Jim Bunning
818 Hart Senate Building
Washington, DC 20510

Congressman Ben Chandler
1504 Longworth Building
Washington, DC 20515

124-O
50

The Kidney and Hypertension Center

September 25, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

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 Dr. McClellan:

I am a practicing Nephrologist for The Kidney and Hypertension Center. Our practice is a leader in outpatient vascular access care. The Kidney and Hypertension Center has 24 physicians and another 60 employees and has served the Greater Cincinnati and Northern Kentucky area for the past 28 years. Our practice operates an outpatient vascular access center in Cincinnati which has successfully treated over 8,000 patients over the last four years.

Interventional nephrology is one of the newest and most rapidly growing specialties in medicine. We are on the leading edge of advances in imaging-guided minimally-invasive medicine. Procedures performed by interventional nephrologist -- through small catheters and other devices under radiological imaging -- are often less costly and significantly less invasive than alternative surgical therapies.

In light of our track record of clinical success, I am writing today to express my grave concern with CMS 2007 Update to the PE RVUs for Interventional Radiology CPT codes.

Impact – Work and PE RVU Changes for Interventional Radiology

I urge CMS to reconsider the drastic 2007 cuts to the PE RVUs for interventional radiology stemming from the changes to the PE calculation methodology.

My practice and I fully understand CMS need to make difficult budgetary decisions to maintain the solvency of the Medicare trust funds. However, we have serious concerns with the proposed practice expense reductions for interventional radiology. Per Table 7 of the CMS-1321-P, the

Steven Dumbauld, M.D., FACP, Danny Fischer, M.D., FRCP, Kenneth Newmark, M.D., Edward Sha, M.D., Amir Izhar, M.D., Tahir Sajjad, M.D., Antoine Samaha, M.D.

Medical Office Building Good Samaritan Hospital
3219 Clifton Ave., Suite 325, Cincinnati, OH 45220
513.861.0800 fax 513.861.5111

combined 2007 impact of Work and PE RVU Changes for Interventional Radiology is estimated to be -14%, the third hardest hit specialty.

A significant portion of our center's vascular access procedures involve imaging, and as such, these reductions will have a dramatic impact on our ability to treat patients. We would not want to see CMS inadvertently limit patients' access to convenient, efficient and clinically successful vascular access care. Their only alternative is to go back to the hospital for these services. This result is truly unfortunate since we can provide these services in their entirety for on average 30% - 40% of hospital rates.

In addition, we are concerned that the reductions did not adequately take into account the costs of providing imaging services. For example, a significant driver of costs is tied to the equipment. The current system does not have a specific mechanism for capturing those costs thus they may have been overlooked.

In closing, I thank you in advance for your thoughtful consideration of these comments. If I can further assist your understanding of the benefits of outpatient vascular access patient care, I would be delighted to do so.

Respectfully submitted,

Amir Izhar, M. D.
AI/nkj

125-0
9

Dr. Mark McClellan MD PhD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I wish to express my serious concern that the Center for Medicare & Medicaid Services proposed rule making adjustments in Medicare Part B practice expenses and relative work values severely cuts Medicare anesthesia payment without precedent or justification. We request the agency reverse these cuts.

The proposed rule mandates 7-8 percent cuts in anesthesiology and nurse anesthetist reimbursement by 2007, and a 10 percent cut by 2010. With these cuts, the Medicare payment for an average anesthesia service would lie far below its level in 1991, adjusting for inflation. The proposed rule does not change specific anesthesia codes or values in any way that justifies such cuts. In fact, during CMS' previous work value review process that concluded as recently as December 2002, the agency adopted a modest increase in anesthesia work values. Further, Medicare today reimburses for anesthesia services at approximately 37 percent of market rates, while most other physician services are reimbursed at about 80 percent of the market level. The Medicare anesthesia cuts would be in addition to CMS' anticipated "sustainable growth rate" formula-driven cuts on all Part B services effective January 1, 2007, unless Congress acts.

Last, hundreds of services whose relative values and practice expenses have been adjusted by the 5-year proposed rule have been subject to extensive study and examination. However, the proposed rule indicates no such examination has been made on the effects that 10 percent anesthesia reimbursement cuts would have no peoples' access to healthcare services, and on other aspects of the healthcare system.

For these reasons, I request the agency suspend it proposal to impose such cuts in Medicare anesthesia payment, review the potential impacts of its proposal and recommend a more feasible and less harmful alternative.

Thank you and Sincerely,

Judith Long of Duluth, MN

Judith Long CRNA

4627 Otsego
Duluth, MN 55804

126-0
17

DONALD L. POMEROY, M.D., PLLC

NITHIN C. REDDY, M.D.

4331 Churchman Ave.
Louisville, KY 40215
Telephone: (502) 364-0902

4001 Dutchmans Ln, Suite 1H
Louisville, KY 40207
Telephone: (502) 899-6277
Fax: (502) 899-6272

September 18, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS 1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Re: Revisions to Payment Policies Under the Physician Fee Schedule

To whom it may concern:

Unless Congress and the Administration act before October 10, the physician payment rate under Medicare will be cut by 5.1 percent effective January 1, 2007. Moreover, because of the arcane formula known as the sustainable growth rate (SGR), cuts of similar size are projected for several years into the future. The Association of Primary Care Physicians is asking you to stand up for America's seniors and the physicians who serve them by taking action this year to stop these drastic cuts.

Because of a flawed and outdated formula, Medicare cut the physician payment rate in 2002 by 5.4 percent. Additional cuts in 2003, 2004, and 2005 were averted by the passage of legislation that provided temporary relief. Physicians greatly appreciated this intervention by Congress and the Administration. But because the fundamental problems with the SGR formula were not addressed, repeated cuts in reimbursement are forecast for the foreseeable future.

The majority of physician practices are small businesses that operate on slim margins with ever increasing costs and do not have the resources to absorb sustained losses or steep payment cuts that are resulting from the SGR formula. Our physician practice can not continue to accept new Medicare patients at an economic loss to our practice. There will need to be significant reductions in services for current Medicare patients. Moreover, at a time when health information technology (H.I.T.) is being emphasized, significant and repeated cuts in the Medicare payment rate work contrary to investment in such technology.

It needs to be pointed out that only physicians are subject to these deep payment rate cuts triggered by the SGR. Hospitals, Medicare Advantage plans and home health agencies, skilled nursing facilities all are subject to rate setting that is based on market basket

DONALD L. POMEROY, M.D., PLLC

NITHIN C. REDDY, M.D.

4331 Churchman Ave.
Louisville, KY 40215
Telephone: (502) 364-0902

4001 Dutchmans Ln, Suite 1H
Louisville, KY 40207
Telephone: (502) 899-6277
Fax: (502) 899-6272

indices. These plans and providers have regularly received and will continue to receive annual increases based on the measure of medical inflation. Data from CMS and MedPac confirm that between 2006 and 2013, inpatient hospital payments are projected to rise over 30 percent while payments to physicians will plummet by the same amount.

As a physician concerned about the health and well being of my patients and our nation's elderly, I urge you to repeal the sustainable growth rate formula and replace it with a fair and predictable payment system. Doing so will bring much needed stability to the Medicare program and give America's seniors the confidence that their physicians' doors will remain open to them.

Sincerely,

Donald L. Pomeroy, M.D.

Cc: Senator Mitch McConnell
361-A Russell Senate Office Building
Washington, DC 20510

Congresswoman Anne Northup
1004 Longworth Bldg
Washington, DC 20515

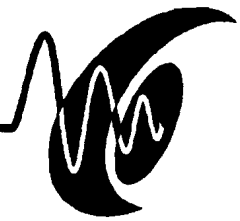
Congressman Hal Rogers
2406 Rayburn HOB
Washington, DC 20515

Senator Jim Bunning
818 Hart Senate Bldg
Washington, DC 20510

Congressman Ben Chandler
1504 Longworth Bldg
Washington, DC 20515

127

AMERICAN ACADEMY OF AUDIOLOGY



October 10, 2006

VIA ELECTRONIC MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS-1321-P -- Comments on the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2007

COMMENT TOPICS: PROVISIONS, IDTF ISSUES

The American Academy of Audiology (the Academy) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule (Proposed Rule).[1] The Academy is the world's largest professional organization of audiologists, and has over 10,000 active members who practice in medical centers, hospitals, private practice, schools, government or military health facilities, agencies, and colleges or universities. Our members provide state-of-the-art hearing and balance diagnostic services and treatment to Medicare beneficiaries exhibiting hearing impairment and balance disorders.

The Academy comments specifically on CMS-1321-P, the proposed rule that would implement the Medicare Physician Fee Schedule (MPFS) for calendar year 2007.

The Academy commented previously on CMS-1512-PN, the proposed notice that introduced fundamental changes to the MPFS practice expense (PE) methodology. In

those comments, we recommended that prior to implementing significant adjustments to payments, the new methodology should be independently validated, which could be done during the four-year transition period for the new PE methodology.

We have also urged CMS to establish work values for the audiology codes that currently have no assigned work RVUs. We are renewing this request and continue to believe that the assignment of work to these codes is the fairest and most consistent solution to the problem of insufficient payment and one that would make it unnecessary to create a special methodology to accommodate codes without work RVU's.

CMS has wisely chosen to remedy the payment problem associated with certain non-physician work pool (NPWP) codes by assigning work RVUs. CMS has proposed assigning work values to the Medical Nutrition Therapy codes, a demonstration that assigning work is a viable solution for former NPWP codes. In the interest of fairness, consistency, and accurate payment, the audiology codes should also be assigned work because there is professional work performed when the services corresponding to these codes are delivered. The professional work in these codes should be valued and paid relative to physician work. This approach should be taken with all current "zero" work codes. It is unnecessary to apply this change to technical components of codes which might be billed separately but do have associated professional work in the professional component.

The work component of each service in the MPFS is used to describe the relative value of the work involved in furnishing that service as compared to other physician services.

Congress decided that certain services typically performed by non-physicians should be considered "physicians' services" for reimbursement purposes and should be paid according to the physician fee schedule.[2] Congress did not direct that these services be reimbursed according to a separate formula that excludes work.

Rather, Congress directed CMS to value these services according to the amount of physician work relative to all of the other services in the physician fee schedule. Because Congress has directed that payment be valued based on the physician work value, it is most coherent and equitable to assign a physician work value to these codes. The fact that payment is based on a value that has been determined to represent an equivalent relative value for physician service fulfills the objective of the relative value fee schedule.

In other words, the professional work of audiologists should be valued relative to equivalent physician work. We are not suggesting necessarily that the work of audiologists be considered physician work. Rather, the audiologist's professional work should be paid based on the relative value of equivalent physician work RVUs. . The Academy respectfully suggests that in order for the work of audiologists to be properly recognized and paid for, CMS should determine a fair and reasonable work value for the audio logy codes, which is indexed to physician work units so that the total RVUs for each code can be treated consistently relative to other codes in the MPFS.

In summary, the Academy notes the progress CMS has demonstrated in dealing with the complex task of changing to the new Practice Expense methodology, especially the

elimination of the "zero work pool" and integration of those codes into the general methodology. We are disappointed that CMS has yet to complete this integration by assigning work RVUs to the audiology codes. We are hopeful that through CMS's recognition of the need for work RVUs to value similarly situated dietician codes, fair and consistent treatment of the audiology codes will soon follow.

The Academy would also like to reiterate the comments it made last year regarding direct practice expense inputs. At that time, we noted that the clinical labor rate for audiologists does not adequately cover all payroll expenses for audiologists. In particular, the clinical labor rate of $.52 per minute does not account for any fringe benefits, which represent approximately 28 percent of a worker's compensation. We request that the clinical labor rate be increased by at least $.15 per minute to cover fringe benefit costs associated with audiologist salaries. We also commented that the direct practice expense inputs for certain audiology equipment are based on old data and do not reflect the full complement of equipment needed, current pricing, or technological advancements. The codes that have inaccurate direct expense inputs for equipment are identified in the attachment to these comments.

Lastly, the Academy would like to express its support for CMS' proposal to establish quality standards for independent diagnostic testing facilities (IDTFs). The proposed standards are intended to prevent "fly by night" operations that may engage in fraud and abuse. The Academy is aware that IDTFs have been used as a vehicle for fraudulent practices. For example, we are aware of at least one instance in which a mobile IDTF

without licensed audiologists or appropriate equipment traveled around to retirement communities furnishing audiology diagnostic services to Medicare beneficiaries. As a result, Medicare may have been billed for audiology services that were sub-standard, unnecessary, or both. The proposed regulation would prevent such fraud by requiring, for example, that IDTFs maintain a physical facility at an appropriate site, house necessary equipment at that site except for portable equipment, and operate in accordance with all applicable federal and state licensure requirements. The Academy endorses this proposal.

The Academy appreciates the opportunity to offer these comments and looks forward to working with CMS on these issues. If you would like to discuss these comments, please contact Lisa Miller, Director of Reimbursement at (703) 226-1063 or via email at LMiller@audiology.org.

Sincerely,

Paul M. Pessis, AuD

Paul Pessis, Au.D.
President

Attachment

[1] See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other changes to payment under Part B, 71 Fed. Reg. 48982 (Aug. 22, 2006).

[2] Hearing and balance tests are covered as "other diagnostic tests," which are included in the definition of "physicians' services" paid under the fee schedule. 42 U.S.C. §§ 1395w-4(a)(1), (j)(3) and 1395x(s)(3). While other services not paid under the fee schedule may also involve professionals, Congress did not provide that those services be reimbursed as "physicians' services."

We have identified several codes that do not reflect the current equipment expenses incurred by audiologists. For your convenience, we have listed these items in the following table:

CPT Code	Direct Practice Expense Input Corrections	Reason for the Correction
92567, 92568, and 92569	Equipment costs for these codes should be increased by approximately $7,847.47. • The equipment costs do not reflect the price of a diagnostic tympanometer, which is approximately $7,995. CMS lists $2,648.53. The price that CMS lists appears to be based on the price for a screening tympanometer, which is being replaced with a diagnostic tympanometer. • A computer desktop with monitor, which should have a price of $2,501, should be added to the equipment list.	Technological Advancement and Missing Equipment
92551, 92552, 92553, 92555, 92556, 92557, 92562, 92563, 92564, 92565, 92571, 92572, 92573, 92575, 92576, 92577, 92579, 92582, 92583, 92596, 92620, 92621 and 92625.	Equipment costs for these codes should be increased by approximately $3,999. The equipment costs do not reflect the current price for audiometers and do not list the additional equipment associated with PC-based audiometers, which is the current technology used by audiologists. • The price for the audiometer should be at least $6,450. CMS lists $6,250. • PC-based audiometers require (a) additional equipment, including insert phones and a sound field, all of which have an additional cost of approximately $1,298, and (b) a computer desktop with monitor, which should have a price of $2,501. CMS does not list any of this equipment.	Price Increase, Missing Equipment and Technological Advancement

CPT Code	Direct Practice Expense Input Corrections	Reason for the Correction
92587 and 92588	Equipment costs for these codes should be increased by approximately $3,721. • The price for the OAE-otoacoustic emission system does not reflect the current price for the equipment, which is approximately $9,000. CMS lists $7,780. • A computer desktop with monitor, which should have a price of $2,501, should be added to the equipment list.	Price Increase and Missing Equipment
92601, 92502, 92603, and 92604	Equipment costs for these codes should be increased by approximately $1,498. The equipment costs do not reflect the current price for audiometers and do not list the additional equipment associated with PC-based audiometers, which is the current technology used by audiologists. • The price for the audiometer should be at least $6,450. CMS lists $6,250. • PC-based audiometers require additional equipment, including insert phones and a sound field, all of which have an additional cost of approximately $1,298. • The cost of the computer desktop with monitor is already listed for these codes.	Price Increase and Technological Advancement
92585	Equipment costs should be increased by approximately $1,275. • The equipment costs listed do not reflect the costs for an ABR with an ASSR capability that audiologists are currently using. This equipment approximately costs $28,275. CMS lists $27,000.	Technology Advancement

Gordon N. Stowe and Associates, Inc.

3420 Cavalier Trail, Unit C1 Cuyahoga Falls, OH 44224-4967
Ph: (330) 926-0594 Fx: (330) 926-0765

QUOTATION

QUOTE#: 34561
PAGE: 1 OF 3
DATE: 9/8/2005

TO:

Debbie Abel, M.A., Ccc-A
Alliance Audiology
Suite E
1207 W. State Street
Alliance, OH 44601

330/821-2012

Please Respond to Office Indicated Above.

VALID THRU: **10/8/2005**

Terms Net 30 Days
Proposed Shipping Date 30 Days AFTER Receiving Order.

ACCT#: ALL601

Sales/Service Centers: Chicago, Cleveland, Dayton, Detroit, Indianapolis, Kansas City, Memphis, Milwaukee, St. Louis
Corporate Headquarters: 1-800-323-4371

QTY	DESCRIPTION	EACH	TOTAL
1	GSI 61 CLINICAL AUDIOMETER W/RS232 PORT Two channel diagnostic audiometer, 125-12000 Hz, -10 to 120dB range, Storage and transmission of audiogram. Separate calibration of transducers. One year warranty. Built-in Free Field Amplifier.	6,450.00	6,450.00
1	Paired eartone 3A inserts	535.00	535.00
1	Grason Stadler GSI-61 basic binaural soundfield speakers (90 dB HL in a 6' by 6' room).	525.00	525.00
1	Installation of audiometer and soundfield, and soundfield equalization	238.00	238.00
1	MADSEN OTOFLEX 100- DIAGNOSTIC INCLUDES: TYMPANOMETRY- 226 Hz AND 1000 Hz REFLEXES REFLEX DECAY ETF-P COMPUTER NOT INCLUDED Computer requirements: Windows XP Pro	7,995.00	7,995.00
1	Biologic Audx Plus- Includes Audx box , Probe, Power supply, Box will hold up to three protocols when used as a hand held unit. One OAE Modality. System can be used connected to computer for complete DP gram analysis or used as a handheld unit for portability and then information can be downloaded into the computer database.(Computer not included)	9,000.00	9,000.00

128

HEALTH INDUSTRY GROUP PURCHASING ASSOCIATION

October 10, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

I write on behalf of the Health Industry Group Purchasing Association ("HIGPA") to comment on CMS' proposal to clarify that administrative fees and other fees paid to GPOs, should not be considered price concessions under §414.804(a)(2).

HIGPA is a broad-based trade association that represents group purchasing organizations ("GPOs"). HIGPA's group purchasing organization members include for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and health care provider alliances.

HIGPA supports CMS' clarification that GPO administrative fees and other fees paid to GPOs are not price concessions under §414.804(a)(2). GPO administrative fees clearly are bona fide service fees. Such fees, typically based on a percentage of actual dollar purchasing volume, are statutorily recognized and have been a critical component of the supply chain business model for decades. In exchange for administrative fees, GPOs provide the manufacturers significant economies of scale and contracting efficiencies in the contracting process. For example, without GPOs manufacturers would have to enter into many thousands of contracts requiring significant administrative resources. Further, manufacturers would have to engage in substantially increased product education and support to providers with respect to their products.

Thank you for your consideration. If I can be of assistance to you in the future, please contact me at 212.506.5449.

Sincerely,

Al LoBiondo
Chair, HIGPA

401 N. Michigan Avenue, Suite 2200
Chicago, Illinois 60611
Phone 312.321.6817 * Fax 312.673.6971
info@higpa.org * www.higpa.org

JONAH SHACKNAI
Chairman and Chief Executive Officer

October 6, 2006

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

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; ASP Issues

Dear Administrator McClellan:

Thank you for this opportunity to comment on the proposed revisions to the physician fee schedule (PFS) for calendar year (CY) 2007. This comment addresses the average sales price (ASP) reporting requirements with respect to bundled price concessions by a drug manufacturer. Medicis Pharmaceutical Corp. requests that CMS provide further guidance regarding how to apportion price concessions granted under a bundling arrangement by a manufacturer that involves both Part B drugs and non-covered drugs. Specifically, Medicis requests that CMS clarify that a drug manufacturer is required to report price concessions granted for a non-Part B drug when the manufacturer conditions those price concessions on the purchase of a Part B drug.

Background on Medicis

Medicis is a leading specialty pharmaceutical company, focusing on the treatment of dermatological and podiatric conditions. Several of Medicis' branded prescription products are market leaders in their therapeutic categories, including fungal infections, psoriasis, seborrheic dermatitis, skin and skin-structure infections, acne, rosacea, and eczema. Medicis is headquartered in Scottsdale, Arizona.

8125 North Hayden Road, Scottsdale, AZ 85258
Telephone: (602) 808-3800 Facsimile: (602) 808-3875
Web Site: http://www.medicis.com
NYSE Symbol: MRX

Impact of Bundling Arrangements on ASP

CMS announced in the proposed rule that the agency is considering developing guidance on "*the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements for purposes of the calculation of ASP.*" CMS solicits comments on, among other issues, whether the agency should issue additional guidance on apportioning bundled price concessions, as well as "*the extent to which sales of Part B drugs are bundled with sales of non-Part B drugs . . . .*"

Medicis supports CMS's decision to provide additional guidance in this area. We appreciate that this is a complicated area that involves potential anti-kickback, self-referral, and antitrust issues. For that reason, it may be appropriate for CMS to undertake a separate notice and comment rulemaking on this subject. As we discuss below, Medicis believes that the issue of bundling Medicare Part B products with non-covered items is an especially strong candidate for guidance.

Bundling of Medicare Part B Drugs and Non-Covered Products

Medicis urges CMS to issue further guidance on the ASP reporting requirements with respect to bundled price concessions. In particular, under some bundling arrangements, a drug manufacturer will condition price concessions for a non-Part B drug on the purchase of that manufacturer's Part B drug. Medicis seeks clarification on how drug manufacturers should apportion such a price concession.

If a drug manufacturer is permitted to report sales data only for the Part-B-drug component of a bundled sale, any price concessions granted for that manufacturer's non-covered products would be excluded from the ASP calculation. Such an arrangement would enable drug manufacturers to insulate certain price concessions that are integral to the sale of their Part B drug from the ASP reporting requirement. The effect would be to artificially inflate the reported ASP of the Part B drug, and, with it, the Medicare payment rate.

The actual market price of Part B drugs is the touchstone of the ASP system. Drug manufacturers therefore should be required to apportion price concessions granted for their non-Part B products when those price concessions are conditioned on the purchase of that manufacturer's Part B drug. Such a clarification is necessary to ensure that drug manufacturers do not misrepresent the actual market price of Part B drugs.

Medicis further requests that CMS clarify that reporting requirements for bundled price concessions apply only to sales made and concessions granted *by a given manufacturer*. For the purpose of the ASP reporting requirements, the term "manufacturer" covers a broad range of entities, including not only parties engaged in the literal production and processing of prescription drug products, but also their "packaging, repackaging, labeling, relabeling, distribution."[1] In order to avoid confusion among manufacturers with respect to the reporting of bundled price concessions, CMS should clarify that a manufacturer is not required to report price concessions granted by some other, independent entity for sales of the manufacturer's product.

Requested Clarification

Medicis respectfully requests that CMS include the following clarifying language in the final rule:

> *For the purpose of calculating ASP, price concessions should be apportioned among all drugs—including both Part B drugs and non-covered drugs—sold together under a bundling arrangement by a given manufacturer.*

Thank you for your attention to this important matter.

Sincerely,

Jonah Shacknai
Chairman and Chief Executive Officer

[1] Social Security Act § 1927(k)(5).

130

American College of Radiation Oncology
5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

October 6, 2006

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

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

Dear Dr. McClellan:

The American College of Radiation Oncology ("ACRO") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule (CMS-1321-P).[1] With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

ACRO would like to extend its appreciation for the opportunity to comment on the proposed regulations. This letter will comment on the following sections:

- Elimination of brachytherapy global period;
- The imaging provisions in the Deficit Reduction Act;
- Conversion factor decrease; and
- Proposed changes regarding reassignment and physician self-referral rules.

[1] Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule (CMS-1321-P). *Federal Register*, Volume 71, No. 162, August 22, 2006, p. 48982.

A. Elimination of Brachytherapy Global Period

ACRO is pleased that CMS is eliminating the global period for remote afterloading high intensity brachytherapy procedures.[2] The change, as proposed by CMS, reflects how clinical care is delivered to patients. We find no data in the proposed rules supporting CMS's elimination of the post operative visit, the registered nurse time and the patient gowns. ACRO encourages CMS to study these procedures prior to eliminating any components. It is our understanding the American Society for Therapeutic Radiology and Oncology has proposed the alternative of returning the work RVUs to their 1992 level when the global period was "XXX." ACRO could support such an approach.

ACRO would be interested in working with the AMA's Relative Value Update Committee (RUC) to assist in any needed revaluation of the work RVUs and practice expense inputs. While ACRO is supportive of the global period elimination, we remain concerned about the dramatic changes in the four afterloading high intensity brachytherapy codes (CPTs 77781 through 77784). The disparity between afterloading 1 to 4 catheters (CPT 77781) and 12 or more catheters (CPT 77784) has widened significantly. It is our belief that the lower codes (CPT 77781 & 77782) are unfairly disadvantaged by the new practice expense methodology.

B. Imaging Provisions in the Deficit Reduction Act

In general, ACRO is concerned about the effect of scheduled cuts in Medicare imaging reimbursement under Section 5102 of the Deficit Reduction Act (DRA)[3] and the impact that they may have upon the care that Medicare beneficiaries receive. Specifically, the DRA includes two provisions to cut imaging services in the Medicare program. The first provision would reduce the payment for the technical component for multiple imaging services performed on contiguous body parts. The second provision stipulates that if the technical component of specified imaging services under the physician fee schedule exceeds the outpatient department (OPD) fee schedule amount for such service, Medicare will pay the OPD amount. The provisions would reduce Medicare reimbursement for imaging services, in some cases by up to 50 percent. ACRO continues to support the passage of the Access to Medicare Imaging Act of 2006.

Specifically, ACRO feels that all radiation oncology codes should be outside of the DRA provisions. As with interventional radiology, these codes are not diagnostic services. These code are specific to the safe and effective treatment delivery of cancer care. Specifically, the following codes should be exempted from the provisions of the DRA:

76370 – CT scan for therapy guide
76950 – Echo guidance for radiotherapy
76965 - Ultrasonic guidance for interstitial radioelement application
77417 - Port films
77421 - Stereoscopic x-ray guidance

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[2] Ibid, p. 48995-6.
[3] Section 5102 of Deficit Reduction Act of 2005 (Pub.L. 109-171).

ACRO believes that radiation therapy or brachytherapy cannot be delivered without the services described in these codes. They are clearly not diagnostic imaging services, but components of care integral to the ongoing treatment of cancer patients.

C. Conversion Factor Decrease

ACRO strongly believes that budget neutrality provisions and the sustainable growth factor have led to unfair compensation to physicians. There have been no increase in compensation since January 2005 and CMS is now proposing a 5.1% decrease. A payment methodology that does not keep pace with the most basic indicators of medical inflation is untenable. ACRO continues to support alternative solutions to the budget neutrality limits.

D. Proposed Changes Regarding Reassignment and Physician Self-Referral Rules

ACRO is becoming increasingly concerned about the growing trend of urologists purchasing or leasing building space for radiation oncology equipment that they also purchase or lease. The urologists will then employ a radiation oncologist and will bill globally for these services under the centralized building component of the in-office ancillary exception to the Stark Law. A practice management group facilitates this business arrangement and emphasizes the financial benefit of this arrangement to the urologist. In many cases, the Medicare payment for the professional component is greater than what the urology practice pays the radiation oncologist for this service.

As CMS well understands, Section 1877 of the Social Security Act (the so-called Stark Law) generally prohibits financial arrangements between physicians and entities providing designated health services (DHS), except under certain exceptions. These provisions were enacted after a number of studies showed a consistent correlation between such arrangements and over utilization of health care services.

While Congress created the in-office ancillary exception to protect some services that were truly ancillary from being prohibited under the Stark Law, ACRO believes Congress also meant to balance such exceptions against the need to protect against program or patient abuse. Indeed, in its Phase I Final Rule on Physician Self-Referrals to Health Care Entities With Which They Have Financial Relationships, published on January 4th, 2001, CMS (then the "Health Care Financing Administration") stated:

> *"We share this commenter's concerns about inappropriate financial incentives driving the provision of DHS. We are concerned that heightened downward pressure on physician incomes will generate increased upward pressure to expand in-office ancillary services as a means of offsetting income losses."*

ACRO believes such incentives are behind this "integration" of radiation therapy services into urology practices. Moreover, ACRO believes that this trend is resulting in a decrease in overall patient choice of radiation therapy (as urologists within such practices tend to refer patients only to the radiation therapy services that they own). It also may be resulting in a diminution in quality radiation therapy and poorer outcomes, as the radiation oncologist usually is not an equal partner in these relationships, but rather an independent contractor, actually dependent on referrals from the urology practice, or an employee of the urology practice.

Moreover, we are finding that these patients with prostate cancer may also have other forms of cancer outside the urologist's specialty, yet the urologist becomes the physician who refers these patients to the urology-owned radiation oncology centers as well. Clearly, the patient in this situation is not receiving optimal care.

CMS notes that Section 1877(b)(2) of the Social Security Act "authorizes the Secretary to determine additional terms and conditions relating to the supervision and location requirements of the in-office ancillary services exception as may be necessary to prevent a risk of program or patient abuse." ACRO urges CMS similarly to use its authority under Section 1877(b)(2) to impose regulations "as needed to protect against program or patient abuse" to curb the increasing practice of the purchasing of radiation therapy services by urology practices.

The urology practice does not become a multi-specialty group practice through this purchase. The radiation oncologist does not become an equal partner in the group. We question whether this annexation of radiation oncology services is truly a service ancillary to the urologist's practice and worthy of an exception to the Stark Law prohibitions.

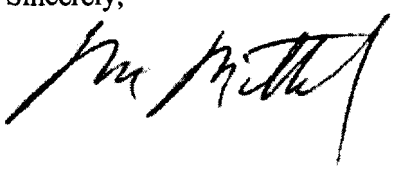
Conclusion

ACRO's comments on the Physician Fee Schedule regulations seek to ensure ongoing access to radiation oncology services. Maintaining patient access is crucial since our patients often require services five days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality. ACRO appreciates the opportunity to comment on the regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients. We look forward to meeting with CMS in the near future.

Sincerely,

D. Jeffrey Demanes, M.D.
President
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

Sincerely,



Michael Kuettel, M.D., Ph.D.
Chair, Socioeconomics Committee
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

cc: Terrence Kay, Centers for Medicare and Medicaid Services
Herb B. Kuhn, Centers for Medicare and Medicaid Services
Leslie V. Norwalk, Centers for Medicare and Medicaid Services

NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

October 10, 2006

HAND DELIVERED

The Honorable Mark McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **CMS-1321-P**

Dear Dr. McClellan:

The National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to healthcare services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling, case management and co-payment relief services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. In fiscal year July 1, 2005 – June 30, 2006, PAF was contacted by 6 million patients requesting information and/or direct professional intervention in the resolution of access disputes. Of that number, 27% were Medicare beneficiaries and 85.1% were individuals dealing with a diagnosis of cancer.

NPAF would like to thank you for the opportunity to comment on Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006.[1] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule. We hope CMS finds our recommendations helpful as it finalizes the physician fee schedule for 2007.

IMPACT

NPAF urges CMS to Work Collaboratively with Congress to Fix the Flawed Sustainable Growth Rate Formula

Because of the operation of the flawed Sustainable Growth Rate (SGR) formula at Social Security Act § 1848(d), the Proposed Rule requires a 5.1% across-the-board reduction in payments to physicians in 2007. Continuing reimbursement cuts are projected to total 35-40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period.

[1] 71 *Fed. Reg.* 48980 (Aug. 22, 2006).

The results of a recent American Medical Association (AMA) Member Connect Survey[2] suggest 45% of physicians will either stop accepting or decrease the number of new Medicare patients they accept in 2007 if the negative 5.1% update in the Proposed Rule is allowed to become effective. A similar AMA survey in 2005 indicated a significant number of physicians would cut back on purchases of new medical equipment or defer plans to buy new information technology in the face of a 5% reduction in Medicare reimbursement.[3]

NPAF is extremely concerned the projected disparity between Medicare reimbursement and practice operating costs will hurt access to care for millions of America's seniors in 2007 and beyond. Further, if physicians cannot afford to retain adequate staff or invest in new diagnostic and treatment technologies or in electronic medical records, it will be difficult to implement the types of meaningful quality improvement programs needed to sustain Medicare into the future. NPAF urges CMS to work collaboratively with the physician community, the patient advocate community and Congress when it returns after the election break to develop a viable multi-year plan that can be implemented beginning in 2007 to provide positive payment updates for physicians, spur development of a permanent solution to the SGR problem, and facilitate voluntary physician participation, across all specialties, in meaningful quality reporting and quality improvement activities.

NPAF urges CMS to Implement Refinements to the PE Methodology to Improve Payment Levels for Chemotherapy Services in 2007

The impact analysis in the Proposed Rule projects an overall reduction in payments to hematology/oncology of 3% in 2007.[4] When the potentially disastrous effect of the 5.1% negative update factor on patient access to physician services is ignored for purposes of analysis, payments for medical oncology increase by 3% in 2007, due to the proposed changes in work and PE RVUs.[5]

NPAF believes this estimated aggregate impact fails to reflect the significant economic challenges that will face oncologists who continue to administer chemotherapy in their offices in 2007 under the Proposed Rule. Early indications from a Duke University Institute of Research study entitled, *"The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?"*, reflect that seniors in rural locations enrolled in Medicare but with no supplemental GAP insurance, are starting to be shifted to hospital programs from physician practices.[6] This is an issue that needs to be further monitored.

When Congress enacted MMA § 303, it intended to better match Medicare reimbursement for drugs and for drug administration with the actual cost of each service component. The

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[2] *2006 AMA Medicare Physician Payment Survey,* available at http://www.ama-assn.org/ama/pub/category/3374.html.

[3] *2005 AMA Medicare Physician Payment Survey,* available at http://www.ama-assn.org/ama/pub/category/14924.html.

[4] 71 *Fed. Reg.* 49070.

[5] 71 *Fed. Reg.* 37170, 37255 (June 29, 2006); 71 *Fed. Reg.* 49070.

[6] *The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15, 2006), funded by The Global Access Project. For complete study, visit www.npaf.org

input we have received during discussions with the oncology community suggests payments for drug administration services already fall substantially short of the costs of providing the services. In fact, we understand the cost of in-office chemotherapy services is likely to outstrip Medicare reimbursement by well over $500 million before bad debt is considered in 2006. The magnitude of the underpayment will obviously grow substantially under the Proposed Rule and continue to increase from 2007 to 2010 as the proposed changes in the PE methodology are phased in. Couple this trend with the reality that not all services are being reimbursed as was demonstrated by the Global Access Project University of Utah Study. The Utah study entitled "Documentation of Pharmacy Cost in the Preparation of Common Chemotherapy Infusions in Academic and Community-Based Oncology Practices" found that the total average "fixed costs" for the preparation of chemotherapy doses averaged $36.00 to $44.00 in both practice and hospital pharmacy setting, which was not captured in any payment. This figure translated into a cost of approximately $143,777,534.00 for the national Medicare population for which doctors had to absorb without payment reimbursement.

NPAF would encourage CMS to consider the promise of MMA to match reimbursement for drug administration services to the actual costs of providing those services in the physician office when CMS finalizes the physician fee schedule for 2007 to help ensure Medicare beneficiaries with cancer continue to have access to community-based chemotherapy. To that end, NPAF urges CMS to refine the proposed new PE methodology to reduce the adverse effects of the proposed methodological change on the drug administration codes. Two specific changes seem appropriate. First, CMS should use unscaled direct cost inputs instead of scaled direct inputs to allocate indirect PE. Second, CMS should use clinical labor costs or staff time to calculate specialty-specific aggregate pools of indirect PE for services with no physician time. This is critical to maintain oncology nursing care for patients.

NPAF urges CMS to Implement a 2007 Cancer Care Demonstration Project

NPAF recognizes that early studies suggest the MMA has not lead to significant dislocations in access to oncology care or notable degradation in the quality of oncology care available to Medicare beneficiaries. When MedPAC assessed the effects of the MMA-mandated change from an AWP-based to an ASP-based system for drug reimbursement in 2005, it found beneficiary access to chemotherapy drugs generally remained good and quality of care had not declined.[7] MedPAC did note, however, that in some areas, beneficiaries without supplemental insurance were more likely to receive chemotherapy in hospital outpatient departments rather than physician offices. MedPAC also concluded issues of beneficiary access and care quality merit continued vigilance as the implementation of MMA plays out.

A baseline study of 2004 Medicare claims data coupled with a Web-based convenience survey of Medicare beneficiaries in early 2005 conducted by the Duke Clinical Research Institute for the Global Access Project came to similar conclusions. That study found no statistically significant differences in time to treatment or site of treatment for Medicare beneficiaries with cancer before the MMA and in the first year (2004) of the MMA's

[7] *Medicare Part B Drugs and Oncology,* Testimony of Mark E. Miller, PhD, Executive Director of MedPAC, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, July 13, 2006.

implementation.[8] Like the MedPAC study, the Duke study also noted some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance. The report recommended interpreting these findings with caution, however, because these beneficiary subgroups were too small to permit the covariate adjustments needed to determine whether the findings reflected baseline differences between the pre-MMA and post-MMA cohorts. That said, the Duke report also concluded Medicare beneficiaries living in rural areas or not having the benefit of supplemental coverage "may be the most vulnerable to changes caused by the MMA. Further research in this area is warranted."[9]

Despite these study findings, NPAF believes the 32% transition drug administration payment in 2004, the cancer quality demonstration project tied directly to drug administration services in 2005, and the revised cancer quality demonstration tied to E&M visits in 2006 have avoided the potential impact of the growing mismatch between the cost of drug administration services in oncologists offices and the reimbursement available from Medicare for these services. The concern is that absent action on CMS's part, 2007 may be the year when underpayments for drug administration services will be unmasked, putting Medicare beneficiaries with cancer, particularly those living in rural areas and those without supplemental insurance, at risk of measurable reductions in access and/or quality of care as affirmed in the recent Duke study cited earlier.

Unfortunately, it does not appear to us that a statutory reversal of the negative update factor coupled with the refinements to the PE methodology we recommended above will be enough to correct the serious reimbursement shortfall for drug administration services facing physicians who provide in-office chemotherapy in 2007. Other approaches to remedying the situation that rely on procedures currently used to develop and refine the physician fee schedule (e.g., collection and use of survey data more reflective of costs actually associated with in-office chemotherapy, reevaluation by the RUC of the RVUs assigned to drug administration codes, etc.) are too long-term. So to are more radical solutions that depart from the current approach to setting physician payment rates such as the ideas discussed in a report entitled "Practice Expense Reimbursement for Cancer Care Services: Methodology Evaluation & Assessment of Alternative Policies" prepared for the Global Access Project in 2004.[10]

NPAF strongly urges CMS to implement a demonstration project in 2007 that builds on the 2006 Cancer Care Quality Demonstration Project. We acknowledge the widely recognized shortfalls of the 2005 Cancer Quality Demonstration,[11] but we submit the problems associated with that demonstration are inapplicable to the retooled 2006 Cancer Care Demonstration Project. Payments under the 2006 program are modest ($23 per visit) and tied to E&M services, not to office visits for chemotherapy administration. The data reporting requirements focus physician attention on the implementation of clinical guidelines developed by (1) the National Comprehensive Cancer Network, an alliance of 20

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[8] *Id.*

[9] *Id.*

[10] *Practice Expense Reimbursement for Cancer Care Services: Methodology Evaluation & Assessment of Alternative Policies,* Donald W. Moran *et al.,* The Moran Company (Sept. 23, 2004), funded by The Global Access Project. For complete study, visit www.npaf.org

[11] *Cost and Performance of Medicare's 2005 Chemotherapy Demonstration Project,* OEI-09-05-00171 (Aug. 2006) available at http://oig.hhs.gov/oei-09-05-00171.pdf.

National Cancer Institute designated cancer centers or (2) the American Society of Clinical Oncology, the medical specialty society representing medical oncologist. The 2006 Demonstration Project permits CMS to encourage increased consistency in cancer care by promoting adherence to best practices shown to lead to improved patient outcomes. It also accustoms oncologists to routine reporting of data for quality improvement purposes. Building on this demonstration to develop a 2007 Cancer Care Demonstration Project that would pay oncologist to report data on adherence to best practice standards or on other indicators designed to facilitate the development of appropriate quality benchmarks for oncology care would enhance a national focus on quality cancer care, reward provider adherence to guidelines and minimize disruption in access to health care.

Adopting a 2007 Cancer Care Demonstration Project to help resolve potential access problems tied to the anticipated shortfall in payments for drug administration services under the Proposed Rule would be consistent with the recommendations of the Institutes of Medicine (IOM) in its recently issued report on pay-for-performance.[12] The report notes one problem with moving toward pay-for-performance for physicians is a lack of good quality measures for specialists. Moreover, the report expressly recommends offering financial incentives to physicians to voluntarily report quality data for a three year period before Medicare decides whether pay-for-performance for physicians should be mandatory and how such a program should be structured. It also recognizes physician office practices face cost and logistical roadblocks to quality data reporting and quality improvement not applicable to other providers, none of whom are subject to cost controls equivalent to the SGR.

DRA PROPOSALS

Section 5102 of the Deficit Reduction Act of 2005 (DRA) includes two provisions that affect payments for imaging services under the Physician Fee Schedule. DRA § 5102(a) requires CMS to exempt any savings attributable to multiple imaging procedure payment reductions implemented initially in the 2006 Physician Fee Schedule final rule[13] from the budget neutrality provision, effectively pulling those savings out of the pool of money available for physician reimbursement. DRA § 5102(b) caps payment amounts for the technical component of imaging services provided in a physician's office beginning in 2007 at the technical component rates available to hospital outpatient departments for the same services under the hospital outpatient prospective payment system (OPPS).

The CMS impact analysis suggests DRA § 5102 will have essentially no impact on payment rates for medical or radiation oncology.[14] As is the case with drug administration services discussed previously, this aggregate analysis fails to illustrate the potentially devastating effect of the DRA, as CMS has chosen to interpret it in the Proposed Rule, on PET/CT imaging services crucial to cancer diagnosis, staging, and treatment by both medical and radiation oncologists and on certain radiology guidance procedures critical to the delivery of targeted, healthy tissue- sparing radiation therapy.

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[12] *Rewarding Provider Performance: Aligning Incentives in Medicare,* Institute of Medicine, National Academy of Sciences (2006) available at http://www.nap.edu/catalog/11723.html.
[13] 70 *Fed. Reg.* 70113-14 (Nov. 21, 2005).
[14] 71 *Fed. Reg.* 49071.

NPAF urges CMS to Assign PET/CT to APC 1514 for 2007 and 2008

Because proper staging of cancers plays a critical role in the effective implementation of clinical guidelines and the provision of high-quality, high-value cancer care and because PET/CT scans are now the technology of choice for staging, as was demonstrated in the case of my husband's care for Stage IV cancer in 2005-2006. NPAF is particularly concerned about the Proposed Rule's astounding 61% reduction in reimbursement for PET and PET/CT, with the bulk of the reduction coming at the expense of the newer PET/CT technology. Most physician practices simply do not have the financial wherewithal to absorb payment cuts of this magnitude in one year, nor do patients in the commercial sector, who would ultimately be impacted, have the resources to be balance billed for the reduction in insurance reimbursement. If CMS moves to this model, the commercial market will follow. If control of over-utilization is the issue, CMS can work with providers to define the Standard Operating Procedure (SOP) for prescribing and collaboratively develop an improved model for cost containment efficient medical utilization.

NPAF urges CMS to mitigate the magnitude of the DRA-mandated cap on PET/CT payment rates under the 2007 Physician Fee Schedule by revising the "Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule" (the "2007 OPPS Proposed Rule") published in the *Federal Register* on August 23, 2006[15] to place PET/CT in APC 1514. Such a change would be consistent with the recommendations of the APC technical panel. CMS also should commit to continue this APC assignment through 2008 so practices have time to adapt to potential cuts in payments for this critical imaging service. The delay we are proposing in the APC change for PET/CT also will allow hospitals time to establish PET/CT-specific charges that more accurately reflect the costs associated with the service. We suspect the claims data being used to set the rates under the 2007 OPPS Proposed Rule are flawed because we understand many hospitals have not yet updated their chargemasters to separate charges for PET and PET/CT and more accurately reflect the cost of the newer technology.

NPAF urges CMS to Exclude All Radiology Guidance Procedures from the DRA Cap

NPAF urges CMS not to finalize its proposal to subject many radiologic guidance procedures, including those used for the administration of radiation therapy, to the DRA cap. The DRA Conference Report clearly indicates the intent of Congress was to limit payments for only "diagnostic" imaging services. Further, the increased utilization of imaging procedures that has been of concern to CMS over the past several years is related to diagnostic imaging procedures, not imaging used in conjunction with therapeutic procedures to improve outcomes.

CMS itself recognized this fact when it excluded from the DRA cap all imaging guidance procedures where the guidance was included in the code for the procedure itself (e.g., diagnostic bronchoscopy). CMS should not base a policy decision as important as that surrounding implementation of the DRA cap on CPT coding descriptors. Whether guidance happens to be included in the coding descriptor for a procedure is not relevant to determining whether the guidance process itself should be included under the DRA cap.

[15] 71 *Fed. Reg.* 49504 (Aug. 23, 2006)

Guidance associated with a procedure, whether it is for radiation therapy delivery or for invasive surgery, is never diagnostic and there was never any floor language by Congress to support this to be included under the DRA cap.

Recent technologic advancement in guidance allows external beam radiation to be more highly focused, resulting in the delivery of higher doses of radiation to tumors and lower doses of radiation to normal tissues. Not only is efficacy improved, but the complication rate is also decreased. Applying the DRA cap to radiologic guidance procedures for radiation therapy likely will have a serious adverse effect on both access to and quality of care available to America's seniors living with cancer.

NPAF is particularly concerned about the adverse impact of the dramatic reductions in payment for guidance procedures such as CPT 76370 (CT guidance for placement of radiation therapy fields) which was paid at $129.61 in 2006 but will be paid at $95.72 in 2007 and CPT 77421 (stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy) which was paid at $116.35 in 2006 but will be paid at $60.13 in 2007. These services preserve functionality of the body area being radiated. Absent these deliberate processes, patients such as my husband will lose their ability to speak, swallow and even chew if the radiation is to the neck and head. Reimbursement decisions impact not only life or death, they also define quality or lack of quality of life during and after treatment. If CMS finalizes its proposal to cap guidance payments in the physician office at the OPPS rate, many physician offices likely will no longer be able to provide guidance for radiation therapy and will instead refer their patients in need of such services to hospitals which will affirm they do not have the staff or capacity to serve. Such a result could cause some patients in rural areas to forego treatment and it clearly will result in longer wait times and care disruptions for many Medicare beneficiaries living with cancers most effectively treated with radiation therapy.

NPAF urges CMS to Rescind the Proposed 25% Multiple-Procedure Reduction

In 2006, CMS implemented a 25% multiple-procedure reduction for the technical component of certain imaging procedures when they were performed on contiguous body parts. The reduction was established because CMS thought it was making duplicate payment for some elements of practice expense (e.g., staff time, certain supplies) when certain ultrasound, CT, or MRI procedures were performed on contiguous body parts during the same session.

NPAF strongly urges CMS to eliminate the multiple-procedure reduction for imaging procedures performed in physician offices because those same procedures will be subject to the DRA cap in 2007. OPPS costs are calculated in the aggregate over revenue centers and they already reflect efficiencies achieved from the performance of multiple procedures. Thus, imposition of the DRA cap will resolve the concern that led CMS to apply the multiple-procedure reduction in the first place and make continuation of the 25% multiple-procedure reduction in 2007 unnecessary and inappropriate from a policy perspective.

ASP

NPAF applauds the decision to reopen the comment period on the regulations governing the calculation of ASP at 42 C.F.R. 414.800 *et seq.* We agree stakeholders, including CMS, lacked real-world experience with ASP when the rulemakings that underlie those regulations were undertaken. We appreciate the opportunity to comment on issues raised in the earlier rulemakings as well as new issues that have arisen under the ASP-based reimbursement system over the course of the last year and a half.

NPAF urges CMS to Exclude Customary Prompt Pay Discounts Extended to Wholesalers from the ASP Calculation

NPAF has long advocated for the exclusion of customary prompt pay discounts extended to wholesalers from the ASP calculation. We understand those discounts are not routinely passed on by wholesalers to their customers that bill Part B and we believe netting the discounts out of ASP undercuts the MMA objective of matching Part B drug reimbursement with prices actually available to physicians in the market.

Congress chose to eliminate the deduction of customary wholesaler discounts when it retooled the definition of Average Manufacturer Price (AMP) under the DRA to convert that pricing statistic into a reimbursement metric for retail pharmacies. The rationale for the AMP change was that wholesalers did not routinely pass their prompt pay discounts on to their retail pharmacy customers. Physicians stand in precisely the same position as retail pharmacies when it comes to their relationships with wholesalers. From a policy perspective, there appeared to be no logical reason why the handling of prompt pay discounts in the ASP calculation should not parallel the handling of the discounts in the AMP calculation.

CMS has the authority to exclude wholesaler prompt pay discounts from the ASP calculation despite the fact that the statutory definition of ASP under MMA § 303(c) includes prompt pay discounts in a list of pricing concessions that are to be deducted when ASP is calculated. "The meaning of statutory language, plain or not, depends on context."[16] Moreover, for purposes of statutory interpretation, "context" relates to "the design of the statute as a whole and to its object and policy."[17] Given the clear intent of Congress when it enacted the MMA to match Part B drug reimbursement with drug acquisition costs *available to physicians* in the market, CMS has the legal authority to instruct manufacturers via regulation to ignore customary prompt pay discounts extended to wholesalers when they calculate ASP while, at the same time, treating prompt pay discounts extended to non-wholesaler direct purchasers as price concessions that must be netted out. If CMS is concerned about manufacturers negotiating with wholesalers to pass a portion of inordinately high "prompt pay discounts" on to their physician customers, it could monitor the situation using the quarterly reports from manufacturers about their prompt payment practices that will be submitted in 2007 pursuant to the DRA.

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[16] *Holloway v. United States,* 526 1, 7 (1999) (cites omitted).

[17] *Gozlon Peretz v. United States,* 498 U.S. 395, 407 (1991) (quoting *Crandon v. United States, 494 U.S. 152, 158 (1990)).*

NPAF urges CMS Collaboration with Congress to Reduce the Lag Time between ASP Reports and Reimbursement Based on Those Reports

NPAF encourages CMS to work collaboratively with manufacturers, physicians, other stakeholders and Congress to find an operationally tenable way to reduce the lag time between ASP reports and reimbursement based on these reports. Currently there is a two-quarter lag between ASP reporting and payment based on reported ASP values.

For a number of expensive single-source cancer drugs considered the standard of care that often are difficult for patients to access, ASP has been rising, frequently on a quarterly basis, and some quarter-over-quarter ASP values have shown price increases of 1% or more. The two-quarter lag effectively reduces reimbursement available to physicians for products with rapidly increasing prices, creates cash flow dislocations for some practices, and may make some Part B drugs used to treat cancer and other chronic, debilitating or life-threatening diseases unprofitable for practices with limited buying power. As a result, NPAF is deeply concerned about the potential effect of the lag on beneficiary access to cutting edge therapies.

NPAF also realizes the two-quarter lag means that Medicare pays too much – often substantially too much – for drugs for several months when prices are falling rapidly as can happen when a single-source drug comes of patent or a therapeutic alternative to the only single-source therapy indicated for a particular condition enters the market. Whenever Medicare pays too much, beneficiaries also suffer with inappropriately high co-payments. NPAF is equally concerned about beneficiary access to the lowest possible prices and wants to see the lag shorten to correct overcharges to patients as well as underpayments to physicians. Balanced, current payments assure sustained access to care.

NPAF urges CMS to Refine the Proposed Definition of *Bona Fide* Service Fees and Codify the Instruction to Ignore Such Fees in the ASP Calculation

For the same reason we oppose the deduction of wholesaler prompt pay discounts, NPAF supports CMS's decision to codify a definition of *bona fide* service fees and an instruction directing manufacturers not to deduct such fees when ASP is calculations. Simply put, we do not view service fees as affecting the drug prices available to physicians in marketplace. We recognize CMS has posted a FAQ to this effect on its website but we understand the precatory nature of the Web posting as well as ambiguities associated with the posted definition of *bona fide* service fees have led to inconsistencies in the way various manufacturers handle the fees. We believe codifying the instructions should help resolve this problem.

NPAF does not have the experience necessary to provide informative input on many of the issues surrounding *bona fide* service fees or other technical aspects of the ASP calculation, and we will not presume to do so. However, NPAF would encourage that no process be introduced around the matter of *bona fide* service fees that would result in the diminished reimbursement to physicians and, therefore, their willingness to treat Medicare patients.

NPAF would again like to thank CMS for the opportunity to submit formal comments on the 2007 Physician Fee Schedule Proposed Rule. We strive to make dialogue with the agency about payment policies a constructive discussion that gives voice to the concerns of

Medicare beneficiaries dealing daily with the burdens of a chronic, debilitating or life-threatening disease. We look forward to continuing our work with CMS to implement both the Part B and the Part D provisions of the MMA in ways that maximize Medicare beneficiary access to both the drugs and the high-quality, high-value professional services they need and deserve.

Respectfully submitted,

Nancy Davenport-Ennis
Chief Executive Officer