GASTROENTEROLOGY CONSULTANTS SOUTHWEST, L.L.P.
Frank L. Lanza, M.D.,P.A. • Robert E. Davis, M.D.,P.A. • J. Guillermo Trabanino, M.D.,P.A. • Keith H. Fiman, M.D., P.A.

September 11, 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

Re: Medicare Program: Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

To Whom It May Concern:

I am concerned about CMS' proposed rule relating to the five-year review of work relative value units, as published in the Federal Register dated June 29, 2006. I am practicing gastrointestinal specialist with offices in Houston and Sugar Land, Texas. I involved in the treatment of patients, including performing colonoscopies for colorectal cancer screening, as well as treatment of patients with indications for any of a myriad of different GI disorders.

It is clear that the RVUs assigned to GI colonoscopies and other procedures are not nearly high enough. Since the Medicare colorectal cancer screening benefit was enacted in 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--if inflation were factored in the reduction would almost certainly be in excess of 50%. No other Medicare service has been cut this much since Congress decided to make the eradication of colorectal cancer a national priority by encouraging every Medicare beneficiary over the age of 50 to receive screening.

Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. CMS has consistently reduced the effectiveness and utilization of that benefit, by relentless and devastating cuts. When one looks at the bottom line on this proposal, it is clear that this disastrous trend would continue with major new cuts.

Increases in RVUs for cognitive and other services necessitate a decrease in the GI work RVUs, and therefore discount the RVUs which the RUC said should remain unchanged. I oppose those increases. And to the extent that CMS's concept of budget neutrality demands a 10% across-the-board cut in the payment for services, I believe the interpretation of budget neutrality adopted by the agency is incorrect and the result patently unfair.

7777 Southwest Freeway, Suite 708 • Houston, Texas 77074 • Tel: 713/776-1074 • Fax: 713/776-3138
16659 Southwest Freeway, Suite 151 • Sugar Land, Texas 77479 • Tel: 281/491-9779 • Fax: 281/491-3551

SHERIDAN CHILDREN'S HEALTHCARE SERVICES®

August 20, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program- the "work adjuster" and proposed changes to the Practice Expense

Dear Dr McClellan:

My name is Barry Chandler and I am Senior Vice President of Sheridan Healthcare. Sheridan Healthcare, Inc.'s subsidiaries and affiliates provide or employ approximately 600 physicians, of whom 100 are Neonatologists.

I am aware that there was a "Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology" which occurred several months ago. Although reimbursement for many pediatric codes were increased in this Five-Year Review, the Critical Care and Continuing Intensive Care neonatal codes will be affected by both the "work adjuster"decrease and by the Practice Expense decrease proposed.

It is my understanding that the "work adjuster" change proposed (a decrease of 10% from current schedule) would be applied to all codes with physician work RVUs. In contrast to other years CMS is utilizing this "work adjuster" change in order to reach budget neutrality. This approach will severely affect neonatologists throughout the country who, through Federal Government Programs, already receive poor remuneration under the present schedule. There is such variability in reimbursemant that a 10% reduction could lead to Neonatal Intensive Care Units (NICUs) being unable to accept patients on the basis of financial considerations. This could severely reduce access to care for the smallest, and most vulnerable, of our patients. I believe strongly that a more equitable approach would be to decrease the Conversion Factor instead.

In addition, the thought of a transition to a new Practice Expense Methodology would also negatively affect neonatology. I have been advised that there is currently a new Physician Practice Survey which will offer updated information and will be available in 2008. I hope that CMS will postpone this Practice Expense Methodology until the new data is available.

Sheridan Children's Healthcare Services, Inc.
1613 N. Harrison Parkway, Suite 200 • Sunrise, Florida 33323
(954) 838-2371 • FAX: (954) 851-1700 • (800) 437-2672

Mark B. Feinberg, MD, PhD
Vice President
Policy, Public Health & Medical Affairs

Merck & Co., Inc.
P.O. Box 4, WP97-A337
West Point PA 19486-0004
Tel 215 652 8664
Fax 215 652 8918

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Rec'd 9/7/06

September 6, 2006

MERCK
Vaccine Division

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

RE: File Code CMS-1321-P; Comment on Proposed Payment for Covered Outpatient Drugs and Biologicals – ASP Issues

Dear Madam or Sir,

We are writing to comment on the proposed rule issued on August 8, 2006 entitled "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" (the "Proposed Rule"). In the Proposed Rule, CMS discusses proposed changes relating to the determination of payment amounts for certain drugs and associated fees. The purpose of this letter is to comment on the administration fee relating to covered Part D vaccines. In particular, we request that the Centers for Medicare & Medicaid Services ("CMS") adhere to the policy articulated in the final rule relating to Medicare Part D ("Part D Final Rule")[1] and explicitly cover, under Part B, the administration of vaccines covered by Part D.

I. Background Information

As a general matter, new vaccines and those previously covered by Medicaid are covered by Part D, not Part B.[2] However, CMS has not articulated a comprehensive policy relating to Part D vaccines. This stems, in large part, from the fact that Part D vaccines, unlike most Part D drugs, are primarily administered by a physician in an office setting.

The need to administer these vaccines in an office raises unique issues under Part D from a reimbursement perspective. The purpose of this comment letter is to focus on one particular issue. Specifically, the reimbursement available to providers under Part B

[1] The Part D Final Rule can be found at 70 Fed. Reg. 4194 (January 28, 2005).
[2] 42 C.F.R. § 423.100; 70 Fed. Reg. 4194, 4230-4231 (January 28, 2005). *See also* U.S. Pharmacopeia, Medicare Prescription Drug Benefit, Model Guidelines Version 2.0, Examples of Drugs in the USP Model Guidelines 2.0, Immunological Agents/Immune Stimulants/Vaccines pages 27-29 (February 6, 2006).

for administering the vaccine, which is a payment in addition to the payment for product costs.

II. Administration Fees for Part D Vaccines

A. Current Law

CMS has issued contradictory guidance on coverage of administration fees associated with the administration of Part D vaccines. Under Part B, physicians are paid a fee for administering Part B covered vaccines. In a couple of instances in the preamble to the Part D Final Rule (issued in January 2005), CMS indicated that costs directly related to the administration of Part D vaccines could be included in the physician fees under Part B, "since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals."[3] CMS restated this policy in the Part D Coordination of Benefits Guidance issued on July 1, 2005.[4] Pursuant to this guidance, physicians and others in the industry believed that costs associated with administering Part D vaccines would be covered by Part B.

On May 8, 2006, the Center for Beneficiary Choices ("CBC") issued guidance to all Part D sponsors relating to access for Part D vaccines (the "May 8th Guidance").[5] The May 8th Guidance is silent on the policy articulated in the Part D Final Rule, but appears to contradict it by stating that Part B administration fees cover only those vaccines covered by Part B. The May 8th Guidance reminds plans and providers that administration fees may not be included as part of the Part D dispensing fee.

On July 11, 2006, CBC issued additional guidance to Part D sponsors stating more explicitly that the administration fee for non-Part B covered vaccines would not be covered under Part B (the "July 11th Guidance").[6] The July 11th Guidance relies on language from the Medicare Benefit Policy Manual in determining that administration fees associated with a non-Part B covered item will not be covered under Part B. Specifically, the language relied upon from the manual is as follows:

> If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury..., the carrier excludes the entire charge (i.e., for both the drug and its

[3] 70 Fed. Reg. at 4328. *See also* 70 Fed. Reg. at 4231.

[4] Part D Coordination of Benefits Guidance from CMS dated July 1, 2005 at p. 27 (stating that "costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals").

[5] Memorandum from Abby L. Block, Director, CBC to All Part D Sponsors relating to increasing Part D vaccine access (May 8, 2006).

[6] Memorandum from Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group to All Part D Sponsors relating to HPMS Q&A – Clarification regarding Part D vaccine administration costs (July 11, 2006).

> administration). Also, carriers exclude from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a nonconvered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury). [7]

Pursuant to this language, the July 11th Guidance concludes that since vaccines are generally considered preventive and not necessary for the diagnosis or treatment of an illness or injury, the administration of a Part D vaccine cannot be covered by Part B.

This discussion of what is "reasonable and necessary" with respect to vaccines in the July 11th Guidance is inconsistent with a similar discussion in the Part D Final Rule. In the Final Rule, CMS discussed which vaccines would be covered under Part D. In the Medicare Modernization Act ("MMA"), the definition of a Part D drug included vaccines;[8] however, the MMA allowed Part D plans to exclude from coverage drugs for which payment would not be made under section 1862(a) of the Social Security Act (the "Act") if applied to Part D.[9] Section 1862(a)(1)(A) generally excludes from payment items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.[10] Vaccines covered under Part B are excepted from this rule.[11]

CMS noted in the Part D Final Rule that, if read literally, Part D plans would be permitted to exclude from coverage preventative vaccines that are covered Part D drugs because they are not "reasonable and necessary for the diagnosis or treatment of an illness or injury."[12] However, CMS argued that since 1862(a) "requires coverage under Part B of covered Part B vaccines, by analogy [Section 1862(a)] as applied to Part D should be read as requiring coverage under Part D of vaccines...."[13] Further, CMS acknowledged that Congress specifically defined Part D drugs to include vaccines.[14] Additionally, according to CMS, MMA references all of Section 1862(a) and the only way to give meaning to the reference to Section 1862(a)(1)(B)(covering Part B vaccines) is to extend the provision to permit coverage of Part D vaccines.[15] For these reasons, CMS interpreted the "reasonable and necessary" standard in the context of Part D vaccines and stated that the standard applicable for coverage of vaccines is those "reasonable and necessary for the prevention of illness."[16]

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[7] This language can be found in the Medicare Benefit Policy Manual, Ch. 15 at § 50.4.3.
[8] 42 U.S.C. § 1395w-102(e)(1).
[9] 42 U.S.C. § 1395w-102(e)(3)(A).
[10] 42 U.S.C. § 1395y(a)(1)(A).
[11] 42 U.S.C. § 1395y(a)(1)(B).
[12] 70 Fed. Reg. at 4230 & 4231.
[13] 70 Fed. Reg. at 4231.
[14] 70 Fed. Reg. at 4231.
[15] 70 Fed. Reg. at 4231.
[16] 70 Fed. Reg. at 4231.

It does not make sense to apply one interpretation of the "reasonable and necessary" standard in the context of coverage of the vaccine, and a completely different standard for coverage of the administration of the vaccine. CMS should be consistent and use the interpretation of the "reasonable and necessary" standard that was articulated in the Part D Final Rule.

Additionally, in the July 11th Guidance, CMS attempts to reconcile the policy set forth in that guidance document with the policy articulated in the Part D Final Rule. In doing so, the agency asserts that the administration costs discussed in the Final Rule (which includes the time and resources in discussing the vaccine), could be billed to Part B, but as part of another qualifying Part B office visit rather than as a separately billable service. It is disingenuous to suggest that, under the Part D Final Rule, CMS intended administration services to be lumped in with the other services provided as part of an office visit. At no time in the Part D Final Rule did CMS indicate that physicians should bill vaccine administration services in that way. Typically, CMS pays for administration services as a separate service using a separate code. Any departure from the typical way of billing for these services could result in significant confusion among providers. We believe there is no reason to develop a new way of billing for vaccine administration services, especially since the existing method is clear and easy to implement.

In addition to contradicting the policy set forth in the commentary to the Part D Final Rule, the July 11th Guidance fails to provide physicians with a clear understanding of which services associated with Part D vaccines are covered and how to bill for those services. Since June, we understand CMS has contemplated permitting physicians to bill a higher level office visit when administering a Part D vaccine to a patient as part of the visit. As mentioned above, the July 11th Guidance states that "time and resources" related to discussions of the vaccine "could be billed as part of another qualifying Part B office visit." However, the July 11th Guidance does not provide physicians with a list of covered services or with any indication of how to bill for those services (e.g., which codes to use). If CMS intends for physicians to bill Part B for any services associated with delivering a Part D vaccine, then the agency must clearly state the services that can be billed and the way to bill for those services. For many reasons, including those noted above, it is preferable to use a separate code to bill for administration services as opposed to adding such services to those performed as part of the office visit. The American Medical Association, among others, has urged CMS to issue clear and unambiguous guidance regarding coverage and payment for Part D vaccines and their administration. Unfortunately, the July 11th Guidance did not come close to satisfying this request.

B. Rationale for Coverage of Administration Costs

Costs associated with administering Part D vaccines should be covered. The commentary to the Part D Final Rule and subsequent guidance issued by CMS (up until May 2006) indicated that administration fees would be covered by Part B. Physicians

and others in the industry have relied on this policy. It is inappropriate to summarily change this policy now.

Additionally, CMS covers the administration fee associated with administrating Part B vaccines. As a matter of fairness and in order to ensure access, Part B vaccines and Part D vaccines should be treated the same. In other contexts, CMS has explicitly acknowledged the cost to the physician associated with drug administration. For example, in the Medicare Benefit Policy Manual, CMS indicates that where a patient purchases a drug and the physician administers it, the cost of the drug is not covered. However, the "administration of the drug...is a service that represents an expense to the physician" and, as such, is payable (assuming the drug would have been covered if the physician purchased it).[17] The same rationale should apply to vaccines covered by Part D since physicians experience the same expense (regardless of the part of the program ultimately paying for the vaccine).

As a practical matter, lack of clear guidance about a direct way to bill for administration services will negatively impact beneficiary access to vaccines (which are covered under Part D) and could end up costing the Medicare program more in terms of the expenses associated with diseases that could have been avoided. Encouraging providers to make-up for direct costs through indirect billing mechanisms is not a sufficient response. Failure to implement a concrete, direct policy will be at odds with the agency's recently renewed emphasis on access to Medicare-covered preventive services.

C. Potential Solution

CMS should provide for an administration fee under Part B for Part D vaccines as was indicated by the Part D Final Rule. CMS should treat the administration of a Part D vaccine as an "incident to" service under Part B in order to compensate the physician for the time spent in administering the vaccine. CMS should assign a HCPCS code for Part D vaccine administration (e.g., an additional G-code like the codes that already exist for administering the influenza (G0008), pneumococcal (G0009) and hepatitis B (G0010) vaccines). Physicians would use this code and submit the claim to the Part B carrier in the same manner that they are accustomed to doing when administering other injectables.

Billing for vaccine administration using a code specific to that service is much cleaner and easier to implement than billing for "time and resources" as part of an office visit as was suggested in the July 11th Guidance. It is also less susceptible to program integrity concerns.

III. Conclusion

[17] Medicare Benefit Policy Manual, Ch.15, §60.1(A).

Pursuant to the policy articulated in the Part D Final Rule, Part B should reimburse physicians for the reasonable costs associated with administering a covered Part D vaccine. In the final version of this Proposed Rule (to be issued later this fall), CMS should provide clear guidance to physicians on how to bill Part B for Part D vaccine administration services by assigning a separate code that can be used for the administration of Part D vaccines.

Sincerely,

Mark Feinberg, MD, PhD
Vice President
Policy, Public Health & Medical Affairs
Merck Vaccine Division

RAPPAHANNOCK GASTROENTEROLOGY ASSOCIATES

WARING TRIBLE, JR., MD, FACP, FACG
BOARD CERTIFIED
INTERNAL MEDICINE AND GASTROENTEROLOGY

August 10, 2006

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

RE: FIVE-YEAR REVIEW OF WORK RVUs UNDER PHYSICIAN FEE SCHEDULE AND PROPOSED CHANGES TO PRACTICE EXPENSE METHODOLOGY IN THE MEDICARE PROGRAM

Dear Dr. McClellan:

As a practicing gastrointestinal specialist who treats patients with many different gastrointestinal disorders and performs routine preventative services, including colonoscopy, I very much would appreciate your listening to my views on the CMS proposed rule regulating the five-year review of work relative value units as published in the Federal Register dated June 19, 2006.

I do think that retaining the identical work RVUs for the major GI codes is appropriate and certainly consistent with the necessary work that it takes to perform our medical services. Unfortunately, it also appears to me that the RVUs assigned to our GI procedures are still not appropriate to the amount of work that we do. As you are undoubtedly aware since the Medicare Colorectal Cancer Screening Benefit was enacted in 1997, CMS has cut the physician fee schedule payment for this by almost 40%. It is difficult for me to understand why there would be a 40% cut, while at the same time, Congress has decided to make eradication of colon cancer a national priority. I am afraid that by continuing these cuts, the Medicare patient population will suffer as access will probably be at some point more difficult and certainly fewer people will feel that this is an appropriate field of medicine in which to engage.

If the current proposal is enacted and especially if a 10% across the board cut in work RVUs in the name of budget neutrality is enacted, then the overall effect will be disastrous.

As you know, SGR has already proposed to cut our Medicare services reimbursement for physicians at approximately 5%. It is also, I think, important to know about a proposal to profoundly reduce the facility fee paid for cases performed in ASCs of perhaps even 30% or so. Again, I feel that CMS and the government have combined to extract so much money out of the system, that we will be seeing an inevitable decline in care in America in our healthcare population.

2201 CHARLES STREET, SUITE 103 • FREDERICKSBURG, VA 22401
TEL: (540) 370-0430 • FAX: (540) 370-0021

I personally feel that with cumulative cuts in excess of 50% that it is logical to somehow not be able to afford to include the Medicare beneficiaries on a daily basis in my practice at the same rate as private pay patients. I am now in my late 40s and soon in the not distant future will be entering the beneficiary pool of Medicare. Obviously, the older generation of my family already has entered this and I say with certainly a heavy heart that it just is disheartening to me and to my older family members and patients that the ability to care for these older Americans will continue to be constricted to the point that I am afraid they will not be a first-class citizen compared with other patients.

I would support a proposal to change the resource base back to expense methodology. I would think that CMS should adopt refinements to GI practice expenses and to GI practice expense RVUs, which was proposed, but then withdrawn by the agency last year. I do feel that using supplemental practice expense data, which could moderate the net Medicare fee reduction for some GI services may be a help in order to provide more reimbursement for these patients, but I am afraid that this sort of modest change in the decline will not be enough to prevent the disasters as predicted above.

In conclusion, I would say that despite retaining the work RVUs for the key GI services at their current level, as recommended by RUC and CMS, I am deeply concerned that the cumulative cuts from this rule, the SGR, and the pending reform to the ambulatory payment system will drive many practices and ASCs out of the Medicare system or perhaps even out of business.

I do appreciate the opportunity to submit my comments on this proposal and if you have any questions from a practicing gastroenterologist in Fredericksburg, Virginia, 50 miles south of Washington, D.C., please feel free to contact me in my office at (540) 370-0430 or the address as above.

Respectfully submitted,

Waring Trible, Jr., M.D., F.A.C.P., F.A.C.G.
WT:drp
cc: American College of Gastroenterology
6400 Goldsboro Road, Suite 450
Bethesda, MD 20817
J: 0810-190

5

ARTHROTEK®
A BIOMET COMPANY

CORPORATE HEADQUARTERS

August 29, 2006

Via FedEx

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

Re: CMS-1321-P -- Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; -- Request for Non-Facility Practice Expense RVUs for Arthroscopy Procedures Falling Under CPT Codes 29870, 29805, 29839, 29840, 29860

Dear Dr. McClellan:

Arthrotek, Inc. is pleased to submit comments on the proposed rule setting payment policies under the Physician Fee Schedule in 2007 as set forth in the 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).

A Biomet company, Arthrotek is one of the world's leading manufacturers of arthroscopy products. On behalf of our physician customers and their many patients suffering from a wide range of joint problems, we are keenly interested in the changes CMS proposes that impact arthroscopy procedures.

Unfortunately, the CPT codes associated with providing arthroscopies in the office setting do not adequately cover the practice expenses associated with providing arthroscopies in the physician office. As a result, patient access to these advanced procedures is placed in jeopardy. **For this reason, Arthrotek respectfully requests that CMS add non-facility practice expense relative value units (PE RVUs) to cover physician office expenses for CPT codes 29870, 29805, 29830, 29840, 29900 arthroscopy procedures.**

Background

Working in conjunction with the most innovative surgeons, Arthrotek focuses research and development efforts on technique-specific instruments for ligament and arthroscopic surgery repair. As a result, there have been significant refinements in the arthroscopes and instruments used for arthroscopy procedures in the past few years. These changes have made it more practical for doctors to furnish arthroscopy procedures in the office setting. Using smaller arthroscopes, doctors are better able to assess, on an immediate basis, the etiology of a patient's complaints and thereby forego ordering more expensive and time consuming MRI

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

EMAIL
Arthrotek@Arthrotek.com

FAX
574.372.1718

scans. In addition, with development of better instrumentation and surgical techniques, many conditions can now be treated arthroscopically, resulting in much easier patient recovery than open surgery.

Under the current physician fee schedule, however, doctors are not adequately reimbursed for the significant practice expenses associated with providing arthroscopies in the office setting.[1] As a result, doctors often can not afford to provide these valuable services and patients may lose access to this extremely valuable tool.

For this reason, Arthrotek respectfully requests that CMS add non-facility 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.

Previous Favorable Reaction from CMS

CMS has previously indicated that it views this suggestion favorably. On March 7, 2006, Michael Kolczun II, M.D of the Cleveland Clinic Foundation and Frank Bonnarens, M.D, of Orthopaedic Associates along with several others met with CMS officials to discuss the assignment of non-facility (office) PE RVUs for the diagnostic arthroscopy procedures which fall under CPT codes 29870, 29805, 29830, 29840, and 29900. At this meeting, CMS representatives recommended that Dr. Kolczun and Dr. Bonnarens follow up with the AAOS and submit comments to CMS requesting that the agency **add physician office values for diagnostic arthroscopy procedures in the 2007 Medicare Physician Fee Schedule Final Rule in November 2006.**

The payment inequity faced by doctors seeking to provide arthroscopy procedures in the office setting can be easily corrected if CMS establishes 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, and 29900. Appropriate payment under the Medicare physician fee schedule will allow doctors to more expeditiously manage their patients' conditions and preserve patient access to in-office arthroscopy procedures.

Thank you for your attention to this critical issue.

Sincerely,

David A Nolan Jr.

David A. Nolan Jr., President

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1 We estimate the costs for supplies and devices used for arthroscopy procedures at approximately $975 to $1,000 in "concrete" non-facility practice expense costs related to the arthroscopy procedures [see attached initial cost estimate].

Attachment:

Initial Estimate of Non-Facility Practice Expense Costs

cc: Carolyn Mullen
Gail Daubert

PE Resources / Items and Supplies & Equipment	Item	Time minutes	Cost ($)
Patient Check-in (*Medical History, Medications, Vitals, Testing)*		*20*	*$ 10.20*
Injection		*8*	*$ 4.08*
Patient education- Procedure explanation		*15*	*$ 7.65*
Procedure Set-Up		*15*	*$ 7.65*
Review patient's condition with physician prior to procedure		*5*	*$ 2.55*
Arthroscopy Procedure		*30*	*$ 15.30*
Wash and dress leg post-procedure		*10*	*$ 5.10*
Finish time *(patient gets dressed, follow-up instructions, walk out)*		*10*	*$ 5.10*
Break down		*15*	*$ 7.65*
Sterilization		*20*	*$ 10.20*
InnerVue Usage**		*60*	*$ 33.61*
Table, power ***		83	*$ 1.80*
Saline bag	1 liter		*$ 5.00*
Ancef (anti-biotic)	1 gram		*$ 5.00*
Disposable arthroscope	1		*$ 700.00*
Disposable cannula set (cannula, obturator, trocar, plug)	1		*$ 80.00*
1% Lidocaine (plain)	30cc		*$ 15.00*
Procedure Kit			*$ 55.00*
72" Infusion tubing with spike	1		
48" Extension tubing w/connectors	1		
Three-way valve	1		
Steri Strip Closures (6 pk.)	1		
Dura Prep Skin Cleanser	1		
20 ml. Syringe	1		
22 guage needle for syringe	1		
6' x 6' IsoDrape eith cutout	1		
#11 scalpel	1		
Shelf Drape	1		
Two adhesive strips	1		
Needle (1 to inject anti-biotic into saline, 1 to fill syringe with anesthetic, 1 to inject anesthetic into joint)	3		
Syringe	1		
Regular ace bandage (post-procedure wrap)	1		
Gown	1		
Gauze pads	4		
Rubberized ace bandage (pre-procedure wrap on foot & lower leg)	1 roll		$ 5.00
Initial Estimate of Non-Facility Practice Expense			$ 975.90
Assumption:			

RN Salary based on 2005 CMS Practice Expense Data file	$ 0.51		
** Based on 3 year life expectancy of InnerVue unit	$ 47,595.00		
Based on one procedure per day maximum	$ 15,865.00	per year	
	$ 67.22	per day	
Based on usuage of 2 hour day(although it is likely much less)	$ 33.61	per hour	
	$ 0.56	per minute	
Additional light box	$ 5,885.00		
Additional hand piece	$ 6,710.00		
*** Based on a 10 year useful life of table @ $6153.63	$ 615.36	per year	
	$ 2.61	per day	
	$ 1.30	per hour	
	$ 0.02	per minute	

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ORTHOPAEDIC
ASSOCIATES, P.S.C.

Jewish Outpatient Care Center
225 Abraham Flexner Way, Suite 403
Louisville, KY 40202
Phone: (502) 585-4376
Fax: (502) 581-1274

Preston Medical Center
7926 Preston Highway, Suite 103
Louisville, KY 40219-3848
Phone: (502) 969-2302
Fax: (502) 968-0592

Springhurst
9422 Brownsboro Road
Louisville, KY 40241
Phone: (502) 425-1983
Fax: (502) 425-9182

Carroll County Memorial Hospital
309 11th Street
Carrollton, KY 41008
Phone: (502) 732-4321, Ext. 204
Fax: (502) 732-3213

Elizabethtown Health Center
1239 Woodland Drive, Suite 104
Elizabethtown, KY 42701
Phone: (270) 763-0238
Fax: (270) 766-1327

FRANK O. BONNARENS, M.D.
ANDREW L. DeGRUCCIO, M.D.
NAVIN R. KILAMBI, M.D.

Specializing in:
- ADULT AND PEDIATRIC ORTHOPAEDICS
- SPORTS MEDICINE
- TOTAL JOINT REPLACEMENT
- ARTHROSCOPIC SURGERY

August 30, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & 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:

I am writing to ask that you establish office-based practice expenses for orthopedic arthroscopy procedures described by CPT codes 29870, 29805, 29839, 29840, 29860. I am referencing the proposed rule which recommends payment policies under the Medicare physician fee schedule for calendar year 2007.This rule is the 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). By making this important revision to the Medicare physician fee schedule, you would allow my fellow orthopaedic surgeons and me to continue to improve the diagnosis and treatment of joint problems afflicting many Medicare patients. Currently we are not being paid any of the equipment expenses of doing these procedures in our office. By making the changes I have requested you will ensure that we can continue to furnish these cost saving services.

I encourage CMS 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.

Significant refinements in the arthroscopes and other instruments used for arthroscopic procedures in the past few years have made it more practical for doctors to furnish arthroscopic procedures in the office setting. Using smaller arthroscopes, we are better able to assess, on an immediate basis, the etiology of a patient's complaints. Often, this allows us to forego ordering expensive and time-consuming MRI scans or arthroscopies under general anaesthesia.

Unfortunately, under the current physician fee schedule physicians are not being 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 costing me 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, many doctors decide not to provide arthroscopy services in the more efficient office setting.

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

ORTHOPAEDIC
ASSOCIATES, P.S.C.

Jewish Outpatient Care Center
225 Abraham Flexner Way, Suite 403
Louisville, KY 40202
Phone: (502) 585-4376
Fax: (502) 581-1274

Preston Medical Center
7926 Preston Highway, Suite 103
Louisville, KY 40219-3848
Phone: (502) 969-2302
Fax: (502) 968-0592

Springhurst
9422 Brownsboro Road
Louisville, KY 40241
Phone: (502) 425-1983
Fax: (502) 425-9182

Carroll County Memorial Hospital
309 11th Street
Carrollton, KY 41008
Phone: (502) 732-4321, Ext. 204
Fax: (502) 732-3213

Elizabethtown Health Center
1239 Woodland Drive, Suite 104
Elizabethtown, KY 42701
Phone: (270) 763-0238
Fax: (270) 766-1327

FRANK O. BONNARENS, M.D.
ANDREW L. DeGRUCCIO, M.D.
NAVIN R. KILAMBI, M.D.

Specializing in:
- ADULT AND PEDIATRIC ORTHOPAEDICS
- SPORTS MEDICINE
- TOTAL JOINT REPLACEMENT
- ARTHROSCOPIC SURGERY

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 arthroscopic procedures in the office setting by establishing non-facility PE RVUs which take into account the costs of the devices, supplies, and other procedure related expenses used to provide in-office arthroscopy services falling under the CPT codes 29870, 29805, 29830, 29840, and 29900.

Appropriate and fair payment under the Medicare physician fee schedule will allow physicians to more expeditiously manage our patients' conditions and preserve Medicare patient's access to the more efficient and cost effective in-office arthroscopic procedures.

Thank you for your consideration of this important matter.

Sincerely,

FRANK BONNARENS

cc: American Academy of Orthopaedic Surgeons
Arthroscopy Association of North America
Carolyn Mullen
Gail Daubert

PATRICK J. KENNEDY
1ST DISTRICT, RHODE ISLAND

WASHINGTON OFFICE
407 CANNON HOUSE OFFICE BUILDING
(202) 225-4911
FAX: (202) 225-3290
Email: patrick.kennedy@mail.house.gov

DISTRICT OFFICE
249 ROOSEVELT AVENUE, SUITE 200
PAWTUCKET, RI 02860
(401) 729-5600
(800) 392-5772
FAX (401) 729-5608

www.patrickkennedy.house.gov

Congress of the United States
House of Representatives
Washington, DC 20515

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September 12, 2006

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

Dear Dr. McClellan:

I am writing to express my concern that the Centers for Medicare and Medicaid Services (CMS) proposed rule making adjustments in Medicare Part B practice expenses and relative work values (71 FR 37170, 6/29/2006) severely cuts Medicare anesthesia payment. I am concerned that these cuts will have an extremely negative impact on access to quality anesthesia services in Rhode Island.

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. It is my understand that 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.

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.

In accordance with all applicable rules and regulations, I would like to request that CMS suspend its proposal to impose such cuts in Medicare anesthesia payment and review the potential impacts of its proposal. I appreciate your attention to this issue and I look forward to hearing from you.

Sincerely,

Patrick J. Kennedy
Member of Congress

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alley
etabolic
Imaging, LLC

September 7, 2006

CMS-1321-P
PO Box 8015
Baltimore MD 21244-8015

RE: File Code CMS-1321-P
Proposed national IDTF policy

Dear Sirs:

I am writing to comment on on your proposed supplier standards as published in the August 22, 2006 Federal Register (Volume 71, No. 162, pages 49060-49062).

As an owner, operator, and Medical Director of an IDTF I heartily endorse the proposed new supplier standards as written, and urge you to implement this new policy without revision.

The proposed standards are reasonable in both nature and scope, and the proposed requirements represent a well thought out and reasonable approach to combating the abuses which have been perpetrated by a few unscrupulous individuals operating "phantom" IDTFs.

At my IDTF imaging center we are currently in compliance with all of these proposed regulations. These proposed regulations ask simply that providers adhere to reasonable medical and business standards while operating an IDTF.

I believe that if all IDTF providers were held to this level of accountability that we could go a long way not only toward fighting Medicare fraud and abuse, but also toward insuring that we protect Medicare beneficiaries quality of care and the financial viability of the Medicare system.

Sincerely,

Daniel Stobbe, MD, FACNP
Medical Director

6121 N. Thesta Avenue, Ste. 207 • Fresno, CA 93710 • 559-449-2640 • Fax 559-432-7020
www.valleymetabolicimaging.com

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THE ASSEMBLY
STATE OF NEW YORK
ALBANY

DEBORAH J. GLICK
Assemblymember 66TH District
New York County

CHAIR
Social Services Committee

COMMITTEES
Children and Families
Environmental Conservation
Higher Education
Ways & Means

August 21, 2006

The Honorable Mark B. McClellan
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

Dear Mr. McClellan:

I am writing to express my serious concerns with your proposed cuts to Medicare reimbursement, due to take effect on January 1, 2007 (**CMS-1512-PN**). These cuts of up to 5.1% will negatively impact Medicare patients throughout the country, including many of my constituents in New York City, discouraging physicians from accepting new Medicare patients and further limiting existing patients' access to quality medical care.

As the author of New York State's Women's Health and Wellness Act, which promotes early detection and prevention of certain medical conditions affecting women, such as breast cancer and osteoporosis, I am particularly concerned about how cuts to reimbursement will affect access to these procedures. In New York State and in many areas across the country, underprivileged women already face enormous difficulties in accessing early detection procedures that are crucial for the diagnosis and treatment of breast cancer. With Medicare reimbursement rates for mammograms already well below the average cost of performing them, additional cuts would further jeopardize this access. The tragic result could be that more cases of breast cancer go undetected, or are detected at a later stage, decreasing the effectiveness of treatment and increasing medical costs.

In all areas of healthcare, policy makers must work to close the gap between reimbursement rates, necessity, and the actual cost of performing procedures in order to ensure that all patients have access to vital medical services. You have proposed cuts which are neither financially sound nor humanely just. I urge you to examine the far reaching damage that cuts to reimbursement could inflict upon patients and reconsider the proposed reimbursement changes.

Sincerely,

Deborah J. Glick

Deborah J. Glick
Assemblymember

DISTRICT OFFICE: 853 Broadway, Suite 2120, New York, New York 10003-4703, (212) 674-5153, FAX (212) 674-5530
ALBANY OFFICE: Room 844, Legislative Office Building, Albany, New York 12248, (518) 455-4841, FAX (518) 455-4649
glickd@assembly.state.ny.us

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ADVANCED UROLOGY ASSOCIATES OF FLORIDA, P.L.

JOSEPH P. CRAWFORD, M.D., F.A.C.S.
STEVEN J. HULECKI, M.D., F.A.C.S.
HUGH K. MCCRYSTAL, M.D., F.A.C.S.
MARC C. ROSE, M.D., F.A.C.S.

VALERIE A. WARD, A.R.N.P.

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

September 18, 2006

Re: **"REASSIGNMENT AND PHYSICIAN SELF-REFERRAL"**

Dear Sir or Madam:

For the last several years, the laboratory services provided by urologists in our offices have improved the quality of care available for our patients. Recently, with this increased competition, large laboratory companies whose best interest is in preserving their previous monopoly of urological pathology services, have promulgated the idea that perhaps these services are inappropriate or would be violations of self-referral. This, we believe, has been done in their own self-interest and in violation of the spirit of free trade. These corporations wish to deny patients the best, most convenient and cost effective care in favor of their own profits. In raising the hypothetical potential for impropriety, they have placed their own profit margins above the interest of the patients. We feel it is within the mandate of the Office of the Inspector General as well as CMS to ensure that patient care is delivered in a careful, professional, proficient and cost effective manner. We believe that laboratory services in urology offices meet these high goals. To this end, we believe that the records will show that urology laboratory services provided by urologists who are responsible not only for the results of these pathology examinations, but also for the care delivered that is indicated by such examinations is in the best interest of their patients. Thus, this should not be a question for the government of the inappropriate profits. The volume of urological pathologic services provided will be the same whether preformed in reference laboratories or urologist pathology offices, paid by the same CPT code and are thus, budget neutral. It is rather for the best interests of patients and the cost-effective delivery of medical care for those that we serve that we are interested in preserving office labs.

1. The performance of complicated urologic specimen evaluation such as the in-situ hybridization studies (FISH), in our experience, has been vastly superior in the environment where we control the collection of the specimen, the performance of the test and the data transfer to the responsible physician and patient. Prior testing at national for- profit labs has shown up to a 75% rejection or hypocellular rate. When preformed under our control in our offices by the designated personnel who perform all of our urological pathology examinations, the rejection and hypocellular rate is at 20% or less. Our labs are open six days a week and the same personnel do the collection, transportation, preparation and evaluation of the specimens. This has allowed us to control the process to an extent that it is not only highly proficient, but specimen processing results in excellent quality results as compared to these large national labs, who wish to interfere with this improved service. It is a seamless process, without the middleman.

2. Certainly there be no doubt the pathology lab is our office. We have multiple offices currently, and this represents a satellite office where our procedures and our laboratory services are performed. The space has been purchased and has been built out by the urologist(s). The purchase of the equipment and disposable supplies is not shared, but is borne by the individual urology practice, not unlike any other payable that is utilized in our practice. The equipment remains in our owned office, and the staff, who provide medical services in this office are under contract and as such provide care for only the individual practice's specimens while in this office. Therefore, there is no potential kickback arrangement among providers, staff, or those who may also have offices in this same complex.

3. Because of the volume of procedures that are performed in our offices and the fact that these are solely urologic pathology procedures, we have become experts in the field. This is certainly related to the volume of the urological biopsies and cytology specimens that we see on a daily basis as compared to that seen by the usual and customary pathologist during a similar time period. Thus, the expertise with which we can accurately deliver care for each patient is far superior than those that are sent off to a "reference lab" that may provide multiple different specialty services which are non-urological. Similarly, the various pathologists who they employ first interest and expertise may not be urology. They often need to order further tests or seek second opinions with the attendant increase in cost and potential therapy delay to the patient. Our pathologists are recognized in their own right as experts in the field. They read ALL of our specimens This is consistent with the government's own model for pathologic excellence as practiced at the Armed Forces Institute of Pathology, where the best of the urologic pathologists read only urology. They do not delegate the pathologic interpretation to non-specialty pathologists, so that they can use their name or reputation to drum up business in this country and abroad.

4. Our model of office pathology laboratory services offers the most direct access for the entire team who is responsible for the individual patient's care. Our pathologist have access to our patients medical records via electronic medical records so they can develop clinical correlations with regard to the patient's history, physical examination, radiologic evaluations, and previous specimens with which they can correlate their findings and provide the best interpretation. In a similar way, as this is one medical record, all records are continuously and contemporaneously updated, so the record of each individual patient is clinically current for all providers and their staff involved with the care of the patient.

5. The close relationship that we have developed with our pathologists who are not only our colleagues, but are on our staff has allowed us to provide excellent care thru timely communication regarding cases that come into question. Rarely have I had a pathologist from one of the national companies call me with questions

MIDTOWN NUTRITION CARE
119 WEST 57TH STREET
NEW YORK, NY 10019
(212) 333-4243

September 11, 2006

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 21244-1850

Re: August 22, 2006 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

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services, 71 FR 48987)

Dear Sir or Madam:

Midtown Nutrition Care (Midtown), a single specialty nutrition group practice with 7 registered dietitians, respectfully submits the following comments.

Table of Contents

Attachment B—July 2000 HCPAC Recommendations and August 1, 2000 transmittal memo (4 pages)

Attachment C—January 3, 2006 letter from ADA to CMS (4 pages)

Attachment D—March 24, 2006 letter from ADA to CMS (3 pages)

Attachment E—Section 105 of BIPA and Statement of the Manager For Section 105 (2 Pages)

Attachment F—March 2000 RUC Update Survey (24 pages)

Summary of Points

The work RVUs for the three individual 15-minute medical nutrition therapy codes CPT 97802, 97803 and G0270 should all be the same. The work RVUs for the medical nutrition therapy codes should be based on the 15-minute consultation code CPT 99241 rather than on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150.

Inadequate Reimbursement = Lack of Access

1. Last year, in the Calendar Year 2006 Proposed Rule, CMS proposed eliminating the nonphysician work pool, formerly known as the zero-work pool, and stated: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change.... We, therefore, welcome all comments on these proposed changes..." (70 FR 45777, second column).

2. As members of the medical community Midtown submitted comments dated September 22, 2005 from our group and from the original sponsor of the medical nutrition therapy benefit bills, Congressman Jose Serrano. Comments were also submitted by our professional society, the American Dietetic Association (ADA).

3. These comments showed that even without further reduction current reimbursement rates are inadequate, and urged that appropriate work RVUs be assigned to the Medical Nutrition Therapy codes in order to give effect to the intention of Congress to provide adequate payment for these services, so that access to these services would become generally available to the Medicare beneficiaries entitled thereto, namely, patients with diabetes or renal disease.

4. That the access to care envisioned by Congress does not exist is shown by the following three items. First, prior to passage of the medical nutrition therapy benefit the Congressional Budget Office estimated the annual cost of medical nutrition therapy

services to be 60 million dollars, but only a few million dollars have been spent annually since the benefit became available in 2002. Second, this represents visits by only about 250,000 beneficiaries out of an estimated 8 million beneficiaries with diabetes or renal disease. Third, only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. For a discussion of these three items, see Journal of the American Dietetic Association, June 2005, p. 990 and p. 995 (footnote references).

5. In our case, as our September 22, 2005 comment showed, Medicare pays less than half the fees paid by insurers in our area that have independently valued these codes. Medicare's fees are well below our break-even level. Therefore we cannot afford to treat Medicare patients and none of us has become a Medicare provider. We turn away a couple of Medicare patients every day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the dietitians in our area accept Medicare.

6. In the Calendar Year 2006 Physician Fee Schedule Final Rule no decision was made regarding medical nutrition therapy work RVUs; that decision was put off to this year: "Because we are maintaining the NPWP for 2006, we are deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussions with the specialties." (70 FR 70134, first column).

7. In the Calendar Year 2007 Proposed Rule CMS stated it would establish work RVUs and remove clinical labor time in the practice expense direct input database: "Because we propose to add the work RVUs to these services, the MNT clinical labor time in the direct input database would be removed with the adoption of this proposal." (71 FR 48987, third column).

8. The assignment of work RVUs coupled with the removal of clinical labor time from the practice expense direct input database would raise the fully implemented non-facility total RVU of the 15-minute new patient visit code CPT 97802 from **0.48** to **0.58**, leave the 15-minute established patient visit codes CPT 97803 and G0270 total RVU of **0.48** unchanged, and raise the 30-minute group codes CPT 97804 and G0271 total RVU from **0.19** to **0.32**. (70 FR 70457, 70462; 71 FR 49231, 49235).

9. Given the approximately 10% adjustment required to preserve budget neutrality (71 FR 37241, first-second columns), this means that the new patient visit code would pay about 5% more than currently, the established patient visit codes would pay about 5% less than currently, and the group codes would pay about 50% more than currently. Although the group fees would be adequate, neither our practice nor the practices or employment settings of other dietitians have many group visits compared to individual visits. Therefore if these RVUs are carried over to the Final Rule our practice and other dietitians will still be unable to afford to treat Medicare patients, allowing the lack of access to care to continue.

The Work RVUs Should Be the Same for the Individual Codes

10. The proposed work RVUs are those recommended on an interim basis by HCPAC in July 2000, transmitted to CMS by memo dated August 1, 2000, a copy of which is attached as Attachment B.

11. These recommendations were based on a RUC survey conducted in March 2000 (Attachment F) for seven proposed, but never adopted, Medical Nutrition Therapy codes, 3 initial visit codes, 3 follow-up visit codes and 1 group visit code, modeled after the office visit code series CPT 99201-99205, 99211-99215.

12. Unlike the time-based codes that were adopted, these 7 codes were based on level-of-complexity. Thus the survey data showed that follow-up visits would have lower RVUs because at the same level of complexity the follow-up visit will take less time than the initial visit.

13. But because a shorter visit will take less time, it will also have fewer 15-minute increments. Therefore there is no need to value the 15-minute follow-up visit increment less than the 15-minute initial visit increment. In fact doing so amounts to a double reduction of the fee, first for fewer 15-minute increments, and then a lower RVU for the each increment.

14. HCPAC stated at the bottom of the first page of the July 2000 Recommendations (Attachment B): "This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association." Somehow HCPAC overlooked the fact that the survey data was based on the never adopted level-of-complexity codes, while the adopted codes were purely time-based codes.

15. Using the survey data, HCPAC valued the15-minute follow-up increment 73% less than the 15-minute initial visit increment, estimating that the typical CPT 97802 visit would take 75 minutes (pre, intra and post visit time), while the typical CPT 97803 visit would take 55 minutes (pre, intra and post visit time), or 73% less time (55 ÷ 75 = 73%).

16. All of the CPT codes that are time-based, other than the Medical Nutrition Therapy codes, use the same code for their initial and follow-up visits, so their initial and follow-up time increments will pay the same. See, for example, the preventive medicine counseling codes CPT 99401-99412 and the psychiatric therapeutic psychotherapy codes CPT 90804-90829.

17. In fact, were it not for CMS's need to use CPT 97803 and G0270 to keep track of the number of follow-up visits and change-of-diagnosis follow-up visits, it would need only one code for all individual visits. But just because CMS needs to use two additional follow-up visit codes is no reason to value the 15-minute increments of those codes less than the 15-minute increment of the initial visit code.

18. CMS recognized that initial and follow-up time-based medical nutrition therapy codes should be valued the same when CMS valued the later-created group change-of-diagnosis 30-minute follow-up code G0271 the same as the CPT 30-minute group code CPT 97804. (70 FR 70457, 70462).

19. But more to the point, the question of whether the individual 15-minute codes would be valued the same or differently was an issue once before, in the preparation of the Calendar Year 2002 Physician Fee Schedule. The Calendar Year 2002 Proposed Rule had proposed a lesser value for the 15-minute follow-up increments. The issue was fully discussed in the Proposed Rule, in comments thereto, and in the Final Rule, which concluded that all of the time-based Medical Nutrition Therapy codes should have the same hourly rate: "A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (68 FR 55280, first-second columns).

20. That reasoning was sound and remains sound and should continue to be followed, rather than create a **0.08** less work RVU for CPT code 97803 and G0270 (0.45 – 0.37 = 0.08). (71 FR 49231, 49235).

Use the Work RVU of the 15-Mintue Consultation Code

21. CMS may accept or reject HCPAC work RVU recommendations. (71 FR 37173, third column). In this instance we submit that CMS should reject the July 2000 HCPAC interim recommendations, which base the medical nutrition therapy work RVUs on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150, and instead base the work RVUs on the 15-mnute consultation code CPT 99241.

22. The July 2000 HCPAC interim recommendations regarding the new Medical Nutrition Therapy codes were unusual in that they were initially submitted for the Calendar Year 2001 Physician Fee Schedule before CMS had the statutory authority to value these codes for Medicare payment (71 FR 48987, first-second columns), because the law that created the medical nutrition therapy benefit was not enacted until later, in December 2000, and created the benefit for these services starting in the Calendar Year 2002. See PL 106-544, Appendix F, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Section 105, Coverage of Medical

Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease, and the published legislative history set forth in the Statement of the Manager For Section 105, both attached as Attachment E.

23. When HCPAC was making its interim work recommendations, HCPAC did not know what the statute would eventually contain. Therefore HCPAC looked solely to the text of the Medical Nutrition Therapy codes CPT 97802-4 which describe medical nutrition therapy services in bare-bones terms as "assessment [or re-assessment] and intervention, individual [or group], face-to-face with the patient, each 15 [or 30] minutes." On the other hand the statute defines medical nutrition therapy services much more comprehensively as "diagnostic, therapy and counseling services for the purpose of disease management", Section 105(b) of BIPA, 42 U.S.C. 1395x(vv)(1), and provides that payment of 85% to dietitians be determined "for the same services if furnished by a physician." Section 105(c)(2) of BIPA, 42 U.S.C. 1395l(a)(1)(T).

24. Since HCPAC was recommending work RVUs when it was not even cognizant of what the statutory definition would be, HCPAC was able to compare the15- and 30-minute individual and group medical nutrition therapy codes to "other modality or treatment codes" (middle of the first page of the July 2000 Recommendations, Attachment B), in this case the 15- and 30-minute individual and group physical therapy codes CPT 97110 and 97150.

25. These treatment codes are poor comparisons given the (now known) statutory definition of medical nutrition therapy in Section 105(b), 42 U.S.C. 1395x(vv)(1), which includes diagnosis and counseling as well as therapy.

26. In the 2002 Physician Fee Schedule Proposed and Final Rules CMS had compared medical nutrition therapy services to the 15-minute preventive medicine counseling code CPT 99401: "Commenters...believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness." (66 FR 55279, third column-55280, first column).

27. In prior submissions to CMS Midtown had also proposed that the work RVUs for the Medical Nutrition Therapy codes could be based on the 15-minute preventive medicine counseling code CPT 99401. However Section 105(b), 42 U.S.C. 1395x(vv)(1), defines medical nutrition therapy services as services provided "for the purpose of disease management", that is, for patients with established illness. So a crosswalk to CPT 99401 would not be appropriate, because the CPT text prior to Sections 99401-99429 states (third paragraph of text): "These codes [preventive medicine counseling codes] are not to be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes [emphasis supplied]."

28. A more appropriate crosswalk, according to the text quoted above, would be to the work RVU of an office visit or consultation code.

29. Section 105(b), 42 U.S.C. 1395x(vv)(1), provides that a medical nutrition therapy visit be "pursuant to a referral by a physician", to whom a report is sent post-visit. Therefore the visit could be considered a consultation. If so, the work RVU could be that of the 15-minute consultation code CPT 99241, which has a work RVU of **0.64** as of the 2006 Physician Fee Schedule, and the same **0.64** is proposed for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

30. The medical nutrition therapy visit could also be considered an office visit. If so, the work RVU could be that of the 15-minute established patient office visit code CPT 99213, which has a work RVU of **0.67** as of the 2006 Physician Fee Schedule (70 FR 70458) and a proposed work RVU of **0.92** for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

31. CMS could use either the work RVU of CPT 99241 or the work RVU of CPT 99213 as the work RVU for the 15-minute individual Medical Nutrition Therapy codes CPT 97802, 97803 and G0270; and as the basis for the work RVU for the 30-minute group codes CPT 97804 and G0271 in the same manner as was done in the Calendar Year 2002 Physician Fee Schedule Final Rule; that is, by multiplying the CPT 97802 RVU by 2 then dividing by 5. (66 FR 55281, first column).

32. The Calendar Year 2002 Physician Fee Schedule Final Rule, however, had rejected a valuation crosswalk to E/M codes, making the following analysis for the first time in the Final Rule, though not in the Proposed Rule (so no comments may have been received questioning such analysis): "We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service [emphasis supplied]." (66 FR 55278, third column).

33. This analysis misread the statute, which specifies that the amount paid be determined by comparing medical nutrition therapy services provided by a physician, not by comparing medical nutrition therapy services provided by a registered dietitian. Section 105(c)(2), 42 U.S.C. 1395l(a)(1)(T), states "the amount paid shall be...85 percent of the amount determined ... for the same services if furnished [i.e., provided] by a physician". (See the third sentence of the Statement of the Manager For Section 105, Attachment E, "... if such services were provided by a physician [emphasis supplied].")

34. CMS has acknowledged that: "Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. (66 FR 55279, second column).

35. If a physician who is also a dietitian has a medical nutrition therapy visit "for the purpose of disease management" the physician will perform the 3 key components, taking a medical history, performing a physical examination and engaging in medical decision making, as part of the service. In fact, the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." (As noted above, since the Section 105(b), 42 U.S.C. 1395x(vv)(1), requires Medicare-covered visits to be for patients with established illness, only the office visit/consultation codes, not the preventive medicine codes, could be used for a Medicare-covered visit.)

36. To qualify for CPT 99241 or CPT 99213 these 3 components do not need to be at high levels. CPT 99241 is a level one E/M code that has the following, a problem focused history, a problem focused examination, and straightforward medical decision making; CPT 99213 is a level three E/M code that has the following, an expanded problem focused history, an expanded problem focused examination, and medical decision making of low complexity. (71 FR 37211, 37214).

37. Similarly, a registered dietitian who is not a physician will take a problem focused or expanded problem focused medical history, reviewing labs and other reports from the referring physician and interviewing the patient; will perform a limited medical examination, which will include anthropometric measurements, and could also include additional examination such as taking blood pressure or blood glucose, or examining affected body areas such as the skin for diabetic acanthosis nigricans, or for pressure ulcers that may be connected with protein-calorie malnutrition; and engage in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake, administration or supplementation, and could include additional medical decision making such as modifying insulin doses to match carbohydrate intake using carbohydrate counting/insulin ratios.

38. Because the levels of the history taking, physical examination and decision making in the visit (whether by a physician who is also a dietitian, or by a dietitian who is not a physician) are often low, the lower levels of medical history, physical examination and decision making contained in the 15-minute consultation code CPT 99241 make the work RVU of that code (current and proposed work RVU of **0.64**) more appropriate than the work RVU of CPT 99213, which has higher levels of history taking, physical examination and decision making (current work RVU of **0.67**, proposed work RVU of **0.92**). Therefore we recommend using the work RVU of CPT 99241.

39. It is also appropriate to use the work RVU of CPT 99241 because time may be the determining factor in assigning the level of the service. When time is the determining factor, the work RVU of CPT 99241 generates the lowest (and therefore most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour.

40. The Evaluation and Management Service Guidelines state, under the heading "Levels of E/M Services": "The descriptors for the levels of E/M services recognize seven components, six of which are used in defining the levels of E/M services. These components are: History, Examination, Medical decision making, Counseling,

Coordination of care, Nature of presenting problem, Time. The first three of these components (history, examination, and medical decision making) are considered the key components in selecting a level of E/M services."

41. However the Evaluation and Management Service Guidelines state later, under the heading "Select the Appropriate Level of E/M Services Based on the Following", "3. When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services."

42. Although the definition of medical nutrition therapy services, Section 105(b), 42 U.S.C 1395x(vv)(1), includes three services, "diagnostic, therapy, and counseling services", counseling services will almost always dominate (more than 50%) the encounter. Therefore, time may be considered the key or controlling factor.

43. The following chart compares CPT 99241 to all other office visit/consultation codes that are 15 minutes or divisible by 15 minutes (all other codes are either less than 15 minutes or not divisible by 15 minutes). The chart shows that for both the current and proposed RVUs, the work RVU of CPT 99241 generates the lowest (most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour. (70 FR 70458; 71 FR 37218, second-third columns; 71 FR 49232):

CPT Code	15-Minute RVU	30-Minute RVU	One-Hour RVU
99241	**0.64** Current	**1.28** (2 increments)	**2.56** (4 increments)
	0.64 Proposed	**1.28** (2 increments)	**2.56** (4 increments)
99213	**0.67** Current		
	0.92 Proposed		
99242		**1.29** Current	
		1.34 Proposed	
99203		**1.34** Current	
		1.34 Proposed	
99244			**2.58** Current
			3.02 Proposed
99205			**2.67** Current
			3.00 Proposed

The ADA Prefers Using an E/M Code RVU

44. All of the registered dietitians at Midtown are members of our professional society, the American Dietetic Association, and we have observed over the past 6 years that the ADA has consistently communicated its preference for work values based on E/M codes, in particular the level three, 15-minute and 30-minute, office visit codes CPT 99213 and 99203. As CMS observed, "the ADA compared work associated with their services to physician E/M services of CPT 99203 and 99213, which have respective work values of **1.34** and **0.67**." (71 FR 48987, second column).

45. Because CMS stated in the Calendar Year 2006 Final Rule that it was "deferring our decision regarding work RVUs for audiology, speech language pathology and medical

nutrition pending further discussion with the specialties", ADA submitted a January 3, 2006 letter (Attachment C). In the letter ADA stated, at page 3, "there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, 'for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes.' If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203)." Nowhere in that letter are the HCPAC interim recommendations even mentioned.

46. In its March 24, 2006 follow-up letter to CMS (Attachment D), ADA again states its preference for E/M work values (bottom of page 1-top of page 2): "The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Medicine codes; the codes physicians are directed to use when they provide MNT services.... Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service [emphasis supplied]."

47. CMS stated in the Calendar Year 2007 Proposed Rule: "More recently, the ADA requested us to reconsider our decision not to accept the HCPAC recommended work RVUs [emphasis supplied]." (71 FR 48987, second column). A more accurate statement would be: "More recently, the ADA requested us to reconsider our decision not to accept work RVUs."

48. When ADA wrote its March 24, 2006 letter it was not clear whether CMS would establish work values, so in an effort to make CMS comfortable with the concept ADA demonstrated to CMS that there were several sources upon which to base work values. ADA listed four such sources in the following order, first ADA's preference, an E/M code, then a preventive medicine code, then the 2000 RUC survey data, then the HCPAC interim recommended RVUs, if CMS "would adjust the HCPAC work professional services upward to recapture the value of the remaining 15%".

49. The HCPAC recommended work RVUs not increased by 15% were not even one of the alternatives! And the difference in compensation by not increasing by 15% (i.e. dividing by 0.85) is significant because the HCPAC recommended base RVU of **0.45** ÷ 0.85 = **0.53**, or **0.08** RVUs higher.

50. But even if increased by 15%, we submit that physical therapy code-based RVUs are not statutorily appropriate because the statute says that payment to dietitians should be 85% of the amount determined for the same services if provided by a physician.

CMS Not HCPAC Should Determine the Value of the Work RVUs

51. ADA has clearly expressed its preference for a comparison to E/M codes. However, even if ADA had no preference, we submit that CMS has the duty to make a reasoned

analysis of whether E/M codes rather than physical therapy codes best describe what a physician who is also a dietitian would report for the service: "we retain the responsibility for analyzing any comments and recommendations received, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether and how to revise the work RVUs for any given service." (71 FR 37172, first–second columns).

52. If after a reasoned analysis CMS determines that medical nutrition therapy services are closer to physical therapy services than to office visit/consultation services, then so be it. But Midtown respectfully submits that CMS owes the public, the beneficiaries entitled to medical nutrition therapy services, and the registered dietitians and nutrition professionals who may provide such services, a thorough, reasoned analysis of the issue.

53. If CMS allows the HCPAC physical therapy code-based work RVU recommendations to become part of the Final Rule, the ADA will be forced to take the issue back to HCPAC. However, we strongly urge CMS to avoid this situation.

54. First, this will delay by at least one year the establishment of adequate work RVUs. And there is no guarantee that HCPAC will act in time for the 2008 Physician Fee Schedule. HCPAC may take 2 or even 3 years to act, prolonging the lack of access to care for 8,000,000 beneficiaries with diabetes or renal disease.

55. Second, now that these services are recognized as physician services there may be a jurisdictional question as to whether the regular RUC or RUC/HCPAC should decide the issue.

56. Third, CMS is fully competent to make its own determination.

57. Congressman Jose Serrano, the original sponsor of the medical nutrition therapy benefit bills, has reviewed this Comment and joins with our request that "you [CMS] perform a prompt, thorough, reasoned analysis of the appropriateness of the work value to be assigned, so that better access to care may be made available as soon as possible." (Attachment A).

Conclusion

58. The current and proposed malpractice RVU for all 5 Medical Nutrition Therapy codes is **0.01**. When added to the current practice expense RVUs, this makes the total current RVUs **0.48** and **0.19** for the individual codes and groups codes, respectively. (70 FR 70458, 70462; 71 FR 49231, 49235).

59. Midtown submits that the assignment of appropriate work RVUs to these codes should be based on the 15-minute consultation code CPT 99241, using its current and proposed RVU of **0.64** for the individual codes and 40% of that amount (multiply by 2 then divide by 5), or **0.25**, for the group codes. (66 FR 55281, first column).

60. If the proposed practice expenses of **0.12**, **0.10**, and **0.04**, for the individual initial visit, the individual follow-up visits, and the group visits (71 FR 49231, 49235), are

added to work RVUs based on CPT 99241 (**0.64** and **0.25**), this would create (including the malpractice RVUs), total RVUs of **0.77**, **0.75** and **0.30**.

61. This would increase provider reimbursement rates for medical nutrition therapy services by about 50%, or perhaps a little less due to adjustments to preserve budget neutrality. (71 FR 37241, first-second columns).

62. With a 50% increase Medicare reimbursement would still be about 25% less than existing market rates but should be sufficient to allow us, and, we believe, the majority of other registered dietitians, to afford to become Medicare providers, and this should provide access to care for the Medicare beneficiaries entitled to these services.

Sincerely yours,

s/ Robert Howard

Robert Howard, RD, JD
Managing Partner

JOSÉ E. SERRANO
16TH DISTRICT, NEW YORK

WASHINGTON OFFICE:
2227 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3216
(202) 225-4361
FAX: (202) 225-6001

DISTRICT OFFICE:
788 SOUTHERN BOULEVARD
BRONX, NY 10455
(718) 620-0084
FAX: (718) 620-0658

www.house.gov/serrano

Congress of the United States
House of Representatives
Washington, DC 20515–3216

September 11, 2006

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
SCIENCE, STATE, JUSTICE, AND COMMERCE
HOMELAND SECURITY

MEMBER, CONGRESSIONAL
HISPANIC CAUCUS

VICE CHAIR
DEMOCRATIC STEERING
COMMITTEE

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

Dear Dr. McClellan:

I was the sponsor of the original medical nutrition therapy benefit bills in the mid-90's and cosponsor of the 1999 bill that eventually became the law, as Section 105 of PL 106-544, entitled "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes or Renal Disease."

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing an appropriate work value for nutrition therapy based upon "the same services if furnished by a physician" would promote access to these services and thus comply with the intent of the law. Therefore I ask that you perform a prompt, thorough, reasoned analysis of the appropriateness of the work values to be assigned so that better access to care may be made available as soon as possible.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

Jose E. Serrano
Member of Congress

12

THE ACADEMY OF MEDICINE
CLEVELAND

Northern Ohio Medical Association

August 22, 2006

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: Proposed Rule CMS-1321-P

As the president of the Academy of Medicine of Cleveland/Northern Ohio Medical Association (AMC/NOMA), an organization representing more than 4,000 physicians in Northeastern Ohio I am writing to comment on the Medicare Program; Revisions to payment policies under the physician fee schedule for calendar year 2007; proposed rule.

Physician payment updates are driven by a flawed formula called the Sustainable Growth Rate (SGR). The underlying flaw of the SGR formula is the link between the performance of the overall economy and the actual cost of providing physician services. The medical needs of individual patients are not related to the overall economy.

By 2015, the 2006 Medicare Trustees report predicts that Medicare physician payment rates will be cut by 37% due to the flawed payment update formula, starting with a cut of nearly 5% in 2007. From 2007-2015, Medicare payments in Ohio will be cut by $7.43 billion. In Ohio, the cuts over this period will average $27,000 per year for each physician in the state.

All patients will be adversely affected by these proposed payment changes because Medicaid and private insurers use Medicare rates as a resource for their reimbursement rates. Of all of the providers serving Medicare patients, only physicians are being subjected to lower payments in the CMS proposed rule. Actually, other Medicare providers are not subject to the SGR. In fact, hospital payments are slated to continue to rise by more than three percent a year under current law, and payment to Medicare Advantage plans are estimated to increase by 7.1 percent in 2007.

The AMC/NOMA realizes that ultimately the administration and Congress will have to act in order to replace the SGR, however, CMS and its' administrators have the ability to review comments from physicians, physician organizations and other healthcare providers regarding the proposed payment and policy changes and try to find ways to improve physician payment without adding to overall Medicare costs.

For the sake of our patients and profession, the members of the AMC/NOMA ask that the proposed payment changes be carefully reviewed and these proposed payment cuts averted. As it is, Medicare payments already lag behind increases in practice costs. The AMC/NOMA believes that the CMS proposed payment changes for 2007 would adversely affect how Medicare patients will be cared for in the future. If you have any questions regarding our comments please feel free to contact me through the AMC/NOMA offices at 216-520-1000.

Sincerely,

Paul C Janicki M.D.

Paul C. Janicki, MD
President
The Academy of Medicine of Cleveland/Northern Ohio Medical Association

FROM THE EXECUTIVE OFFICES

6000 ROCKSIDE WOODS BLVD., STE. 150
CLEVELAND, OHIO 44131-2352
www.amcnoma.org
216-520-1000 • FAX 216-520-0999

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

Introduction: Cardiodiagnostics of Colorado Springs is an independent diagnostic testing facility (IDTF) and has served Colorado Springs since 1989. We provide non-invasive diagnostic imaging services in the areas of vascular imaging, echocardiography and nuclear cardiology. We are certified by the Intersocietal Accreditation Commission (IAC) in the areas of vascular noninvasive imaging (ICAVL), echocardiography (ICAEL) and nuclear cardiology (ICANL). Our technical services are utilized by many of the specialists in the area. Additionally, we provide imaging services to several rehabilitation hospitals as well as three small rural hospitals in southeastern Colorado. My partners and I (all technologists and one business manager) have been in health care since the late 70's. Given this background, I feel qualified to make comment on several areas of the proposed rule relating to IDTF's.

IDTF Issues: With regard to the proposed **"Performance Standards"**, I would agree that the majority of these standards would not be opposed by legitimate businesses but why re-invent the wheel? The Intersocietal Accreditation Commission has established practice standards in several diagnostic areas to include vascular noninvasive imaging, echocardiography and nuclear medicine laboratories (ICAVL, ICAEL and ICANL), that address the majority of issues raised (the American College of Radiology has parallel guidelines). The IAC organization has been in existence since 1990 and is endorsed by most professional imaging societies to include, The American College of Cardiology, American Society of Echocardiography, Society for Vascular Ultrasound and the American Society of Nuclear Cardiology. The credentialing process to date has been voluntary. These guidelines were written to set minimum standards for laboratories performing testing in the specialty areas of echocardiography, vascular imaging and nuclear cardiology. The standards address the qualifications of the technology staff as well as the physician interpretive staff. Continuing education requirements are addressed as well. The appropriateness of diagnostic equipment and how that equipment is maintained must be documented (to meet industry standards). Issues relating to turnaround time for reports and their diagnostic content are also standardized. Laboratories must submit evidence of ongoing quality assurance as well as samples of diagnostic studies performed for review by experts in their respective fields. Labs must re-certify every three years. Gaining accreditation is by no means easy, but does make a statement that you are serious enough about the quality of your work to submit for peer review. There is an expense associated with submitting and maintaining these credentials but it is my feeling that most legitimate organizations can not dispute that this is good medicine and thus worth the cost. If this is good medicine, and I believe it is, then these

standards should be applied to all providers including physician offices and hospital out-patient departments and not just singled out for IDTF's.

With regards to minimum **liability insurance**, this is not addressed by the IAC. Your recommendation represents minimum liability coverage, which I feel is more than reasonable. Most institutions that we provide services for already require proof of adequate liability coverage.

With regard to IDTF's not being allowed to **advertise to the general public**, I would refer you to section "R", of the proposed rule titled "Heath Care Information Transparency Initiative". In that section you identified that "Part of the reason health care cost are rising so quickly is that most consumers of health care—the patients—are frequently not aware of the actual cost of their care." You go on to further state that "thus, providers of care are not subject to the competitive pressures that exist in other markets for offering quality services at the best possible price". Our advertising to date has been limited to our referring physicians but, with the insurgence of HSA's and Consumer Driven Health Plans, the buying public will need information on cost and quality. In my experience most physicians recommend to their patients where to have their diagnostic procedures performed but they are often not knowledgeable about price. An example of this is that recently my son's primary care provider referred him to a local hospital for a routine chest x-ray. Imagine my surprise when I got a bill for $250.00 (TC only). This same procedure Medicare approves for about $60.00 (global). Needless to say, I shopped around and had his follow-up x-ray done elsewhere for $90.00.

Cardiodiagnostics was the first vascular laboratory in Colorado to gain ICAVL certification (1997) and as such is well qualified to perform the limited abdominal ultrasound (AAA Screening) that has been approved for 2007. We have always offered an alternative to the other more costly institutions as it relates to quality and price, a fact that may go unnoticed without general advertising. You can't have it both ways; either the public needs to know their options regarding quality and cost or they don't. This issue is too important to be limited to only a select group of providers. If competition is to work, let's level the playing field and require the same regulations for all providers, not just IDTF's.

With regard to the **abdominal screening**, the U.S. Preventive Services Task Force in their recommendations stated that "There is good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists), is an accurate screening test for AAA." In the proposed rule, I saw no mention of the qualifications of those people performing the screening. I would strongly recommend that quality standards (ICAVL or ACR) be imposed on any laboratories performing this testing. If not, this will be an area where abuses might occur.

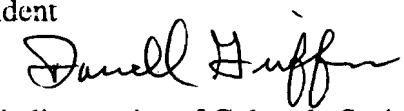
Regarding **unannounced site visits**, it is my feeling that this represents an unnecessary disruption to our service. On any given day we will have mobile equipment at multiple sites in Colorado Springs as well as rural southeastern Colorado. Additionally our

downtown laboratory is quite busy. An unannounced visit would be very disruptive to patient care. I have no problem with a site visit but feel it only appropriate to get at least three(3) to five(5) business days advance notice. This will increase the efficiency of the visit for both parties. Additionally, if this is felt to be a deterrent to abusive business practices, then it should extended to all providers.

I am concerned with negative light in which IDTF's are being portrayed. It is my hope that all providers will not be judged by the sins of the few. After many years in healthcare, I am convinced that the majority of providers are honorable people who struggle on a day to day basis with how to provide the best and most efficient care to their patients. It is unfortunate that there are abuses in the system. Those individuals should be singled out and dealt with but not with a broad paintbrush of expensive mandates and regulations that penalize all providers. Independent Diagnostic Testing Facilities play an important role in today's health care. We offer quality and convenience when compared to many larger institutional care settings and this does foster competition. Choice will play an increasing role in maintaining (or lowering) price in a consumer driven health care model. In our case we have always put quality first and the economics have always worked out. Additionally, there are underserved areas that are often overlooked because they don't (at first glance) make economic sense. Cardiodiagnostics provides imaging support to three (3) small rural hospitals in southeastern Colorado. The volume of work in those areas is small but the patients get the same quality imaging that they would get in the "big city", and are always appreciative. Major restrictions to the way IDTF's practice and the proposed reduction in reimbursement could inadvertently limit these rural practice settings from getting the diagnostic support they need.

Thank you for the opportunity to comment on these important issues. If I can be of further service, please don't hesitate to contact me.

Darrell Griffin, B.S. RDCS
President



Cardiodiagnostics of Colorado Springs, Inc.
1633 Medical Center Point, Suite 143
Colorado Springs, CO 80907

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Coalition For The Advancement Of Brachytherapy

660 Pennsylvania Avenue, S.E.
Suite 201
Washington, D.C. 20003
(202) 548-2307
Fax: (202) 547-4658

September 18, 2006

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

Re: 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 Coalition for the Advancement of Brachytherapy (CAB) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 22, 2006 *Federal Register* notice regarding the 2007 Physician Fee Schedule proposed rule.

The Coalition for the Advancement of Brachytherapy was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer (see attachment 1).

CAB recommends that CMS more closely examine the impact of <u>all</u> 2007 Medicare Part B payment policies that impact imaging procedures. Reductions in the proposed practice expense relative value units (RVUs) combined with the forecasted reductions in the annual update factor, and the Deficit Reduction Act imaging provisions could have a significant impact on the provision of radiation oncology procedures to Medicare beneficiaries in a freestanding radiation oncology center.

I. Sustainable Growth Rate

The proposed rule indicates that payment rates for physicians' services will be reduced by 5.1 percent for 2007, a reduction required by the statutory formula that takes into account substantial growth in overall Medicare spending in 2005. CMS anticipates further negative updates in future years.

While we understand that CMS is required by law to update the conversion factor on an annual basis according to the sustainable growth rate (SGR) formula, we do not support reductions under the SGR system forecasted for 2007 and subsequent years. The SGR formula is unreasonable and impractical as it is tied to the overall U.S. economy (gross domestic product) and does not accurately reflect the health care costs of treating Medicare patients. The SGR formula should not include the costs of Medicare-covered outpatient drugs. Additionally, the current formula does not account for the costs and savings associated with new technologies. The current SGR formula must be replaced with a method that allows payment updates to keep pace with practice cost increases.

CAB recommends that CMS replace the Sustainable Growth Rate in 2007 with an annual update system like those of other provider groups so that payment rates will better reflect actual increases in physician practice costs.

II. Miscellaneous Coding Issues: Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

Currently, the Remote Afterloading High Intensity Brachytherapy procedures (CPT 77781-77784) have a 90-day global period. CMS proposes to assign a global period of "XXX" to all Remote Afterloading High Intensity Brachytherapy procedures.

As CMS notes, Remote Afterloading High Intensity Brachytherapy procedures are used to treat many clinical conditions. Patients usually receive multiple fractions over a one to thirty day period. Many patients receive multiple fractions per day making accurate reporting of Remote Afterloading High Intensity Brachytherapy procedures difficult. Further, each individual patient treatment regimen varies greatly based upon the type and stage of cancer being treated, making the current 90-day global period quite burdensome for almost all cases treated. CAB agrees that it is difficult to assign relative value units (RVUs) for a "typical" patient based on a 90-day global period.

CAB recommends that CMS finalize their proposal to assign a global period of "XXX" to Remote Afterloading High Intensity Brachytherapy procedure codes 77781, 77782, 77783 and 77784.

III. DRA Proposals

CAB is appreciative that the majority of radiation oncology procedures were exempted from the Deficit Reduction Act (DRA) cap on technical component payments under the Physician Fee Schedule. Radiation oncology procedures, including brachytherapy, should never be considered imaging procedures.

Further, we applaud CMS for their decision not to implement in 2007 the 50% reduction for multiple diagnostic imaging procedures performed on contiguous body parts.

Conclusion

Brachytherapy offers important cancer therapies to Medicare patients. Appropriate payment for procedures and sources required to provide brachytherapy is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in a freestanding radiation oncology center or physician office.

We hope that CMS will take these issues under careful consideration during the development of the 2007 Physician Fee Schedule final rule, as they will have a great impact on provider's ability to offer important cancer treatments to Medicare beneficiaries. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

Lisa Hayden
Chair

Janet Zeman
Vice-Chair

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytyc Corporation
IsoRay
MDS Nordion
Mentor Corporation
Nucletron Corporation
Oncura
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
Xoft, Inc.

CAB Advisory Board

American Brachytherapy Society
American College of Radiation Oncology
Association for Freestanding Radiation Oncology Centers
Society for Radiation Oncology Administrators

American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
Fax (301) 209-0862
http://www.aapm.org

September 18, 2006

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

Re: 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 Association of Physicists in Medicine (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 22, 2006 *Federal Register* notice regarding the 2007 Physician Fee Schedule proposed rule.

AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 5,000 medical physicists.

AAPM recommends that CMS more closely examine the impact of all 2007 Medicare Part B payment policies that impact imaging procedures. Reductions in practice expense relative value units (RVUs) combined with the forecasted decreases in the annual update factor, and the Deficit Reduction Act imaging provisions could have a major impact on the provision of radiation oncology and related procedures to Medicare beneficiaries in the freestanding radiation oncology center setting.

I. Provisions

Major changes to the practice expense methodology for 2007 were discussed in the June 29, 2006 proposed notice. AAPM is compelled to reiterate our concerns regarding the significant reductions to Medical Physics codes proposed for 2007 and subsequent years (see Table 1).

Table 1 Practice Expense Reductions in Medical Physics Codes

CPT	2006 PERVU	2007 Proposed PERVU	2010 Proposed PERVU	2006-2007 Proposed Percentage Change	2006-2010 Proposed Percentage Change
77336 Continuing medical physics consult	2.99	2.48	**0.93**	-17.1%	**-68.9%**
77370 Special medical radiation physics consult	3.50	3.22	**2.36**	-8.0%	**-32.6%**

CPT 77336 Continuing Medical Physics Consult has significant practice expense RVU reductions under the proposed practice expense methodology. CPT 77336 has a 17.1% reduction in 2007 practice expense RVUs and a 68.9% reduction in 2010 practice expense RVUs at the end of the transition period. This reduction in practice expense RVU needs to be re-evaluated. CPT 77336 is one of only two codes directly attributable to Medical Physicists and is the major procedure code in terms of reimbursement for Medical Physicist services.

Further, the one-year impact of all the CMS Physician Fee Schedule proposals results in a 21% reduction of payment for CPT 77736 Continuing Medical Physics Consult in 2007 (see Table 2). A large decrease in RVUs leads to significant reductions in reimbursement, which could result in the disastrous end effect of poorer quality and safety of treatments for those cancer patients undergoing radiation therapy.

Table 2 Total Reduction in 2007 Payment for Medical Physics Codes

CPT	2006 Payment	2007 Proposed Payment	2006-2007 Proposed Percentage Change
77336 Continuing medical physics consult	$119.38	$94.59	-20.8%
77370 Special medical radiation physics consult	$139.46	$121.56	-12.8%

Although there is Medical Physics work implicitly included in the valuation of 28 other CPT codes in the 77XXX series in radiation oncology, most administrators look to the literal wording of CPT codes 77336 and 77370 for budgeting staffing levels for Medical Physicists in this country. If the value of these codes drops significantly as they are slated to do under the new practice expense methodology, staffing levels of Medical Physicists will drop proportionately. If Medical Physics work is not adequately compensated, the cost of hiring qualified Medical Physicists will be difficult to recover by freestanding facilities.

Shortages of qualified Medical Physicists will result in decreased availability for consultations with Radiation Oncologists on many of the new, complicated procedures for the precision delivery of radiation therapy, such as IMRT, IGRT and SRS/SBRT. Some cancer clinics may have to delay or forgo such high-tech therapies.

Further, the "unintended consequences" of reducing the value of Medical Physics CPT codes may be an increase in the misadministration rate of radiation therapy doses to cancer patients in this country since there will not be adequate Medical Physics staff to intervene for prevention of these errors.

The ultimate victim of this payment policy is patients needing quality care for their cancer treatment. Qualified Medical Physicists are responsible for accurate delivery of radiation dose to patients to be consistent with the Radiation Oncologists' prescription. Our patients will suffer, and the cost of correcting for misadministrations of radiation therapy will drive up health care costs, if quality Medical Physics services are not available.

AAPM recommends that CMS review and refine the direct practice expense inputs for Medical Physics CPT codes 77336 and 77370 early in the transition so that accurate salary and time data for Medical Physicists can be assigned to these codes for 2008.

II. Sustainable Growth Rate

The proposed rule indicates that payment rates for all physician services will be reduced by 5.1 percent for 2007, a reduction required by the statutory formula that takes into account substantial growth in overall Medicare spending in 2005.

While we understand that CMS is required by law to update the conversion factor on an annual basis according to the sustainable growth rate (SGR) formula, we do not support reductions under the SGR system forecasted for 2007 and subsequent years. The SGR formula is unreasonable and not viable as it is tied to the overall U.S. economy (gross domestic product) and does not accurately reflect the health care costs of treating Medicare patients. Further, the current formula does not account for the costs and savings associated with new technologies. The current SGR formula must be replaced with one where payment updates keep pace with practice cost increases.

CMS should replace the Sustainable Growth Rate in 2007 with an annual update system like those of other provider groups so that payment rates will better reflect actual increases in physician practice costs and take into account Medicare Part B savings associated with new technologies.

III. Miscellaneous Coding Issues

A. Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

Currently, the Remote Afterloading High Intensity Brachytherapy procedures (CPT 77781-77784) have a 90-day global period. CMS proposes to assign a global period of "XXX" to all Remote Afterloading High Intensity Brachytherapy procedures.

As CMS notes in the proposed rule, Remote Afterloading High Intensity Brachytherapy procedures are used to treat many clinical conditions. Patients usually receive multiple fractions over a two to ten day time period, however, the treatment regimen varies greatly based upon the type and stage of cancer being treated. AAPM agrees that it is difficult to assign relative value units (RVUs) for a "typical" patient based on a 90-day global period.

AAPM recommends that CMS finalize their proposal to assign a global period of "XXX" to Remote Afterloading High Intensity Brachytherapy procedure codes 77781, 77782, 77783 and 77784.

B. Assignment of RVUs to CPT Codes for Proton Beam Treatment Delivery Services

Currently, the Proton Beam Treatment Delivery codes (CPT 77520-77525) are carrier-priced and the payment in the facility or non-facility setting is established by each Medicare carrier. Given the small number of proton therapy centers in the United States, AAPM agrees that these procedures should remain carrier-priced at the local level at this time.

IV. DRA Proposals

The AAPM appreciates that the majority of radiation oncology procedures were exempted from the Deficit Reduction Act (DRA) cap on technical component payments under the Physician Fee Schedule. AAPM believes that the Congressional intent of the DRA was to control the use of "diagnostic" imaging. Imaging performed as part of a therapeutic process, whether therapy port films, image guided radiation therapy (IGRT), or imaging associated with interventional radiology is not an option, but a requirement for quality care. Most imaging procedures used in radiation oncology are integral to the therapeutic radiation planning and treatment delivery process, and, hence are not over utilized as an individual service because they are part of the process of cancer care.

Further, we applaud CMS for their decision not to implement in 2007 the 50% reduction for multiple diagnostic imaging procedures performed on contiguous body parts

Conclusion

Appropriate payment for radiation oncology procedures and medical physics services is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in freestanding radiation oncology centers. The effect of multiple proposals on the technical component and global payment for radiation oncology procedures could be devastating to freestanding radiation oncology centers that provide cancer care to Medicare beneficiaries.

We hope that CMS will take these issues under consideration during the development of the 2007 Physician Fee Schedule Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

James Hevezi, Ph.D.

James Hevezi, Ph.D.
Chair, AAPM Professional Economics Committee

DHPPC (receipt) FYI-Regs #598702 16-0 1/1

SWEDISH PHYSICIANS

Dr. Mark A. McClellan
CMS Administrator
US Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

AUG 25 [illegible]
10:02 A.M.

Dear Dr. Mark A. McClellan,

I am an internist, certified in clinical densitometry practicing in Seattle.

I am gravely concerned about the proposed drastic cuts in payment for dual energy X-ray absorptiometry (DXA; CPT code 76075) and vertebral fracture assessment (VFA; CPT code 76077). These cuts have been proposed as part of a new five-year review of the Medicare Physician Fee Schedule.

If these cuts are not reversed, when fully realized in 2010, they would amount to a decline in payment of 71% for DXA and 37% for VFA.

It is my opinion that this action will severely reduce the availability of high quality bone mass measurement, having a profound adverse impact on patient access to appropriate skeletal healthcare.

Ironically, these proposed cuts for DXA and VFA testing for patients with suspected osteoporosis are completely contrary to recent forward-looking federal directives. Multiple initiatives at the Federal level including the Bone Mass Measurement Act, the US Preventive Services Task Force recommendations, the Surgeon General's Report on Osteoporosis, as well as your recent "Welcome to Medicare" letter, all highlight the importance of osteoporosis recognition using DXA, and the value of appropriate prevention and treatment to reduce the personal and societal cost of this disease. HEDIS guidelines and the recent NCQA recommendations also underscore the value of osteoporosis diagnosis and treatment in patients at high risk.

These patient-directed Federal initiatives, coupled with the introduction of new medications for the prevention and treatment of osteoporosis, have improved skeletal health and dramatically reduced osteoporotic fractures, saving Medicare dollars in the long run.

Moreover, in contrast to other imaging procedures where costs are escalating but improvements in patient outcome have not been clearly demonstrated, DXA and VFA are of relatively low cost and of proven benefit. Additionally, DXA and VFA are readily available to patients being seen by primary care physicians and specialists alike, thus assuring patient access to these essential studies.

Importantly, it appears that some of the assumptions used to recalculate the Medicare Physician Fee Schedule were inaccurate. For example, CMS calculated the equipment cost at less than half of what it should be, because they based it on older pencil beam technology that is now infrequently used. They also calculated the utilization rate for this equipment at a falsely high rate that does not reflect the average use of equipment used to evaluate single disease states. Rather than the 50% rate assigned, DXA and VFA equipment utilization rates should be estimated at 15-20%. In addition, many densitometry costs such as necessary service contracts/software upgrades and office upgrades to allow electronic image transmission were omitted. Finally, CMS concluded that the actual physician work of DXA interpretation is "less intense and more mechanical" than was accepted previously. This conclusion fails to recognize that high quality DXA reporting requires skilled interpretation of the multiple results generated by the instrument.

I urge you to withdraw these substantial cuts in the proposed rule that reduces Medicare reimbursement for these important technologies used to screen people at risk for osteoporotic fracture. The aging of the US population provides a clear demographic imperative that this preventable disease be detected and treated, thereby preventing unnecessary pain and disability, preserving quality of life and minimizing the significant societal costs associated with bone fractures. Please do all you can to support bone health and quality patient care by requesting that these proposed cuts be reversed.

Thank you,

Amy Deans, MD

Amy Deans, MD
Swedish Physicians Ballard
2208 NW Market St. Suite 410
Seattle, WA 98107

SWEDISH PHYSICIANS-BALLARD
2208 NW MARKET #410
SEATTLE, WA 98107

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Dr. Mark A. McClellan
CMS Administrator
Dept. of Health & Human Services
200 Independence Ave. SW
Washington, D.C. 20201