Submitter : **Wendy Wifler** **Date: 10/10/2006**

Organization : **Accuray Incorporated**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED PDF FILE . . . As a manufacturer and provider of image-guided robotic stereotactic radiosurgery (r-SRS) equipment, we appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

Submitter : Yasuo Yoshinari **Date:** 10/10/2006

Organization : Hitachi America, Ltd

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-827-Attach-1.PDF

827

HITACHI
Inspire the Next

Hitachi America, Ltd.
Power Systems Division
50 Prospect Avenue
Tarrytown, NY 10591
Tel: +914.524.6735 Fax: +914.332.5388
Email: yasuo.yoshinari@hal.hitachi.com

October 4, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

Submitter : **Dr. John Mulcahy** **Date: 10/10/2006**

Organization : **Coalition forthe Advancement of Prosthetic Urology**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment letter. Thank you for your consideration.

CMS-1321-P-828-Attach-1.DOC

#828

The Coalition for the Advancement of Prosthetic Urology
1301 K Street, N.W., Suite 1100
Washington, DC. 20005
202-414-9241

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Anderson, South Carolina

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8010
Baltimore, MD 21244-8010

Delivered via http://www.cms.hhs.gov/eRulemaking/01_Overview.asp

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment, Specifically **Provisions Regarding Standard Supplies & Equipment for Procedures with a 90 day Global Period and Resource-Based Practice Expense (PE) RVU Proposals for CY 2007**

Dear Dr. McClellan:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and other Changes to Payment under Part B. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

Over the past few years, CAPU has been concerned regarding the Relative Value Units (RVUs) assigned to prosthetic urology procedures. We are encouraged by CMS' actions regarding some of the elements of the proposed practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to prosthetic urology procedures. Therefore, as explained in greater detail below, CAPU has the following recommendations:

I. Summary

- Standard Supplies and Equipment for CPT Codes with 90 day Global Periods:
    - Many of the prosthetic urology procedures have been negatively impacted by the use of standard packages for various practice expense inputs, partly because of the assertion by CMS that most 90 day global period codes only contain three post-operative (post-op) visits. This is not the case with prosthetic urology procedures where the average number of post-op visits is five. Thus we recommend that CMS re-evaluate the number of post-op visits packaged into each 90 day global period code.

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- We appreciate CMS soliciting comments regarding standard packages of supplies and equipment for post-operative visits associated with a 90 day global period procedure. With regard to standard supply inputs, CAPU would recommend to CMS that for each post-op visit standard supplies should include the following:
  - Office visit supply package
  - Post-surgical incision care kit

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- Two sets of gloves
- Exam table paper
- Drape, non-sterile sheet
- Additional items recommended by the RUC/PERC.

- With regard to standard equipment inputs, CAPU would recommend to CMS that for each post-op visits that standard equipment should include the following:

  - Exam Table
  - Exam Light
  - Additional equipment recommended by the RUC/PERC.

- Proposed Changes to Practice Expense Methodology:

  - CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments.

  - In general, CAPU is concerned that compared to last year's "bottom-up" methodology for calculating PE RVUs, this year's method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. CAPU urges CMS to investigate these steps.

  - CAPU appreciates CMS using the American Urological Association's supplemental survey data as part of the process of creating a more accurate, intuitive and stable Practice Expense (PE) methodology.

II. Detailed Discussion

A. Provisions - Standard Supplies and Equipment for CPT Codes with 90 Day Global Periods

1. Number of Post-Operative Visits Packaged in Codes with 90 Day Global Periods

The results of the CAPU Survey of Post-Operative Office Visits and Clinical Staff Time demonstrate that the number of post-operative visits in the Centers for Medicare and Medicaid Services (CMS) Practice Expense (PE) Inputs Database are not representative of a typical prosthetic urology practice.

In general, the total number of visits in the CMS PE database for prosthetic urology procedures is three (3). The results of the CAPU survey demonstrate an average of four (4) to five (5) and, in some cases, six (6) post-operative visits depending on the CPT code.

Created Pre- 1990 - Prosthetic Urology CPT Codes 53445, 53447, & 54405:

The CAPU survey results for three CPT codes (53445, 53447, & 54405) created before 1990 reflect that the use of the 90-day global period standardized package of three (3) post-operative visits for most surgical CPT codes as the PE input is not representative of actual prosthetic urology practice.

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202-414-9241

In conjunction with the 2003 PEAC review, the PEAC recommended a standardized package of three (3) post-operative visits for "all" surgical procedures with a 90-day global period. However, the results of this survey show that three (3) post-operative visits is not representative of actual prosthetic urology practice.

The CAPU survey results demonstrate that for all three of these CPT codes the mean number of post-operative visits is five (5). The median is also at least five (5) visits, with one exception. For CPT code 53445, the median is six (6) office visits.

Created in 2002 - Prosthetic Urology CPT Codes 53444, 54410, 54411, 54416, & 54417:

While the differences between the CAPU aggregate results for this group of CPT codes and the clinical staff inputs in the CMS PE database are not as wide as the group of CPT codes discussed above, the survey results of prosthetic urology codes created in 2002 also confirm that using standard packages for 90 global period codes is not representative of typical prosthetic urology practice.

The CAPU survey results for the CPT codes in this group, with the exception of CPT code 54417, demonstrate that mean and median number of post-operative visits in a typical practice is four (4) – five (5). This is one -two visits more than the standard of 3 post- operative visits for a 90-day global CPT code.

2. Standard Supplies and Equipment for 90 day Global Period Codes:

A review of the CPEP data used to calculate the proposed 2007 PE RVUs for PU codes revealed that most of the CPT codes have an office visit package and a post-surgical incision care kit assigned to them. However, the number of visit packages and the number of incision care kits in the CPEP data base is three versus the typical number of post-operative visits which is five. CMS needs to update the number of packages and kits based on the results of the CAPU survey, stated above.

Also, CMS needs to include as "standard" supplies that are used to prevent any risk of infection or for patient comfort, such as gloves for the physician and clinical staff, exam table paper, gowns, and drapes.

With regard to equipment, all of these CPT codes were assigned an exam table under the CPEP data for equipment. This is appropriate; however, we would also recommend that an exam light be included as this is standard equipment in an exam room and can be used to illuminate the wound site for greater inspection by the physician.

B. Practice Expense (PE)

1. Bottom-Up Methodology

CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments. CAPU is pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and CAPU strongly supports the change in methodology that does away with the need for scaling factors.

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1301 K Street, N.W., Suite 1100
Washington, DC. 20005
202-414-9241

2. Budget Neutrality

In the newly-proposed PE methodology discussed in the proposal, CMS applies a budget neutrality adjustment three times – to the direct inputs, to the indirect allocators and also as a final step. It is unclear why CMS does not apply budget neutrality just once as a final step in the methodology, and we seek clarification on the impacts of applying three separate budget neutrality adjustments in the new methodology. We are concerned that physicians are being forced to "pay" CMS a 30% discount on all of their direct costs because those direct costs are being subjected to a greater than 30% budget neutrality adjustment.

3. Use of Supplemental Survey Data

CAPU applauds CMS for proposing to use the urology supplemental survey data that AUA submitted originally for use in calculating PE RVUs for the 2006 fee schedule. We were disappointed that although CMS accepted AUA's data last year based on Lewin's recommendation that the data met all of the necessary criteria; an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually use the data in calculating the PE RVUs for 2006. Nevertheless, CAPU strongly support the use of AUA's supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

***

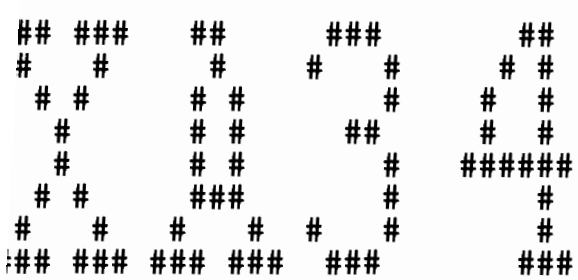
As always, we look forward to working with CMS to address these important issues. If CAPU can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202.414.9241.

Sincerely,

John J. Mulcahy, MD

John J. Mulcahy, M.D., Ph.D., F.A.C.S.
Chair

cc: Dr. Jim Regan, Chairman of Health Policy Council, AUA
Robin Hudson, AUA
CAPU Board Members (via email only)



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Heart House
2400 N St., NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

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**ex officio*

Interim Chief Staff Officer and General Counsel
Thomas E. Arend, Jr.

October 10, 2006

Leslie V. Norwalk, Esquire
Acting 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 21244-8018

Dear Ms. Norwalk:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS 1321-P)** published in the *Federal Register* on August 22, 2006. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

DRA Proposals

Section 5102 Multiple imaging procedures

The ACC supports CMS's proposal to maintain the payment reduction for the technical component of certain multiple imaging procedures at 25 percent for the second and any subsequent procedures instead of the previously proposed 50 percent. As we noted in comments submitted previously, we recognize that physician practices may achieve some savings in practice expenses when multiple imaging procedures are performed on contiguous body parts during

the same patient care session. However, the ACC disagreed that the data on direct practice expense inputs supported a reduction of 50 percent. We are pleased that CMS has responded favorably.

As a result of the savings from the multiple imaging procedure payment reduction, CMS increased the 2006 practice expense RVUs by 0.3 percent. The proposed rule notes that this increase will be removed from the 2007 practice expense RVUs to comply with the Deficit Reduction Act (DRA) requirement that the multiple imaging procedure payment reduction be exempted from the budget neutrality requirement. The ACC understands that CMS is merely complying with the statute in making this change. We must note, however, our strong objection to singling out one type of physician service to achieve savings in overall Medicare physician payments.

Section 5102 Limit on payment for technical component of imaging procedures

The ACC strongly opposes the DRA provision limiting payment for the technical component of imaging services to the lesser of the payment amount under the Medicare physician fee schedule or the payment amount under the hospital outpatient prospective payment system (OPPS). We object to the process through which it was enacted without full discussion and public debate, to the precedent it sets of targeting imaging services to achieve savings in physician payment, and to the invalid comparison it makes between two fundamentally different payment systems. We recognize, nevertheless, that CMS must implement the statutory requirement. ACC's comments on several aspects CMS's proposal for implementing this DRA provision follow.

Definition of imaging services

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the OPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS proposes to define imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We believe this proposed definition is overly broad and, theoretically, could even apply to open surgical techniques. We recommend the following definition of imaging for purposes of implementing the DRA:

Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization, or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the

absence of minimally invasive diagnostic procedures and interventions; and without this type of imaging only open surgical procedures would be possible.

The ACC does not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors. We believe that these services should not be subject to the DRA reimbursement cap.

Services included in Addendum F

The preamble to the proposed rule states "We excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap." However, Addendum F includes 93555 and 93556 (Imaging, cardiac catheterization). Under OPPS imaging guidance is bundled into the payment for cardiac catheterization, so there is no separate OPPS payment corresponding to either 93555 or 93556. We believe CMS included these two codes in error and we urge that they be removed from Addendum F.

The ACC also recommends that CMS exclude Category III CPT codes from the list of procedures subject to the DRA cap on payments for the technical component of imaging services. By definition, Category III codes describe emerging technology. Thus, no RVUs have been assigned to reflect costs in the physician office setting and OPPS payment rates do not reflect the costs of providing these procedures in the hospital outpatient setting. Therefore, the ACC believes it is inappropriate to apply the DRA payment limitation to emerging technology services currently identified by Category III CPT codes.

Services subject to both the DRA cap and the multiple procedure payment reduction

The ACC supports CMS's decision to apply the multiple procedure payment reduction first for those services subject to both the cap on the technical component payment and the multiple imaging procedure payment reduction.

Resource Based Practice Expense RVU Proposals for 2007

The ACC's comments on the June 29, 2006 proposed rule included a discussion of our concerns about the significant decreases in practice expense RVUs proposed for cardiac catheterization services performed in the non-facility setting (CPT 93510 - 93533). As we noted, we believe that the magnitude of the proposed cuts for these services reflects, in large measure, weaknesses in data used for establishing both the direct and indirect cost portions of the RVUs.

In the August proposed rule, CMS proposed carrier pricing for these codes. We agree that the data problems affecting these codes are so significant that even the proposed first year

transition values are probably inappropriate and could adversely affect patient access. We believe, though, that carrier pricing is not the most appropriate strategy for establishing 2007 values. It is our understanding that other commenters will be submitting to CMS data on direct expenses. The ACC has not yet reviewed these data. We plan to work closely with all affected stakeholders to review existing data, gather any additional data needed, and request prompt review by the PERC. Until the ACC and the PERC can complete this review, we recommend that CMS use the 2006 non-facility RVUs for CPT 93510 - 93533 as interim values for 2007.

Cardiac monitoring

The ACC remains concerned that the significantly reduced practice expense RVUs proposed for remote cardiac monitoring services could threaten patient access to these important services. We are pleased that CMS has requested additional practice expense data for these procedures. We note that CPT 93236 (24 hour electrocardiographic monitoring) should be added to the list. The ACC concurs with CMS's assessment that remote cardiac monitoring services do not fit the typical physician service model for purposes of developing direct practice expense inputs. Consequently, the current direct practice expense inputs do not capture all practice expenses required to provide remote cardiac monitoring services. We look forward to working with CMS and remote cardiac monitoring services providers to gather and review the necessary data.

Supply and equipment information

Tables 1 and 2 in the preamble to the proposed rule identified several supply and equipment items for which CMS needs of current price information. Following is ACC's response to this request.

Table 1 Supply items needing specialty input for pricing			
Code	Description	New price	Source
SK 105	Blood pressure recording form	NA	
This item can be deleted. The ambulatory blood pressure monitoring system for which we are providing new price information generates the form, so separate pricing is not necessary.			
SD 140	Pressure bag	$95.00 per 5 unit box	McKesson
SD 213	Tubing, sterile, non-vented (fluid administration)	$47.46 per 50 unit box	McKesson
Table 2 Equipment items needing specialty input for pricing			
Code	Description	New price	Source
EQ 269	Ambulatory blood pressure monitor	$1920	Tiba Medical
EQ 008	ECG signal averaging system	$17,900	GE
System includes ECG cart ($12,500), software for late potential QRS ($3,200), and software for P-wave measurement which is less common ($2,200).			

We have forwarded this information, along with documentation of the prices to the responsible CMS staff.

PLI RVUs

Currently, CMS assigns professional liability insurance (PLI) RVUs to the professional and technical components of codes by allocating the PLI RVUs for the global code on the basis of the division of practice expense RVUs between the two components. The ACC believes that in the case of imaging services, this approach results in PLI RVUs that do not accurately reflect the relative professional liability costs associated with the professional and technical components. Although the technical performance of an imaging service does entail some professional liability risk, the liability risk associated with the physician interpretation of the imaging service is much greater. We urge CMS to develop a more accurate method for distributing the PLI RVUS between professional and technical components. Development of such a method may not be accomplished quickly. In the short term, therefore, we recommend that CMS reverse the current assignment of PLI RVUs between technical and professional components.

Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

The ACC has strongly and consistently supported efforts to eliminate or severely reduce opportunities for fraud and abuse in the Medicare program. The proposed rule revisions to the physician self-referral rules appear to target apparent abuses within pathology services. The ACC, therefore, recommends that CMS strictly limit the application of these changes—if adopted—to the field of pathology at the present time.

We believe this is the most appropriate course of action for CMS to pursue at this time, as it is our understanding that the medical societies representing pathologists initiated the development of these proposed rule changes with the agency out of concern for the specific practices emerging in that field (i.e. "pod-labs."). Further, we also understand that the proposed revisions are the product of a collaborative effort between CMS and those pathologist groups, and that the revisions generally meet with the pathology groups' approval. The ACC commends CMS for taking this collaborative approach to rulemaking.

As noted by the preamble itself, CMS is seeking comments on whether the proposed changes should apply strictly to pathology services, or if they should also extend to diagnostic imaging and other services beyond pathology (71 Fed. Reg. 49056; August 22, 2006).At the present time, we believe that the impact of these proposed regulations on diagnostic imaging and other non-pathology services cannot be accurately studied within the relatively short timeframe afforded by the comment period for the proposed 2007 Medicare Physician Fee Schedule. Among possible ACC concerns requiring additional study:

- The proposed conditions of permissible billing for technical and/or professional components (TC/PC, respectively) of testing services may significantly interfere

with physician group practices' flexibility in legitimately contracting with independent physicians, thereby potentially increasing costs to the Medicare program; and

- The proposed changes to the reassignment rules, along with the modifications to the "centralized building" requirements may also significantly impede the incorporation of certain diagnostic imaging services into (non-radiology) physician group practice settings—potentially closing opportunities to reduce costs and inefficiencies in the delivery of these critical services to Medicare beneficiaries.

To ensure that such rules with potentially wide-ranging and disruptive effects on the quality of care are adequately studied prior to adoption, the ACC reiterates its strong recommendation that CMS limit the application of these proposed revisions strictly to pathology services (e.g. pod-labs, etc.), and that the agency engage with the ACC and other stakeholder groups to study and develop solutions to potential fraud and abuse concerns in other areas of care. The ACC remains eager to work with CMS on such an endeavor.

Independent Diagnostic Testing Facility (IDTF) Issues

With regard to the application of the proposed standards to IDTFs, the ACC recommends that CMS carefully evaluate whether, as currently written, they should apply uniformly to the diverse array of services provided by these entities. We also encourage CMS to consider accreditation status as an alternative mechanism for compliance with the proposed standards. Specifically, we suggest that entities that have been accredited by a nationally recognized accreditation body, such as the Intersocietal Accreditation Commission, could be deemed to be in compliance with Medicare's IDTF standards. In the alternative, the ACC urges CMS to work with IDTFs and other stakeholders to ensure that the proposed standards properly target questionable practices while not impeding the provision of legitimate and beneficial services for Medicare beneficiaries.

Promoting Effective Use of Health Information Technology (HIT)

The ACC strongly supports the incorporation of health information technology (HIT) into the practice of medicine and throughout the health care industry in general, out of recognition for both the potentially significant improvements to the quality of care provided to patients and the administrative cost savings involved.

We agree with CMS' conclusion that the selection and promotion of voluntary data and systems standards is key to achieving effective HIT implementation among providers and payers. It is critical to the success of HIT implementation that the process for developing standards must include thorough consideration by HHS/CMS of the input from all stakeholders.

For these reasons, the ACC recommends that CMS continue to collaborate with all stakeholders in the process of developing HIT standards and implementation timeframes, only establishing and promoting such standards after carefully considering such input.

Health Care Information Transparency Initiative

The ACC shares with CMS concerns regarding rapidly escalating health care costs and expenditures, and recognizes the need to implement reforms aimed at introducing cost efficiencies while also improving the quality of care provided. While "transparency" of costs and prices may indeed have an important role to play in helping to curb the growth of health care costs, we have concerns regarding possible misrepresentations or misinterpretations of such data, particularly in the latter example by patients. To ensure complete and accurate data is assembled for these consumer resources, we urge CMS not to rely exclusively on claims data, and instead incorporate information from a variety of sources.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,

Steven E. Nissen, MD, FACC
President

Submitter : Dr. STEPHEN DAUGHERTY **Date:** 10/10/2006

Organization : VEINCARE CENTERS OF TENNESSEE

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I wish to provide comment regarding CMS-1321-P regarding proposed revision to payment to physicians under the physician fee schedule for 2007 and 2008 for CPT 36478 and 36479 for endovenous LASER ablation of veins. The proposed physician fee schedule for non-facility services would reduce the RVU for 36478 substantially from the reduction we already suffered in 2006.

The RVUs drop from 46.91 in 2006 to 43.53 in 2007 and to 40.84 in 2008. Additonally, we are projected for a 5.1% across the board reduction in physician payments beginning January 1, 2007 which compounds the reduction to us.

My two surgeon group performs a substantial number of services for Medicare patients who have serious symptomatic vein disease. We have viewed our serices to Medicare and Tricare pateints (for whom we receive Medicare levels of payment) as a community service since many of these procedures do not reimburse adequately for the time and resources necessary to provide the services.

Our estimated cost of disposable supplies and drugs for CPT 36478 is $389.76. Additionally, we must provide a large treatment room; an ultrasound machine (generally costing $40,000 to $200,000); a registered nurse to set up for the procedure, to assist with the procedure, and to manage the patient afterward with instructions and evaluation prior to discharge home. I estimate that we have three to four hours of staff time (mostly RN time) invested in each Medicare patient who undergoes the procedure.

I remain concerned that endovenous LASER ablation, CPT 36478, is valued at less that radiofrequency ablation, CPT 36475. The LASER costs typically range from $35,000 to $40,000 and the radiofrequency generator typically costs, I am told, $20,000 to $25,000. I realize that the disposable costs for the radiofrequency procedure are higher than the LASER ablation costs, but the higher cost for capital equipment suggests to me that there should be little difference in reimbursement between the two procedures.

If the proposed reductions in payment for CPT 36478 are enacted as proposed, our vein center will begin restricting the volume of Medicare and Tricare patients that we see for venous problems. This is a simple matter of economics for us. We are aware that many vein centers around the country do not participate with Medicare because of the poor payment issues already. We must be able to collect enough payment to cover our supply, staff, and equipment costs and to provide a modest income for the physician if we are to provide these services to any substantial number of Medicare patients.

We already lose money on the reimbursements fo venous ultrasound studies to work up the patients. Our Registered Vascular Technologist costs us more than $70,000/year for salary and benefits and must spend about two hours to perform a detailed venous ultrasound study of both legs, CPT 93970, with a $200,000 ultrasound unit.

Please reconsider your proposal and look more closely at the real costs of providing these services. Thank you.

Submitter : Dr. Darrell Kirch **Date:** 10/10/2006

Organization : Association of American Medical Colleges

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-831-Attach-1.PDF

#831

October 10, 2006

Association of
American Medical Colleges
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0460 F 202 862 6161
www.aamc.org

Darrell G. Kirch, M.D.
President

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

Dear Administrator McClellan:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide comments regarding the Centers for Medicare and Medicaid Services' (CMS) proposed rule on 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.* 48,982 (August 22, 2006). The AAMC represents 125 U. S. allopathic medical schools employing approximately 90,000 clinical faculty, approximately 400 major teaching hospitals and health systems, 96 academic societies and residents and students.

CY 2007 PHYSICIAN PAYMENT RATES

CMS estimates in the proposed rule that CY 20007 Medicare payment rates for physicians and other health care practitioners will be cut by 5.1%. The AAMC is grateful for the interventions implemented by Congress and the Administration for each of the last four years that have averted steep cuts to the Medicare physician payment rates. Along with other physician organizations, AAMC is hopeful that CMS and Congress can intervene once again and address the CY 2007 cut resulting from the flawed Sustainable Growth Rate (SGR) formula and ensure that physician payment updates for 2007 and subsequent years accurately reflect increases in medical practice costs.

As a result of the SGR, physicians can expect drastic Medicare payment cuts totaling almost 40% over the next nine years, a time during which physician practice costs are expected to increase by approximately 20%. CMS noted the inadequacy of Medicare physician payments in a proposed rule released earlier this year, the "Five-Year Review of Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology." Data in that proposed rule indicate that current Medicare payments cover only about two-thirds of the labor, supply and equipment costs of each service.

According to surveys by the American Medical Association (AMA) and Medical Group Management Association (MGMA), 45% of physicians and 40% of group practices will limit the

number of new Medicare patients they accept when the first cut of at least 5% goes into effect January 1, 2007.

Some group practices, and certainly academic faculty practice plans, are comprised of a variety of specialists and subspecialists. Many of these clinical disciplines provide services that are critical to geriatric patients. This reality, combined with the missions of academic medical centers, has resulted in an ongoing willingness of academic medical canters to accept and treat patients that need specialized care not otherwise available in the community and/or patients that are not accepted by community providers, such as the indigent, underinsured/uninsured and dually eligible Medicare-Medicaid beneficiaries. If community providers decrease the number of new Medicare patients accepted, the patients are likely to turn to, or be referred to, group practices and academic medical centers that continue to accept Medicare patients. This potential decline in the number of providers available to Medicare patients is likely to result in access problems for patients, as providers continuing to treat Medicare patients reach capacity.

OTHER POLICIES IMPACTING PHYSICIAN PAYMENTS

In addition to the 2007 physician payment cuts resulting from the annual calculation of the SGR system, Medicare physician payment policy changes recently announced by CMS also will take effect on January 1, 2007. These changes relate to:

- changes in both the physician work and practice expense relative values under CMS' recently-proposed five-year review rule

- payment cuts in imaging services furnished in physicians' offices, as mandated by the Deficit Reduction Act of 2005 (DRA).

- expiration of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) provision that set a floor on geographic practice cost adjusters for the work component of Medicare's physician fee schedule

These policy changes will have a significant impact on a large number of physicians who could experience combined pay cuts of 10% or more for many physicians' services. Analyses conducted recently by the AMA indicate that if the SGR cut is allowed to take effect in 2007, 13% of physicians will face cuts exceeding 10%, and 32% will see cuts of 6% to 10%. Thus, almost half of physicians will face cuts in addition to the 5.1% across-the-board cut that is scheduled for January 1, 2007.

Recent AAMC analyses of CMS-1512-PN, Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology indicate that academic clinical faculty will face a greater impact from the proposed changes than will the general physician population. AAMC has also found his trend in prior analyses of the impact of the annual fee schedule changes.

CMS estimates the impact of CMS-1512-PN Five Year Review to vary across specialties, ranging from an 8% decrease (nurse anesthetist) to an 8% increase (infectious disease). Other specialties that are expected to receive at least a 5% increase due to the WRVU proposal are emergency medicine (7%), endocrinology (6%), family practice (5%), and pulmonary disease (5%). Similarly, specialties whose payments are estimated to decrease by at least 5% include anesthesiology, nuclear medicine, pathology, and physical/occupational therapy.

The AAMC analysis of Medicare services provided by 66 faculty practice plans associated with U.S. medical schools indicates an even wider impact for specialties at academic health centers. Results of the analysis indicate the range to be from negative 15.7% (nuclear medicine) to positive 12.7% (family medicine without obstetrics).

ADMINISTRATIVE ACTIONS TO IMPROVE PAYMENTS

AAMC urges CMS to administratively address issues related to payments to physicians and other providers that will assist with diminishing the negative impact on physicians. Specific areas include:

- CMS Should Remove Drugs Retroactively from the SGR

Drug expenditures continue to grow rapidly. The majority of all physician-administered drugs are used to treat cancer patients, however, other factors — such as a rise in the number of patients with compromised immune systems and the number of drug-resistant infections in the U.S. — also have contributed to the rapid growth of drug expenditures. This growth has outpaced the growth of physician services that the SGR was intended to include, and Medicare actuaries predict that drug spending growth will continue to significantly outpace spending on physicians' services for years to come. This unbalanced growth lowers the SGR target for actual physicians' services and significantly increases the likelihood that Medicare spending on "physicians' services" will exceed the SGR target.

- Program Related Increases in Spending on Physicians' Services should be Accurately Reflected in the SGR Target

Greater use of physician services results from legislative actions and various regulatory decisions. These initiatives benefit patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many initiatives have either been ignored or undercounted in the calculation of SGR targets. Since the SGR is a cumulative system, omitted or erroneous estimates compound each year and create further deficits in Medicare spending on physicians' services.

CMS has not provided details of how its estimates of new or expanded physicians' services are calculated, and certain questions remain. CMS reportedly does consider multiple year impacts and the cost of related services; however, the agency has not provided itemized descriptions of how the agency determines estimated costs. AAMC requests that CMS provide these itemized

descriptions, and accurately reflect in the SGR increased spending due to all government initiatives for purposes of the 2007 physician fee schedule rule.

- Rebasing the Medicare Economic Index (MEI)

In establishing the MEI each year, CMS adjusts the MEI downward to account for physician productivity. The productivity adjustment to the MEI for 2007 is 1.3%. The AMA believes that a 1.3% productivity adjustment for physicians' services is too high. It is nearly impossible for physicians to increase their productivity in treating patients in light of various new Medicare initiatives, such as the new welcome to Medicare benefits and comprehensive Medicare Part D drug benefit, each of which impose numerous time and paperwork burdens on physicians. This would tend to slow productivity, not increase it. Also, CMS assumes and calculates increased productivity levels for physicians while other providers do not have assumed or automatic productivity adjustments.

Additionally, AAMC encourages CMS to examine and address the broader problem that the MEI only measures changes in specific types of practice costs that existed in 1973. Inputs to the MEI are vastly different now than when the MEI was first developed in the early 1970s, and thus additional inputs may be needed to ensure that the current MEI adequately measures the costs of practicing medicine. For example, physicians must comply with an array of government-imposed regulatory requirements that did not exist in 1973, including those relating to the Medicare Part D drug benefit, fraud and abuse, billing errors, quality monitoring and improvement, and patient safety. Further, some physicians, including many academic medical centers, are implementing electronic systems to improve patient safety and care and population management strategies. These systems are costly unto themselves and require additional resources for technological implementation and human resource training, as well as ongoing maintenance.

AAMC appreciates the opportunity to provide input on these matters and looks forward to opportunities to work with CMS on these issues.

Sincerely,

Darrell G. Kirch

Darrell G. Kirch, M.D.

cc: Robert Dickler, Senior Vice President
Denise Dodero, Associate Vice President

Submitter : Mr. William Erickson **Date:** 10/10/2006

Organization : New England Mammography

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-1321-P-832-Attach-1.DOC

#832

October 10, 2006

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.

To Whom It May Concern:

I appreciate the opportunity to comment on the Proposed Notice published by CMS in the ***Federal Register*** of August 22, 2006, which describes proposed changes to the practice expense relative value units used to establish payment for services to Medicare patients under the Physician Fee Schedule. I am concerned about the projected 39% reduction of the Medicare payments for Computer Aided Detection (CAD) when used with mammography (CPT 76082 and 76083) by the year 2010.

CAD systems for mammography are important diagnostic tools which can increase breast cancer detection rates, especially in the early stages. The use of CAD requires the purchase and maintenance of medical equipment which is operated by our certified mammography technologist. The process of digitizing images for CAD is time and labor-intensive. There is no rationale to reduce in the valuable service by 39% because of modification in payment calculations. I am deeply concerned that the combined a fact of all the proposed changes in reimbursement, along with an anticipated reduction of the conversion factor of 5.1%, may make it economically impossible for New England at mammography to continue providing mammography with CAD analysis to our Medicare patients.

Please seriously consider withdrawing the proposed reduction, or at a minimum delay the implementation of this new practice expense methodology, especially in light of the other payment reductions planned for other imaging procedures.

Thank you for your serious consideration.

W. Scott Erickson, MBA

Garrison Women's Health Center
770 Central Avenue
Dover, NH 03820
wserickson@GWHC.com

Submitter : **Dr. David Collins** **Date: 10/10/2006**

Organization : **The Collins Vein Center**

Category : **Physician**

Issue Areas/Comments

Background

Background

Do to my practice being soley a Vein Center the lowering of the reimbursement for RF Vein Ablation would greatly have a negative impact on my practice. We do this procedure in our office which make the costs of the procedure higher to us. The cost of the catheter along with the other disposables is very high. This will impact as well negatively on the Medicare populations access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

GENERAL

GENERAL

I am responding to the CMS proposal of 08/08/2006 regarding the proposed changes in the physician fee schedule for CPT 36475 and CPT 36476 Radiofrequency Ablation. I have reviewed the proposed 2007 RVUs and have issues of concern. The levels have consistently been reduced while practice expenses consistently rise. There is already as you know a 5.1% cut in reimbursement accross the board. Additionally there are proposed cuts for non-invasive vascular imaging. All of these cuts will cripple the ability of physicians to perform this procedure. I would request that the fully implemented, non-facility expense RVU remain at the 2006 rate for 36475 and 36476.
I would be happy to discuss this further with members of your committee.

Respectfully submitted,

David Collins, MD, FACS, FACC
Pikeville, KY 41502
khli@tiusa.net

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below

Submitter : **Dr. Pamela Roberts** **Date: 10/10/2006**

Organization : **Dr. Pamela Roberts**

Category : **Other Health Care Provider**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Pamela Roberts,MD
Port St Lucie,FL 34986
pamroberts@adelphia.net

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : **Dr. Curtis Hitt** **Date: 10/10/2006**

Organization : **The Urology Team**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

My comments concern the Reassignment and Self Refferral proposals about "pod Labs". As an owner in a Pod lab managed by Uropath, I do not believe this violates any present regulation. This arrangement allows the best possible integrated services between the urologist and pathologist, and affords the patient the best of care.

Sincerley,
Curtis Hitt, M.D.

Submitter : Mr. Peter Clendenin **Date:** 10/10/2006

Organization : National Association for the Support of Long Term

Category : Long-term Care

Issue Areas/Comments

Background

Background

CMS Should Assume Greater Leadership in Urging the Congress to Enact Legislation Preventing a Negative Conversion Factor
See Attachment.

GENERAL

GENERAL

See Attachment.

Impact

Impact

The Medicare Part B Therapy Cap is a Particularly Harsh Policy for Nursing Home Residents
The Proposed Cut in Imaging Services Should be Moderated
Support for Adding Ultrasound Screening for Abdominal Aortic Aneurysms (AAA)
Blood Glucose Monitoring Provision Should be Eliminated from the Final Rule
See Attachment.

CMS-1321-P-836-Attach-1.DOC

#836

#836

NASL Insight • Advocacy • Action

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS— 1321-P
Mail Stop 4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Revisions to Payment Policies Under the Physician Fee Schedule for calendar year 2007; Proposed Rule

The National Association for the Support of Long Term Care (NASL) submits the following comments in response to the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, Proposed Rule.

NASL is a trade association representing providers of both ancillary services and products to the long-term care industry. Our member companies provide speech-language pathology; physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy; long term care (LTC) software systems; and other ancillary services. NASL members also provide products such as complex medical equipment; parenteral and enteral supplies, equipment and nutrients; and additional specialized supplies for post-acute care settings nationally.

Listed below are our comments covering several issues that need to be addressed before the implementation of the final rule.

CMS Should Assume Greater Leadership in Urging the Congress to Enact Legislation Preventing a Negative Conversion Factor

If Congress does not pass legislation superseding the proposed rule, the CY07 conversion factor will be negative 5.1 percent with negative increases projected for future years. In the proposed rule, CMS points to the underlying statute which includes the specific formula for calculating the sustainable growth rate as the reason why the agency cannot prevent the rate calculation reduction.

NASL cannot emphasize enough the disruptive impact that would come from a reduction in the physician fee schedules. At the same time that CMS is rolling out new survey and certification requirements for medical direction in skilled nursing facilities, the agency is proposing to reduce payments. Presently, many NASL members struggle to attract and retain qualified, responsive

NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE
1321 DUKE STREET • SUITE 304 • ALEXANDRIA, VIRGINIA 22314-3563 • (703) 549-8500 • (703) 549-8342 FAX • WWW.NASL.ORG

professionals to meet the needs of their nursing residents. In all markets, practice costs are rising, the supply of physicians specializing in geriatrics is limited, and trade offs are being made between preferred settings and preferred patient load.

It should be noted that the Resource-Base Relative Value Scale (RBRVS) fee codes extends to non-physician services including an array of therapy services, SLP, OT, PT, and RT. Historic flaws in the underlying data are magnified in the projected reductions in per unit delivery of these services. For example, members of rehabilitation and respiratory companies struggle to attract qualified professionals. The current payment formula undervalues the complexity of these services in the SNF setting and under pays for their delivery to Medicare beneficiaries.

The severe cuts proposed by the rule for 2007 and projected forward are not sustainable. They would cause irreparable damage to patient access to health care. CMS should assume the leadership in pushing the Congress to enact legislation preventing a negative conversion factor and the Agency should pressure the Congress to enact the correction adjustment before the end of this year.

The Medicare Part B Therapy Cap is a Particularly Harsh Policy for Nursing Home Residents

Provisions of the Deficit Reduction Act (DRA) of 2005 allowed outpatient therapy caps to take effect January 1, 2006, but with a clinically-based exceptions process that allows beneficiaries needing care above the cap to apply for additional care. The DRA only authorized the exceptions process for the 2006 calendar year, so if Congress adjourns without repealing the caps or extending the exceptions process, rehabilitative care for our nation's most frail citizens will be restricted severely with no regard for patient needs.

As evidenced by the delayed implementation of the exceptions process and the retroactive application of the 2006 physician fee schedule, services to beneficiaries in need will be interrupted again if there is not quick action on the part of Congress.

The proposed rule affirms the agency's intention to implement the caps, although it does not articulate how the level will change from the current level of $1740. The therapy cap is a particularly harsh policy for nursing home residents. The therapy cap only serves to deny access to services for those patients in greater need. Those with co-morbidities and medical complications that warrant more extensive treatment find their care restricted while utilization under the cap is ignored.

For skilled nursing facilities, Part B therapy services are secondary to Part A coverage. A high percentage of facility admissions are Part A Medicare. Approximately 3 out of 4 new admissions are in RUG rehabilitation categories. About half of these individuals are discharged within 45 days; for those not discharged, a high proportion become eligible for Medicare Part B therapy services because the intensity of services decrease below the thresholds required for Part A

coverage. It is critical to emphasize that for nursing facilities, the volume of Part B therapy services is dependent on the admission and discharge patterns and case mix of the facility. It is clinically difficult and cost prohibitive for nursing facility residents to avail themselves to the therapy cap's safety valve of outpatient hospital services.

Paired with continual increases in edits from the Correct Coding Initiative (CCI), this makes provision of medically necessary care challenging for skilled nursing rehabilitation providers. Currently under the CCI edits, a Medicare Part B beneficiary in need of multiple therapy services cannot receive care because of mutually exclusive codes that cross the therapies (physical, occupational and speech-language pathology).

Therefore, CMS should be aggressive in urging the Congress to intervene to alter the current law. To assure rehabilitation services for nursing home residents, CMS should separately address the therapy cap impact for these beneficiaries protecting their access to clinically necessary services. NASL supports strongly the development of a condition-based payment as a viable alternative to the arbitrary therapy cap. While that system is being developed, Congress should extend the exceptions process to the therapy caps.

The Proposed Cut in Imaging Services Should be Moderated

We recognize that provisions of the DRA with respect to imaging services bind CMS, but NASL urges you to look for ways in which the drastic cuts in imaging services might be mitigated. Portable x-ray suppliers provide valuable services in SNF settings, and they would be affected severely by the proposed cuts.

Support for Adding Ultrasound Screening for Abdominal Aortic Aneurysms (AAA)

NASL is pleased to see CMS move forward with the implementation of Section 5112 of the DRA. Adding ultrasound screening for AAA is an important step in providing preventive care to Medicare beneficiaries.

Blood Glucose Monitoring Provision Should be Eliminated from the Final Rule

NASL believes that the blood glucose monitoring provision contained in the proposed rule would needlessly undercut effective disease management for nursing home patients. The provision should be stricken from the final rule, and CMS should work with the provider community in developing public policy that would promote quality diabetes management for nursing home residents. NASL endorses the detailed comments put forth on this issue by the American Health Care Association (AHCA) and the Alliance for Quality Nursing Home Care.

Conclusion

Several of the issues outlined in our letter represent recurrent themes. NASL is concerned that many of the successful programs focusing on the most clinically complex and medically needy populations are again being threatened. NASL hopes that these comments will help stimulate CMS to reexamine the impact of its rule-making on special needs populations residing in skilled nursing facilities.

Thank you for your time in considering these comments and suggestions. NASL appreciates the Agency's efforts to expand access to the regulatory process to providers and suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly by telephone at (703) 549-8500, or by e-mail at clendenin@nasl.org with any questions that you may have regarding these comments.

Sincerely,

Peter C. Clendenin

Peter C. Clendenin
Executive Vice President

Submitter : Hadley C. Ford **Date:** 10/10/2006

Organization : ProCure Treatment Center Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-837-Attach-1.PDF

#837

ProCure
TREATMENT CENTERS, INC.

October 9, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year. These positive clinical results also indicate a marked reduction in normal tissue damage and resulting co-morbidities thereby reducing short and long term complications and cost.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

444 Park Avenue South New York, NY 10016-7321 212-584-0960 - Tel

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	—	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules. This is of paramount concern to ProCure Treatment Centers as this company has invested significant resources to increase the availability of this important technology, and is actively preparing to expand to multiple states. It is very important that this technology is appropriately applied and equally important that the technology be properly and consistently reimbursed be it a freestanding and or hospital based facility.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients. Over time Proton Therapy has been carefully evaluated and reviewed in the Academic setting, and now as is the classic free market approach, the technology is being embraced in the mainstream clinical setting and programs are developing bringing not only the clinical benefits, but significant economic benefits to the communities in the form of jobs, and investment.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

ProCure Treatment Centers has carefully approached this technology with an interest in making it available for appropriate use within the cancer treatment milieu. It is clearly a technology that has demonstrated clinical and financial efficacy, it is in demand by clinicians and patients, and it has reached the stage where free market principles will support the development of these important programs. It is very important that the CMS system not create undue penalties based upon organizational structure. Free standing and/or hospital-based programs have markedly similar cost and operational structures and as this letter has outlined fair and balanced reimbursement is important for the appropriate development of this technology and the clinical benefit it will have on patients.

Sincerely,

Hadley C. Ford
Chief Executive Officer

444 Park Avenue South New York, NY 10016-7321 212-584-0960 - Tel

Submitter : **Wendy Wifler** **Date: 10/10/2006**

Organization : **Accuray Incorporated**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED PDF DOCUMENT . . . As a manufacturer and provider of image-guided robotic stereotactic radiosurgery (r-SRS) equipment, we appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

CMS-1321-P-838-Attach-1.PDF

#838

ACCURAY

Accuray, Incorporated
1310 Chesapeake Terrace
Sunnyvale, CA 94089

T: 408.716.4600
F: 408.716.4601
www.accuray.com

October 10, 2006

Reference file code: CMS-1321-P

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

As a manufacturer and provider of image-guided robotic stereotactic radiosurgery (r-SRS) equipment, we appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

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

Image-guided robotic stereotactic radiosurgery programs are substantially more resource-intensive than other forms of linac-based systems. It was for this reason that CMS created separate HCPCS codes to distinguish these technologies. Further, it is clear that the resources required for r-SRS are the same for each treatment regardless of whether that treatment is a single (first) or a subsequent treatment, up to a maximum of five.

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

Comment:

A number of temporary codes have been established to enable hospitals to report the technical component costs of image-guided robotic stereotactic radiosurgery (r-SRS) treatment (HCPCS Codes G0339 and G0340). The proposed Rule regarding the Physician Fee Schedule for 2007 designates codes G0339 and G0340 as "C – Carriers price the code."

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

Recommendation:

We respectfully recommend and encourage CMS to:

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

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

We appreciate your consideration of our comment.

Sincerely,

Wendy E. Wifler
Sr. Director, Health Policy & Payment
Accuray Incorporated

to get instant consults on difficult cases and provides an ongoing quality assurance program in the field of Urologic pathology.

The proposed regulations seem to be based on the assumption that all pathology pod labs are inherently bad, provide kickbacks & fee splitting and create over utilization with medically unnecessary biopsies which result in a higher cost to Medicare. As we are set up, this is not the case. We practice Urology based on the current accepted medical guidelines. We decide to biopsy patients based on the findings from a digital rectal exam and their PSA tests, and we do not perform biopsies unnecessarily. Our medical records are available for review. The number of patients we biopsy and the number of biopsies per patient would be the same & the cost to Medicare would be the same whether we sent these specimens to an outside pathology lab or our internal pathology pod lab.

Much of the information that promulgates the premise that pathology pod labs are bad and create over utilization is coming from "commenters" who are other pathologists, outside reference labs and special interest groups that stand to lose revenue to the Urological pathology labs. To date neither CMS nor the OIG has documented any abuse or over utilization in pathology pod labs. Instead this is a turf war between physicians and unless CMS actually sees over utilization or abuse, there is no reason for these regulations if the pathology lab is properly structured within the Urologist group practice.

We would like to comment on the specific proposals outlined in the proposed regulations. With respect to the billing limitations in the Reassignment Rule, even after reading these sections numerous times and asking our legal counsel to review it, we really never understood what CMS is proposing. It is very ambiguous and the proposals are not clear. It appears that this section needs further development and input. Our pathologist is considered a "member of the group" under Stark and we bill the global fee for the preparation of the slide by our employees in our lab and the interpretation by the pathologist as a member of our group. We do not purchase these tests. We perform all the work within our group practice. No where do the proposed regulations define how this arrangement is to be addressed.

The proposed regulations dealing with the Self Referral Rule are also ambiguous and need further development before implementation. Our lab is of sufficient physical size to process the specimens, prepare the slides and read the results. There is no need for CMS to propose specific square footage regiments that are arbitrary and that may not be needed to provide quality pathology services. The size of the lab should be based on the work requirements and CLIA regulations. With respect to the physical location of the centralized building we again question whether this is truly a quality of care issue or is this simply a mechanism to stop pathology pod labs. With computers, telephones, efficient information technology and the other developments in the field of communications the physical location of the lab is simply not important. What is important is the overall quality of the pathology service and this is a function of the medical group including its pathologist and the process they follow to prepare the specimens, not a function of the physical location.

The same is true with respect to the number of employees needed. This is already addressed and regulated under CLIA and to impose an arbitrary requirement that X FTEs are required simply is not related to the quality of pathology service provided.

Our pathology lab is of adequate size & used exclusively by our group 24 hours per day, 7 days per week. We own all the equipment and we have group practice leased employees preparing all the slides. Our Pathologist is a member of the group as an independent contractor which is approved under Stark. In short we have established a complete pathology lab supervised and directed by a Board Certified Pathologist that is a member of our group and we are providing our patients with high quality pathology services.

While others may allege that these arrangements are abusive and create over utilization, the revenue derived from our pathology lab simply is not enough income per Urologist that we would risk our patient's well being and lives and our professional reputations to set up this pathology lab solely to make additional income. We strongly resent that implication in these proposed regulations.

Sincerely.

Thomas Moody, M.D.
President

CC: Senator Richard Shelby
Senator Jeff Sessions
Congressman Spencer Bachus
Congressman Artur Davis

#839

Urology Birmingham
CENTERS OF ALABAMA

3485 Independence Drive
Homewood, Alabama 35209

(205) 930-0920

October 9, 2006

Centers for Medicare and Medicaid Services
Department of Health & Human Services

Via Web site http://www.cms.hhsgov/eRulmaking

File Code CMS-1321-P

Re: Reassignment and Physician Self-Referral

I am writing on behalf of our 16 Urologists that practice as a group practice and that includes a Pathology lab, supervised and directed by a Board Certified Pathologist.

We established our own Pathology services lab for a number of reasons these proposed regulations fail to take into consideration. The proposed regulations seem to assume that all pathology pod labs exist solely for the purpose of making a profit for the physician group and the regulations appear to be designed solely to eliminate these legitimate labs which are providing high quality pathology service.

Within our group we strive to offer the highest quality Urology service to our patients and that includes controlling the quality of the pathology service that interprets our pathology specimens. Our pathology lab is CLIA certified and our Pathologist is Board Certified. In addition our Pathologist has specialized in prostate and other urologic related specimens. We could not find that type of specialization with any local pathology group. Over a one year period, our pathologist looks at several thousand prostate biopsy specimens compared to the local pathologist who might look at only one to two hundred per year. By sub-specializing in this manner he has been able to develop his expertise and competency in just the area of urologic pathology. We set up our pathology lab in conjunction with Uropath, LLC and in doing so not only were we able to achieve the desired sub-specialization but our pathologist is working directly with other Urological pathologists in the same building which gives him with the ability

to get instant consults on difficult cases and provides an ongoing quality assurance program in the field of Urologic pathology.

The proposed regulations seem to be based on the assumption that all pathology pod labs are inherently bad, provide kickbacks & fee splitting and create over utilization with medically unnecessary biopsies which result in a higher cost to Medicare. As we are set up, this is not the case. We practice Urology based on the current accepted medical guidelines. We decide to biopsy patients based on the findings from a digital rectal exam and their PSA tests, and we do not perform biopsies unnecessarily. Our medical records are available for review. The number of patients we biopsy and the number of biopsies per patient would be the same & the cost to Medicare would be the same whether we sent these specimens to an outside pathology lab or our internal pathology pod lab.

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We would like to comment on the specific proposals outlined in the proposed regulations. With respect to the billing limitations in the Reassignment Rule, even after reading these sections numerous times and asking our legal counsel to review it, we really never understood what CMS is proposing. It is very ambiguous and the proposals are not clear. It appears that this section needs further development and input. Our pathologist is considered a "member of the group" under Stark and we bill the global fee for the preparation of the slide by our employees in our lab and the interpretation by the pathologist as a member of our group. We do not purchase these tests. We perform all the work within our group practice. No where do the proposed regulations define how this arrangement is to be addressed.

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Sincerely.

Thomas Moody, M.D.
President

CC: Senator Richard Shelby
Senator Jeff Sessions
Congressman Spencer Bachus
Congressman Artur Davis

Submitter : Terese Ghio **Date:** 10/10/2006

Organization : Ligand Pharmaceuticals Incorporated

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-840-Attach-1.PDF

#840

October 10, 2006 **By Electronic Delivery**

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

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)

Dear Administrator McClellan:

Ligand Pharmaceuticals appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2007 payment rates, published in the Federal Register on August 23, 2006 (the "Proposed Rule").

Ligand is a San Diego based emerging specialty pharmaceutical company that discovers, develops and markets innovative small molecule drugs and one biological to address critical, unmet medical needs with four Orphan-designated products for oncology and dermatology: ONTAK (denileukin diftitox), TARGRETIN capsules (bexarotene), TARGRETIN gel and PANRETIN gel (alitretinoin), and AVINZA in the area of chronic pain management (morphine sulfate extended-release capsules).

One of Ligand's products, ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is covered by Medicare under Part B in both hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). This product and the patient population in services truly meet the intent of the legislature's definition of Orphan Product.

Lack of equitable Medicare reimbursement in the hospital outpatient setting and physician setting has historically had a negative impact on patient access to this product, which is for many patients the only option for this debilitating and sometimes deadly disease. Our research indicates that the historical reimbursement structure unfairly discriminated against many patients, including those patients in rural areas.

The transition over the past few years to equivalent reimbursement rates for both the hospital outpatient and physician office settings has partially solved the historical issue of reimbursement rates inappropriately manipulating the practice of medicine by influencing the site of service for products like Ontak that can be administered in either setting based on the specific medical need of the patient. The CMS proposal to cut reimbursement to ASP+5% in the outpatient setting will return us to inequitable and lopsided reimbursement between these two settings. Therefore, we urge CMS to at a minimum maintain equal payment between settings to minimize the influence that reimbursement has on the site of service.

In last years comments Ligand expressed concerns that reimbursement at ASP+6% may not be adequate to ensure beneficiary access. We continue to be concerned and we believe that reducing the payment further to ASP+5% will place additional burdens on hospitals and continue to impede access. For not only does CMS propose to reduce reimbursement for drugs and biologicals, but it also asserts that the proposed rates are sufficient to cover hospitals' pharmacy handling costs. We strongly disagree with this assertion. Pharmacy services can be complex and are labor and resource intensive, especially when working to safely and accurately deliver a complex biological product.

For example, Ontak is a very special product requiring very special handling at both the wholesaler and the hospital pharmacy or physician's office. ONTAK has some very unique requirements including:

a. Its treatment regimen: 3-5 vials/day for 5 days on a 21 day cycle. Therefore patients must usually begin treatment on a Monday. This requires very coordinated planning with the patient and the wholesaler to order the product for drop shipment on a Friday.
b. ONTAK is stored at our distributor at -80 degrees C and must remain frozen and shipped in special packaging to the site of administration who in turn must keep it frozen at -10 degrees C until just before use.
c. ONTAK has specific requirements in its label for solution preparation.
d. Patients typically require pre-medication with steroids (oral or IV) and extra intravenous hydration prior to treatment with ONTAK.
e. In addition, label warnings which require additional monitoring include Acute Hypersensitivity-type reaction (69% patients) and Vascular Leak Syndrome (27% patients). The latter of which can be delayed (usually in first two weeks) and require follow-up phone calls by staff to monitor.

In addition to the fact that the ASP+5% methodology is woefully inadequate for products like ONTAK, CMS should clearly respond to industry's repeated requests for clarifications to the procedures for calculation of ASP. This response should be in the form of a separate proposed rulemaking once CMS receives responses to its broad request for information in the physician fee rule proposal. Only then will industry be able to submit what they feel is accurate and consistent ASP data.

We urge CMS to monitor patient access and increase rates as necessary to ensure that Medicare beneficiaries retain access to critical therapies. This is especially important for

orphan products and for patients with rare disorders and special attention should be paid to the monitoring of access for these entities.

Ligand supports in full the comments submitted by the Biotechnology Industry Organization (BIO). We sincerely appreciate the opportunity to comment on these rules and the open and interactive approach CMS has taken with stakeholders across the medical and health care communities. Please contact me with any questions or to request additional information related to our products or ideas and positions on Medicare policy at 858-550-7569 or tghio@ligand.com.

Respectfully Submitted,

Terese M. Ghio
Vice President Government Affairs and EH&S
Ligand Pharmaceuticals Incorporated

Submitter : **Dr. Steven Petak** **Date: 10/10/2006**

Organization : **American Association of Clinical Endocrinologists**

Category : **Physician**

Issue Areas/Comments

Background

Background

See attachment for AACE comments on this section of the proposed rule.

GENERAL

GENERAL

Comments from the American Association of Clinical Endocrinologists (AACE) are in the attachment.

Impact

Impact

See attachment for AACE comments on this section of the proposed rule.

CMS-1321-P-841-Attach-1.PDF

#841

American Association of Clinical Endocrinologists

1000 Riverside Avenue • Suite 205 • Jacksonville, FL 32204 • Ph: (904) 353-7878 • Fax: (904) 353-8185 • www.aace.com

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Jacksonville, FL
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Rochester, MN
Editor-in-Chief, *Endocrine Practice*

EMERITUS 2007

Yank D. Cobin, Jr., MD, MACP, MACE
Neptune Beach, FL

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore MD 21244-1850

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

Dear Administrator McClellan:

The American Association of Clinical Endocrinologists (AACE) represents over 5500 endocrinologists and is the largest association of clinical endocrinologists in the United States who concentrate on the treatment of patients with endocrine and metabolic disorders. AACE appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2007, published in the August 22, 2006 Federal Register.

PROVISIONS

Bone Mass Measurement Test

AACE is in agreement with the revisions made to the 1998 Balanced Budget Act 42 CFR 410.31 (Bone Mass Measurement: Conditions for Coverage and Frequency Standards). Specifically, we commend CMS for introducing the important concept of quality and standardization in axial DXA testing and reporting. *"As there are many sources of variability in the measurement of BMD, a quality control system related to both the methodology and reporting of test results is important to ensure the validity of DXA analysis."* Axial DXA is also cited for its superior accuracy and precision as it compares to older technologies. As such, we agree with the CMS recommendation to restrict monitoring over time to axial DXA technology; *"DXA is precise, safe and low in radiation exposure and permits more accurate and reliable monitoring of individuals over time."*

AACE shares the CMS concern that to ensure accurate and reproducible bone density measurement, DXA centers must perform a precision assessment on their equipment and patients be followed over time on the same machine to determine if a true change in BMD has occurred. AACE notes that this will be disrupted if physicians in non-hospital practice settings are forced to abandon axial DXA testing.

We also are in agreement with the CMS decision to lower the cut point for DXA testing in patients on glucocorticoids from less than or equal to 7.5 mg for at least 3 months to less than or equal to 5 mg a day for at least 3 months. This change is supported by the current literature and brings the CMS recommendations for a qualified individual into line with those of the American College of Rheumatology.

American Association of Clinical Endocrinologists
1000 Riverside Avenue • Suite 205 • Jacksonville, FL 32204 • Ph: (904) 353-7878 • Fax: (904) 353-8185 • www.aace.com

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Rochester, MN
Editor-In-Chief, *Endocrine Practice*

EMERITUS 2007
York G. Cobb, Jr., MD, MACP, MACE
Neptune Beach, FL

AACE supports the decision to restrict monitoring over time to axial DXA technology and also agrees with the CMS decision to lower the cut point for DXA testing in patients on glucocorticoids from less than or equal to 7.5 mg for at least 3 months to less than or equal to 5 mg a day for at least 3 months.

DRA PROVISIONS

DRA Reductions in Payments for Imaging Services

Section 5102 of the Deficit Reduction Act (DRA) contains arbitrary payment cuts in medical imaging services provided under the Medicare physician fee schedule. Specifically, we refer to Section 5102 (b) that requires payment for the technical component of an imaging service paid under the Medicare Physician Payment Schedule should be capped at the Outpatient Prospective Payment System (OPPS) payment amount for the same imaging service. AACE believes these cuts could lead to a wide range of adverse, unintended consequences for Medicare beneficiaries.

The DRA imaging cuts cannot be considered in isolation. The proposed changes to relative value units and the practice expense methodology published in the June 29, 2006 Federal Register (CMS-1512-PN), the negative 5.1% physician payment update as a result of the Sustainable Growth Rate (SGR) formula, and the application of the DRA imaging payment provision will result in substantial and unsustainable cuts in endocrine based imaging services. These regulatory and legislative actions will severely restrict patient access to critical imaging services thereby undermining the efforts by CMS to focus on disease prevention as opposed to a treatment based approach to health care.

If section 5102(b) of the DRA is implemented, the ultrasound fine needle aspiration guidance procedure (CPT code 76942) performed as part of a minimally invasive biopsy of thyroid nodules will be reduced from a 2006 global fee of $146 (unadjusted for geographic area) to $107 in 2007, or a reduction of 26%. Similarly, payment for DXA (CPT code 76075) will be reduced from a global fee of $140 (2006 global fee unadjusted for geographic area) to $85, or a 40% reduction, in 2007.

While these payment reductions may provide short-term savings, there is no evidence that decreasing payment rates will reduce utilization. Rather, these reductions will drive imaging services back to the hospital outpatient departments where beneficiary co-pays for services are higher and wait times for services will be longer. The end result will be reduced patient access to diagnostic technologies capable of preventing the onset of more serious conditions requiring more complex and expensive treatment interventions.

As pointed out at a July congressional hearing, CMS has not evaluated the potential impact of the cuts on growth in utilization of imaging or on patient care, nor have they conducted a detailed analysis of offsetting savings and efficiencies brought about by imaging as opposed to more invasive and costly procedures.

AACE supports repeal of the unwarranted imaging payment cuts, and we recognize that this will require an act of Congress. However, CMS has the administrative authority to mitigate the impact of this arbitrary and ill-conceived payment policy.

American Association of Clinical Endocrinologists

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First, AACE supports the RUC recommendation urging CMS to use its administrative authority to reverse the technical component and professional component professional liability insurance (PLI) relative value allocations under the Physician Payment Schedule. Currently the higher PLI portion is applied to the technical component and the lower PLI portion to the professional component. Reversing the inappropriate allocation of the PLI RVUs would be a modest step to help alleviate the significant impact of the DRA imaging cuts on physicians who provide imaging procedures and prevent the loss of resources from the Medicare Part B program.

Secondly, there has been little detail on what the payment changes mean for claims submissions and processing. Physicians will be dependent on carriers/contractors to provide a revised fee schedule of imaging procedures affected by the DRA. Without correct payment information, physicians will be unable to accurately bill Medicare patients and will receive overpayments and underpayments from the Medicare contractors. Subsequently, this would subject physicians to accusations of fraudulent billing practices. Administration of the changes could be complicated by the first phase in a six-year transition to Part A/Part B Medicare Administrative Contractors from the current fiscal intermediary and carrier structure.

AACE urges CMS to use its administrative authority to reverse the technical component and professional component PLI relative value allocations and delay implementation of Section 5102 of the DRA until all implementation issues surrounding the new payment policy have been fully addressed and resolved.

IMPACT

Proposed RVU Changes for DXA (CPT code 76075) and VFA (CPT code 76077)

AACE remains very concerned about the impact of the proposed changes in work and practice expense relative value units on CPT code 76075 DXA (dual energy x-ray absorptiometry) and CPT code 76077 VFA (vertebral fracture assessment), as published in the June 29, 2006 Federal Register. Moreover, the modifications to these proposed changes published in the August 22nd Federal Register (CMS-1321-P), further reduce the relative value units and reimbursement for DXA and VFA.

Osteoporosis is a major health care problem in the United States with annual costs of more than $18 billion dollars. Currently 300,000 Americans are hospitalized annually for hip fractures with one in five (20%) dying within the first year following fracture. Given population demographics, osteoporotic fractures are projected to increase for the foreseeable future emphasizing the importance of effective prevention and treatment strategies. To this end, the Centers for Medicare & Medicaid Services (CMS) is to be commended for establishing bone density testing as a key preventive service available for Medicare beneficiaries and highlighting the role of axial DXA in diagnosis and monitoring response to therapy. Despite this, bone density screening remains underutilized. Efforts to increase screening rates for axial DXA above the current level of 20% require a different approach within the existing framework that values access over efficiency.

In our earlier comments to CMS 1512-PN, AACE documented concerns about the marked decline in RVU assigned to axial DXA and the chilling effect this would have on physicians' ability to identify and treat the millions of Americans with osteoporosis. We detailed flaws in input for the physician work and practice expense RVUs and a resultant rank order anomaly when axial DXA was compared to peripheral DXA. We also presented the results of a clinical society survey that AACE worked on with the International Society for Clinical Densitometry (ISCD)

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and which was nearly identical in format and content to the 2005 American College of Radiology (ACR) Relative Value Update Committee (RUC) survey used to determine physician work value. As the physician payment for axial DXA has now been further reduced in the current proposal, we would like to take this opportunity to expand on our earlier comments.

In our earlier letter, we demonstrated other apparent flaws in the input and assumptions used to determine physician work and practice expense. The clinical society survey also underscores some of those key points as follows:

1. 93% of respondents have a fan-beam axial DXA system, which is valued at $85,000. Only 7% currently use an older pencil-beam system valued at $41,000. The Practice Expense survey used a pencil beam densitometer at $41,000 for calculation of machine costs.
2. Utilization rates across all locations in the clinical society survey were calculated to approximate 21%. This is vastly different than the 50% utilization rate used in the Practice Expense methodology for all procedures. Rates of 50% and often higher are more typically seen in large diagnostic imaging centers where patients are referred and devices are used for multiple disease states.
3. Median service contracts of $5,000, software upgrades of $2,000 per year and phantom costs were listed by the clinical society survey respondents. None of these expenses were included in the Practice Expense survey.

Additionally, it is important to recognize that osteoporosis care in the United States, and worldwide, is on the verge of a WHO driven paradigm shift based on international consensus that optimal targeting of individuals for receipt of pharmacologic intervention should be determined using an estimate of absolute 10-year hip fracture risk. The National Osteoporosis Foundation (NOF) is developing a United States-specific absolute fracture risk WHO prediction model that will identify the fracture probability at which treatment intervention becomes cost effective. This model will specifically input femoral neck BMD (necessitating axial DXA) and presence of vertebral fracture for calculation of fracture probability and thus need for pharmacologic intervention. VFA can be performed at the same time and location as an axial DXA study, thereby optimizing integration of vertebral fracture status with femoral neck BMD into a United States -specific absolute fracture risk WHO prediction model providing clinicians with essential point-of-care information for appropriate assessment of need for therapeutic intervention. Thus, the future of osteoporosis care in the United States will be based on present day axial DXA equipment, upgraded with special software licensed by the WHO and NOF providing automatic linking of a patient's BMD and fracture status into the aforementioned NOF cost effectiveness model that will be reported by axial DXA equipment.

AACE also disagrees with the RUC recommendation to decrease the physician work RVU component to 0.2, a 33% reduction from the previous value of 0.3 for DXA. In the AACE comment letter regarding CMS-1512-PN we discussed what we believe are a number of flaws in the determination of the physician work RVU component for DXA.

Unlike other procedures where an increase in volume is assumed to lead to increased efficiency and less work, this does not appear to be the case for DXA. In the ACR RUC survey of 51 radiologists, 59% of the radiology respondents felt that the complexity of DXA had increased within the last 5 years. Similarly, in the clinical society survey of 453 physicians from multiple specialties (30% of whom were primary care), 61% felt that complexity had increased. Only 12% of radiologists and 19% of the clinical society survey respondents felt that DXA had become

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"more familiar" (less work). These results are at odds with the RUC subgroup that rejected the recommendations of the ACR and ruled that the physician work RVU for axial DXA should be reduced from 0.3 to 0.2 because the procedure was felt to be "less intense and more mechanical than the ACR survey results would indicate." Data to support this contention does not exist.

The axial DXA report has many elements of an E/M visit. As such, it is not surprising that in the clinical society survey, the key reference codes selected most often were 99213 (19.9% of respondents), followed by 99212 (16.3%) and 99214 (15.9%) with RVUs of 0.67, 0.45 and 1.10 respectively. The clinical society survey also demonstrated internal consistency in that the median estimated work RVU for axial DXA was 0.5 (with 25th percentile of 0.35 and 75th percentile of 1.00).

Consistent with an E/M type approach being taken by clinicians, a substantial difference was seen between the ACR RUC survey and the ISCD sponsored clinical society survey in physician work time. As we previously reported, the median physician work time for a DXA study was 25 minutes (5 minutes pre-service, 10 minutes intra-service, 10 minutes post-service). For radiologists who were surveyed in the ACR RUC survey, the median physician work time was either 6 or 8 minutes (1-2 minutes pre-service, 4 minutes intra-service, 1-2 minutes post-service). Such differences in physician work time could in part be explained by what are considered "essential elements" of an axial DXA report. If the report were to only provide a densitometric diagnosis without reviewing the patient's history, risk factors and providing broad treatment recommendations, the work time would be anticipated to be substantially less.

On September 26, 2006 AACE participated in a Refinement Panel call with members of the American College of Rheumatology and other related specialties to further refute the basis for the RUC recommended reduction in the physician work RVU component for DXA.

As our three societies have strongly suggested, there simply is no evidence to support the proposed reduction in the work RVU that grossly under values the physician work component for central DXA. We urge CMS to reverse the proposed reduction in the work RVU based on the following:

- Work complexity has in fact increased based on 2 separate surveys.
- The physician time is greater than originally noted.
- The current assigned value would create a rank order anomaly with other reference services.
- Incorrect assumptions were made in the valuation of the service. This is based on flawed methodology of the RUC working group and a survey that does not reflect the current composition of physicians performing this service.

As noted above, osteoporosis is a major health care issue in this country. Federal initiatives to detect this disease using DXA and VFA and appropriately treat individuals at high risk are crucial. Although axial DXA testing has increased significantly in the last decade as evidenced by 77,133 claims in 1994, 1.265 million in 1999 and 2.43 million in 2004, this still represents less than 20% of affected Medicare beneficiaries who have been tested. While the data indicates that testing is increasing, it still remains vastly under-utilized. As such, we propose that special resource considerations are necessary, for both DXA and VFA, to ensure widespread availability of high-quality screening in the United States.

Given the importance of axial DXA and VFA screening as key preventive services, one could argue that not only do the services need to be appropriately valued compared to other CPT codes, but that value could be set higher than other services to further increase incentives and improve

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the proportion of beneficiaries screened. MEDPAC in their report to Congress in March 2006 outlined the dangers of undervaluing a service noting that physicians may opt not to provide the service which threatens access to care, and additionally that Medicare is not a good steward by not paying enough for the undervalued service and thus not spending the taxpayers money wisely.

AACE suggests that special resource considerations are necessary for these procedures to ensure the widespread availability of high-quality screening in the United States. Therefore, AACE respectfully requests that no changes be made to the current total RVUs for DXA (CPT code 76075) and VFA (CPT code 76077).

Continuous Glucose Monitoring

On September 26, 2006 AACE participated in the CMS Refinement Panel call to seek acceptance of the RUC recommended RVU values of 0.85, for which AACE worked closely with the RUC to survey and develop, for CPT code 95251 *Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report.*

In the 2006 final rule, CMS disagreed with this recommendation and published an interim work RVU of 0.52 stating that an appropriate reference service for this new procedure is 93268 *Patient demand single or multiple event recording with presymptom memory loop, 24-hour attended monitoring, per 30- day period of time; includes transmission, physician review and interpretation.*

AACE respectfully disagrees with this identified reference service and reiterates the RUC's previous rationale for the value of 0.85. The RUC carefully reviewed the survey data for this service. The reference service selected by those surveyed was 99214 *Office or other outpatient visit for the evaluation and management of an established patient, which requires 2 of 3 key components: a detailed history; a detailed examination; medical decision making of moderate complexity. Physicians typically spend 25 minutes face-to-face with the patient and/or family* (Work RVU=1.09). When comparing the reference code to the surveyed code, the RUC noted that although the surveyed codes required greater intensity, technical skill and mental judgment than the reference code, the reference code had 8 minutes more total time than the surveyed code. Therefore the RUC supported the specialty society's recommendation of the 25th percentile of their survey, 0.85 work RVUs.

Although the time period associated with cardiac event recording (CPT code 93268) is 30 days, the amount and complexity of data that needs to be reviewed for ambulatory continuous glucose monitoring (CPT code 95251) is considerably greater. As noted in the RUC's recommendations, ambulatory continuous glucose monitoring requires approximately 30 minutes of physician time, including interpretation of over 900 glucose values, overlaid with a patient log of several variables (caloric intake, physical activity, symptoms of hypo-- or hyper--glycemia, and other symptoms as they occur). Thus continuous glucose monitoring interpretation is a four-dimensional analysis as opposed to a two dimensional analysis with CPT code 93268.

AACE urges CMS to reconsider its decision concerning CPT 95251 and to assign the RUC recommended work value of at least 0.85 for this service.

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Education and Training for Patient Self-Management

AACE would like to take this opportunity to revisit a specific coding issue related to education and training for patient self-management, CPT 2006 includes the following new codes for the reporting of education and training for patient self-management:

98960	Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient
98961	2–4 patients
98962	5–8 patients.

In the final rule for 2006, CMS assigned a status indicator of "B" for these services, stating "they are bundled into another covered service under Medicare." We question this conclusion and would like to note that these services would seem to fit into the Medicare statutory benefit category of "incident to" services. Also, there should be no question about the clinical value of these services for patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcomes and where such services have been incorporated into nationally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health.

AACE has held two face-to-face meetings with representatives from CMS to discuss the rationale behind this decision; however, to date a satisfactory answer has not been given.

CMS has recognized the importance of diabetes outpatient self-management training services by conforming CMS regulation in the current proposed rule to be consistent with Section 5114 of the DRA that adds diabetes self-management training services to the list of Medicare covered and reimbursed services under the Medicare Federally Qualified Health Center benefit. AACE commends CMS for this action and asks that the same consideration be given to diabetes outpatient self-management training services when billed under the Physician Fee Schedule.

Coverage of codes 98960 – 96962 will support the implementation of this benefit through the physician office and will improve access to proper medical care and prevent delayed disease complications. CMS already supports G0108 and G0109 codes and these codes extend that principle of providing and documenting nationally approved curricula for the improvement of our patients' health.

AACE requests that CMS reconsider its decision and change the status of these codes from "bundled" to "active" and separately payable under the Medicare Physician Payment Schedule. The AMA Relative Value Update Committee (RUC) recommended RVUs could then be considered for assignment to these codes.

Sustainable Growth Rate (SGR) Formula

AACE believes the Medicare Sustainable Growth Rate (SGR) formula used to calculate annual physician payment updates is flawed and should be repealed. Physicians once again face an annual cut in reimbursement – calculated at 5.1% in 2007 – based on a methodology that has no bearing on the medical needs of patients or the cost of providing care.

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Editor-in-Chief, *Endocrine Practice*

EMERITUS 2007

Yank D. Coble, Jr., MD, MACP, MACE
Neptune Beach, FL

AACE continues to work with the AMA, on behalf of organized medicine, in urging Congress to pass legislation to replace the SGR formula with a system that reflects actual physician practice costs. Continued utilization of this formula and failure to enact meaningful fixes to the system will negatively impact quality through limited access to care.

Until Congress acts to replace the SGR, AACE urges CMS to use its administrative authority to make adjustments to the SGR methodology, such as removing Part B drug payments from the calculation of expenditures and including the full cost of new Medicare benefits and coverage decisions in the SGR target. Congressional leaders from committees of jurisdiction in the Congress have called on CMS to take similar action.

AACE urges CMS to take these necessary administrative steps to mitigate the 5.1% cut scheduled for 2007. The promise of health care made to older Americans will be undermined if annual physician payment cuts resulting from the SGR formula are not addressed.

As America ages and substantial numbers of citizens become Medicare-eligible, it is clearly inappropriate for federal policy to negatively impact the ability of physicians to provide care to beneficiaries. Physicians simply cannot continue to absorb payment reductions, unfunded mandates and the unpredictability of Medicare physician payment policy. The growing Medicare population will find it increasingly difficult to find a physician who will accept them if reimbursement rates are continually cut. The solo and small group practice will become unsustainable, resulting in more expensive emergency care.

AACE appreciates this opportunity to comment on these important issues. We welcome any further dialogue with CMS regarding the issues we have outlined in this letter. Please contact Sara Milo at smilo@aace.com or 904-353-7878 with any questions.

Sincerely,

Steven M. Petak, MD, JD, FACE, FCLM,
President

Submitter : **thomas clark** **Date: 10/10/2006**

Organization : **acp**

Category : **Physician**

Issue Areas/Comments

Background

Background

The proposed changes will severly limit access for treatment in a population reaching the period when most of the complications of non treatment reach the most.

GENERAL

GENERAL

The cost of technology and trained personel required for effective treatment continues to increase.The other costs to maintain a practice for the elderly rises each year.In our field of phlebology,timely ,effective outpatient treatment saves thousands of dollars,not only on very costly hospitalization,but cost of expensive wound care and other expences of limb threatening risks.

Submitter : **Mr. Eduardo Bhatia** **Date: 10/10/2006**

Organization : **Puerto Rico Federal Affairs Administration (PRFAA)**

Category : **State Government**

Issue Areas/Comments

Background

Background

CMS 1321 P: Geographical Practice Cost Indexes (GPCI); Practice Expense Components, Work Components, Work Floor

GENERAL

GENERAL

See Attachment in Word format entitled 'PRFAA comments to CMS on GPCI 10oct06'

Submitter : **kenneth wilhelm** **Date: 10/10/2006**

Organization : **kenneth wilhelm**

Category : **Physician**

Issue Areas/Comments

Background

Background

Making these revisions as proposed will negatively impact Medicare population's access to highest quality care. These treatments at lower reimbursement rates will limit the access to physicians who perform these procedures.

GENERAL

GENERAL

I am responding to the CMS proposal of 8/8/06 regarding changes in the physician fee schedule for CPTcodes 36478 and 36479.

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

   Practice expenses consistently rise,(rent,utilities,salaries for staff,etc) it is exceedingly difficut to provide services at lower rate of reimbursement. Given the limited number ot procedures that the average physcian can perform in a safe and effective manner per year guidelines will not be able to be met if RVU's continue to fall.

2. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher than those for laser ablation:
   d. 2006: 51.5
   e. 2007: 47.77
   f. 2008: 47.52

Each of these methods are comparable especially if initial capital acquistion cost ($45,000 for laser and $25,000 for RF) and the only difference is supply costs per procedure is the cost of the RF catheter then the cost to the physician is probably higher for the laser ablation than the radiofrequency procedure.I would request that the fully implemented, non-facility practice expense RVU for 36478 and 36475 be at the same level of 51.5.
Respectfully submitted,

Kenneth G Wilhelm M.D.
5333 McAuley Dr R-5017
Ypsilanti, Mi 48197

Impact

Impact

See comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See comment below.

Submitter : Dr. Jodi Schoenhaus **Date:** 10/10/2006

Organization : Cosmetic Foot, Ankle & Leg Vein Center

Category : Physician

Issue Areas/Comments

Background

Background

By implementing the changes proposed, physicians who accept Medicare assignment and Medicare's covering population, prospectively, will be limited in their ability to provide and recieve care for the treatment of superficial venous insufficiency.

GENERAL

GENERAL

After reviewing the proposed changes for 2007, there are several issues of concern.

1. As the background information attests, superficial venous insufficiency is being treated by new and current modalities in an office setting. The procedures have decrease the post op morbidity and long term recurrence rate. This in itself has saved Medicare a considerable amount of money as the procedure is not being performcd in a hospital, no anesthetia is needed, and complication treatment rates and hospital stays are relatively nonexistent.

2. While the overall Medicare fee schedule will decrease 5.1%, additional cuts in the RVU's for codes 36478 and 36479 will make it extremely difficult to continue to provide these treatments to Medicare's beneficiaries.
The rising cost of equipment (laser $38,000 and ultrasound $35,000), surgical pack of disposables and supply costs (over $400) and employment salaries which must be performed by registered technicians ($70,000 /year plus benefits) will drive the cost of the treatment provided to rates with extremely high operating expenses and inadequate reimbursement.

3. Radiofrequency ablation produces a similar result for superficial venous insufficiency. Although the supply costs for RF are higher on a case by case basis, the start up cost and initial supply cost for laser is significantly higher.

I emplore you to implement that the non facility practice expense RVU for 36478 be comperable to the RVU for radiofrequency ablation 36475 at 51.5.

Impact

Impact

Medicare revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B

Specific focus: CPT 36478 and CPT 36479

Date: August 8, 2006

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Surgical ligation and stripping was the standard treatment for superficial venous insufficiency. Until recent years, medical quality assurance has been enhanced with the development of endovenous laser ablation and radiofrequency. These procedures are now being performed independently in an office setting. The long term outcomes are more reliable and the risk is much lower.

Submitter : **Date: 10/10/2006**

Organization : **American Academy of PM&R**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-847-Attach-1.DOC

#847

American Academy of Physical Medicine and Rehabilitation

aaPM&R

330 North Wabash Avenue, Suite 2500 phone 312/464.9700
Chicago, Illinois 60611-7617 fax 312/464.0227
www.aapmr.org info@aapmr.org

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October 10, 2006

Leslie Norwalk, Esq.
Acting Administrator
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: Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; CMS-1321-P

Dear Ms. Norwalk:

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) appreciates this opportunity to submit comments on the *Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007*, as published in the August 22, 2006 *Federal Register*.

AAPM&R is the national medical specialty society of more than 7,000 board certified physical medicine and rehabilitation physicians, also called physiatrists. Approximately 90% of all physiatrists practicing in the United States are members of AAPM&R. Physical medicine and rehabilitation (PM&R), recognized as a board-certified medical specialty in 1947, focuses on restoring function to people with problems ranging from simple physical mobility issues to those with complex cognitive involvement. Physiatrists also treat patients with acute and chronic pain and musculoskeletal disorders, neurological disorders and those in need of prostheses, orthoses and mobility devices.

Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

1. Reassignment of Professional Interpretations

In the August 22 *Federal Register*, CMS is proposing changes to the exceptions to reassignment rules to address certain abusive situations involving "pod laboratories" which would have the effect of applying the current rules on purchased interpretations, as set forth in Ch. 1, Section 3.2.9.1 of the Medicare Claims Processing Manual, to reassignments permitted under the exception for independent contractors.

This change would impose conditions on reassignment even more restrictive than those in place prior to the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA). Before the enactment of section 952 of the MMA, the rules related to purchased interpretations only applied if the interpretation was applied off the premises of the billing entity. CMS is now considering imposing those requirements even if the interpretation is provided on the premises. Further, the proposed policy would undermine the intent of the MMA which was to broaden the types of arrangements in which reassignment was permitted.

AAPM&R contends this proposal is excessive in its endeavor to address abuses associated with pod laboratories by also prohibiting various legitimate arrangements which do not present risk of abuse. It is a common and well-established practice for physicians to enter into independent contract arrangements with physician group practices to provide part-time services at the offices of those physician groups. Such arrangements not only provide both parties with financial flexibility but more importantly afford patients with access to specialty care, especially in rural or other under-served areas.

Physiatrists, physicians specializing in physical medicine and rehabilitation, frequently provide services on a contract basis to orthopedic and other physician practices. Under such arrangements, the physiatrist sees patients in the offices of the orthopedic practice on a part-time basis (e.g. a half a day a week) during which the physiatrist may perform consultations or see new or established patients and may also order and/or perform electrodiagnostic tests. The physiatrist reassigns his billing rights to the orthopedic practice as permitted under the independent contractor exception to the reassignment rules and is typically compensated on an hourly rate or percentage of collections basis. (Because these services are provided on the premises of the billing entity, reassignment was permitted even before passage of section 952 of the MMA.)

Electrodiagnosis, consisting typically of nerve conduction studies (NCSs) and electromyography (EMG), provides medical data on the function of nerves and muscles to assist in the diagnosis and treatment of neurological and musculoskeletal conditions. Physiatrists and neurologists primarily perform these complicated procedures, often as an extension of the physical examination.

Although the professional and technical components can, in theory, be performed by separate individuals and thus billed separately under the Medicare fee schedule, from a clinical standpoint we believe it is more appropriate for the physician to do both the technical portion and the interpretation. We note that Medicare requires that the test be performed by a physician or by a physical therapist certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist (if state law permits the therapist to perform such tests). There are relatively few physical therapists with the required certification. For example, in 2004, less than one half of one percent of the most common EMG service (Code 95860) was billed by physical therapists. This means that in the overwhelming majority of cases, the technical component (TC) and the professional component (PC) are performed by the physician.

If CMS were to adopt the policies under consideration, the physiatrist, in the above situation, would be unable to furnish medically necessary diagnostic services such as EMGs in an orthopedic practice because the physiatrist could not reassign the professional interpretation.

AAPM&R believes this prohibition would have a negative effect on patient care, without any corresponding benefit in terms of protecting the Medicare program. Part-time independent contractor arrangements between physiatrists and physician groups increase beneficiary access to physiatric services. Further, when those services are provided at a single site, coordination of care between the physiatrist and other physician specialists, such as orthopedists, is improved and in turn, can result in better patient outcomes. The coordination of care at a single site also provides the Medicare patient with the convenience of seeing the physiatrist and other physician specialist without having to travel to multiple locations.

If CMS were to implement its proposal these types of arrangements would be prohibited because it would be impossible to meet any of the conditions applicable to purchased interpretations. Thus, the physiatrist would be unable to perform the interpretation of the test he or she orders for a patient under his or her care.

The implications of the proposed policy extend far beyond just physical medicine and rehabilitation. The proposal would also prohibit a part-time independent contractor pulmonologist from interpreting a pulmonary function test he or she orders for a patient; an independent contractor cardiologist seeking a diagnosis for a cardiac patient could not interpret an echocardiogram or stress test; and a neurologist could not interpret a motor nerve conduction test even when all of these services are provided in the context of diagnosing and treating the patient. AAPM&R does not believe CMS intended to disrupt these legitimate arrangements which are well-established throughout the healthcare industry and which often improve efficiency and beneficiary access and to care. In this spirit, AAPM&R urges CMS not to impose these additional requirements with respect to reassignment of professional interpretations.

2. Extension of Anti Mark-Up Rules to Physician Interpretations

Also in the proposed regulation, CMS is considering to extend to purchased interpretations the anti mark-up rule applicable to technical components of diagnostic tests. This would mean that the bill to Medicare would not be permitted to exceed the amount the billing entity paid the contracted physician who performed the interpretation. AAPM&R believes, again, that this too would undermine a number of legitimate relationships such as those described above in which the interpretation is performed on the premises of the billing entity which incurs the overhead associated with the service. Further, the service is generally an integral part of patient diagnosis and treatment performed by the independent contractor physician. If the anti mark-up rule is extended to professional component services, the billing entity that provides all of the overhead associated with the interpretation (e.g. office space, transcriptionist services, patient scheduling, and billing) could not be compensated for these expenses.

#848 - 1

COMMONWEALTH OF PUERTO RICO
PUERTO RICO FEDERAL AFFAIRS ADMINISTRATION

Aníbal Acevedo-Vilá
Governor
Eduardo Bhatia
Executive Director

October, 6th, 2006

File Code **CMS—1321—P**
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: HHS, CMS - 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 - Federal Register Vol. 71, No. 162, August 22, 2006

CMS—1321—P: Geographical Practice Cost Indexes (GPCI); Practice Expense Components, Work Components, Work Floor

I would like to take this opportunity to write to you regarding the Geographical Practice Cost Indexes (GPCI) proposed for the Commonwealth of Puerto Rico by the Centers For Medicaid Services (CMS), as published in the August 22, 2005 Federal Register. Specifically I write to urge that you reconsider the Work and Practice Expense components of the GPCI as well as, the prudence of maintaining the Work Floor. In each case, we believe the GPCI should be revised to reflect operational cost increases particular to Puerto Rico.

In this effort, HHS and CMS should account for the individual characteristics of our Commonwealth as well as those of the any State's particular care marketplace. We counsel such action as the best means of ensuring that any final rule builds upon the successes which Puerto Rico and the States have had in expanding access and controlling the cost of care without undermining the fundamental incentives of our care market. In doing so, we believe HHS and CMS can achieve an outcome which does not weaken existing incentives for individual care providers to continue to render needed services for our Commonwealth and its citizens.

To our view, the following four (4) characteristics of the island care market merit additional consideration:

1. **Nurse Wage Cost:** Law Number 27, enacted on July 20, 2005, regulates nurse salaries in both the public and private sectors, excepting locations that only employ one nurse. The law has a three year phase-in period, commencing in October 2006. Prior to the mandated wage increases, the median nurse salary in Puerto Rico was approximately half of that in the U.S. After adjusting for the mandated increases, the

wage index increases from .500 to .593. The vast majority of nurses in Puerto Rico qualify for the mandated increase, because of educational and work experience. The employee wage index represents 39.1% of the Practice cost GPCI, therefore the Practice cost GPCI should increase by .036. The current Practice cost index for Puerto Rico is .699, and with the proposed adjustment, it should increase to .735.

In addition, Puerto Rico is one of the geographic areas that would be directly affected by the **proposed elimination of the work floor** of 1.000. The proposed work GAF for Puerto Rico in CY 2006 is 0.0905 and for CY 2007 is 0.883. Upon adjustment for the median wage for nurses following the legislatively mandated raises, the component should reflect an increase to 0.924 for both years, when adjusting for the increase in the median hourly wages for nurses and recalculating weights.

2. **Water Costs:** The costs for both basic utilities in Puerto Rico, water and electricity, have risen dramatically over the last several years. The Puerto Rico Water Authority, faced with crippling deficits, raised its rates anywhere from 166% percent to 387%. As an example, the base residential charge increased from $8 to $32, or a 300 percent increase, effective July 1, 2006. Given that the increases are of recent implementation, the rent index used for purposes of the Practice Expense GPCI calculation does not reflect this increase. The 2005 reported rent index for Puerto Rico is 0.631, or an 8.3% reduction from the previous reported index of 0.688. No index is reported in the draft regulation for 2006. Based on Census data, water costs represent 5% of gross rent, prior to the rate increase. Rent index represents 27.6% of the Practice Expense GPCI; therefore, the GPCI should be adjusted to reflect the increase. The corresponding increase would be 0.026 (rent index * [1 + (rent index)(% gross rent affected)(% cost increase).

3. **Electricity Costs:** The costs for both basic utilities in Puerto Rico, water and electricity, have risen dramatically over the last several years. Electricity rates in Puerto Rico are significantly higher than the rates in the U.S. In 2003, the average kilowatt hour in Puerto Rico cost 12.61 cents, while the same kilowatt hour in the U.S. cost 7.42 cents. In 2005, the increase in the power rates for Puerto Rico was 24% while in the US that same increase averaged out to 12%. Therefore, the corresponding GPCI for Puerto Rico should reflect that differential in rates. Using 2000 US Census data, electricity costs account for 10.6% of the median gross rent paid for a two bedroom apartment. Applying the 12% increase to 10.6% of the rent index yields an increase of 0.008. Given that 27.6% of the Practice Expense GPCI is comprised by the rent index, the corresponding increase in the component due to electricity rate cost differentials would be 0.002.

4. **Transportation Costs:** Transportation costs in Puerto Rico are estimated to be approximately 15% higher than in the Continental U.S as reported by Waltham in "Updating the Geographic Practice Cost Index: The Practice Expense GPCI. Final Report and Appendices to Final Report", Health Economics Research, Inc. Therefore, we recommend that there be an adjustment to the portion of the Practice Expense GPCI in the amount of 0.002, to account for transportation costs. Approximately 4.4% of the total import costs are because of transportation costs. The equipment and supplies cost accounts for 33.3% of the Practice Expense Index. The transportation cost portion corresponds to 1.5% of the total cost ((.333*.044)*100). Increasing this portion by the 15% add-on for increased

transportation costs to Puerto Rico yields a 1.7% share ((0.015*1.15)*100). Hence, the adjustment increased transportation costs would be 0.002 (0.017-0.015).

For the above stated reasons, in the case of Puerto Rico, the Commonwealth asks the Department and CMS to reevaluate the Practice Expense and Work components of the GPCI as well as the prudence of maintaining the work floor. Where the Practice Expense is concerned the cumulative suggested adjustments result in a component of .763 up from .699. For the Work GPCI, suggested adjustments put the necessary change on the order of .018 up from .906 to .924.

In recent years, States and the Commonwealth have succeeded in our efforts to provide competitive and worthwhile health care precisely because of our ability to be creative, flexible and responsive to our local conditions—our population and our health care market place. The Commonwealth is concerned that without adequately accounting for the above listed factors which, by their nature are market specific to Puerto Rico, the proposed rule and subsequent action shall undermine our continuing efforts to improve the quality and accessibility of care in Puerto Rico.

On behalf of the Commonwealth, I urge the Department and CMS to reconsider the GPCI in light of those factors particular to Puerto Rico.

Sincerely,

Eduardo Bhatia, Esq.

#848-2

COMMONWEALTH OF PUERTO RICO
PUERTO RICO FEDERAL AFFAIRS ADMINISTRATION

Aníbal Acevedo-Vilá
Governor
Eduardo Bhatia
Executive Director

October, 6th, 2006

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Department of Health and Human Services
Attention: CMS-1321-P, Mail Stop C4-26-05
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In this effort, HHS and CMS should account for the individual characteristics of our Commonwealth as well as those of the any State's particular care marketplace. We counsel such action as the best means of ensuring that any final rule builds upon the successes which Puerto Rico and the States have had in expanding access and controlling the cost of care without undermining the fundamental incentives of our care market. In doing so, we believe HHS and CMS can achieve an outcome which does not weaken existing incentives for individual care providers to continue to render needed services for our Commonwealth and its citizens.

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On behalf of the Commonwealth, I urge the Department and CMS to reconsider the GPCI in light of those factors particular to Puerto Rico.

Sincerely,

Eduardo Bhatia, Esq.

Submitter : Dr. M. Nasar Qureshi **Date:** 10/10/2006

Organization : QDxPathology Services, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-1321-P-849-Attach-1.DOC

CMS-1321-P-849-Attach-2.DOC

#849-1

Comments:

CMS-1321-P

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

CMS has proposed that:

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  ~~o~~ We support this proposal. It should not be possible to bypass the purchased diagnostic/anti-markup rules using the liberalized reassignment rules.

In addition CMS is considering that:

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- **The physician or group billing for the interpretation also performed the technical component of the test.**

The interpretation of the first paragraph is not clear to me. Possible interpretations include:

- That "financially independent of the group performing the test" means the group i.e. clinical practice billing for the test. If that is true and the CMS were to adopt the above changes under consideration, contractual arrangements between practices and pathology groups would no longer comply with the assignment rules, because the physician who orders the test is part of the group that bills for the test and the interpretation. This rule will then essentially prohibit the practice of billing for internalized practices by clinical groups. In as far as that is the intent than institution of above rules are called for. **If the intent is to prevent abuse** then such a measure may not be called for.

- The second and more probable interpretation is that the technical services (processing) are performed by a group that is financially independent of the

ordering physician. Likewise it states that the pathologist/group contracted to provide the professional component, i.e. interpretation, has no financial interest in the group. This is an ideal non-abusive situation in as far as the contracting pathologist/group is paid a fair market value negotiated at an arms length for the services provided, and the reimbursement is not bundled in some kind of a flat fees which has the potential of unduly benefiting either the interpreting group or the practice.

- This last proposal regarding technical component, on the face of it, appears appropriate. However, when the current practice of histology is considered it may not be the most appropriate action for the following reasons;
    - It is well established that we have a shortage of histotechnologists. Either as an internal service at the site of practice or as a "pod lab" the cost involved and the lack of adequately trained staff will inevitable lead to cutting corners by the group which may or may not be abusive to Medicare system but is guaranteed to compromise the quality of the slide preparation and therefore the service to the patient. This indirectly is abusive of the system. Rather than making it compulsory to perform the technical component if billing the (performed in-house) interpretation, it may be prudent to allow technical component to be performed by well established laboratories which have all the required supervision and credentialing by the appropriate national and local agencies. In fact if the practice decides to perform histological processing it should be mandatory that their work is mandated by all the national and local credentialing agencies and rules at a minimum. It is obvious that when the practices internalize processing they will not internalize all the facets such as special procedures, Immunostains and esoteric testing. All or some of these may be necessary for an adequate interpretation of a sample. The specimen will then be unduly split in various laboratories, with all the consequences in terms of delay, mistakes in identification and reporting of the specimens etc.

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    - Any full service pathology practice assumes the following charges as over head when providing pathology services traditionally;
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      These costs are now taken over by the billing clinical practice on whose site the services are being provided.
      Medicare's current fee schedule and the rules to determine them incorporate all the above costs. It is fair to allow the billing practice to recoup these costs, especially if intending to bring pathology in-house to increase quality of patient care, and not simply to make money at the expense of a pathologist. Then the clinical practice should be allowed/mandated to pay ~60% of the Medicare fee schedule to the pathologist/group and be able to keep remaining ~40% of the Medicare schedule to recoup their cost.
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Thank you for considering these comments and for the timely effort CMS has undertaken to address these issues. Please feel free to contact me if needed.

Submitted by:

M. Nasar Qureshi, MD, PhD
President,
QDx Pathology Services, Inc,
11 Ellington Place,
Englewood Cliffs, NJ 07632

Ph: (201) 951 7233
Email: EMESProfessional@aol.com

#849-2

Comments:

CMS-1321-P

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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Thank you for considering these comments and for the timely effort CMS has undertaken to address these issues. Please feel free to contact me if needed.

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11 Ellington Place,
Englewood Cliffs, NJ 07632

Ph: (201) 951 7233
Email: EMESProfessional@aol.com

Submitter : Mr. Terry Wicks **Date:** 10/10/2006

Organization : American Assoc. of Nurse Anesthetists

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

See Attachment.

GENERAL

GENERAL

See attachment.

Impact

Impact

See Attachment

CMS-1321-P-850-Attach-1.PDF

850

Advancing the Art & Science of Anesthesia for 75 Years

AANA 1931-2006

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Ave., SW
Washington, DC 20201

ATTN: CMS-1321-P

Re: Comments on Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, Proposed Rule (71 Fed. Reg. 48982, August 22, 2006).

- **IMPACT - V. Regulatory Impact Analysis**
- **Criteria for National Certifying Bodies – Advanced Practice Nurses**

Dear Sir/Madam:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule for the Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B. *(71 Fed. Reg. 48982, Aug. 22, 2006)* The AANA is submitting comments for Section V. Regulatory Impact Analysis. We are particularly concerned with the combined impact of the proposed -5.1 percent Physician Fee Schedule (PFS) cut with Centers for Medicare & Medicaid Services' (CMS') proposed 10 percent cut in work values for all practitioner services on nurse anesthesia practice and Medicare beneficiaries' access to anesthesia services. We have also included comments on the AANA's willingness to work with CMS on its list of recognized and approved national certifying bodies for the certification of advanced practice registered nurses, knowing that CMS already recognizes the certifying bodies relevant to Certified Registered Nurse Anesthetists.

American Association of Nurse Anesthetists Office of Federal Government Affairs
412 First St., SE, Suite 12, Washington DC 20003 // 202-484-8400 // fax 202-484-8408 // www.aana.com

The AANA is the professional association for more than 36,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States.

CRNAs are advanced practice nurses who administer about 27 million anesthetics given to patients each year in the United States, according to the 2005 AANA Member Survey. Nurse anesthetists have provided anesthesia in the U.S. for over 150 years, and high quality, cost effective CRNA services continue to be in high demand. CRNA services include administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide assessment and evaluation for acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Forces. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists, and all varieties of specialty surgeons.

IMPACT

Need to Reform Current SGR Formula

We echo the comments we have made previously to CMS and those comments by medical and other professional societies in regards to establishing a better methodology for calculating the SGR. We understand that the intent of the Balanced Budget Act (BBA) in replacing the Medicare Volume Performance Standard (MVPS) calculation with the SGR methodology was to curb Medicare expenditures. We also understand that Section 1848(f)(2) of the Act specifies the formula for establishing yearly SGR targets for physicians' services under Medicare and that it is up to Congress whether to change the SGR formula.

CMS has noted that two of the most volatile factors used to calculate the SGR are the number of fee-for-service enrollments and gross domestic product (GDP). Linking Medicare

expenditures to GDP growth burdens both the healthcare community and Medicare patients for any economic slowdown.

Further, the SGR as it is calculated does not use the most current figures related to the rising costs of drugs and new technology, the increases in malpractice premiums, and the growth in Medicare utilization over projected amounts. Therefore, the SGR calculated minus 5.1 percent estimate for the 2007 physician fee schedule update does not accurately account for these actual increases in health care provider costs for quality services.

SGR Cuts + RVU Cuts =
Drastic, Unprecedented and Unjustified Cuts for Anesthesia Services

The SGR driven –5.1 percent cut is not the only cut anesthesia providers would face. Piled on top of the SGR cut is CMS' proposed 10 percent budget neutrality adjustor cut for Relative Value Unit (RVU) work values. This means that beginning in 2007, anesthesia providers would face a whopping 13 percent cut in payment for their already undervalued services. Additionally, these slated cuts for anesthesia services are not congruent with CMS' call for healthcare providers to participate in Pay for Performance programs, nor with its goal of rewarding healthcare providers for taking the initiative to improve quality and patient safety. The Institute of Medicine found in its 2000 report *To Err is Human* that anesthesia is 50 times safer than 20 years previous.[1] In effect, with CRNAs providing approximately 27 million anesthetics each year, these cuts to anesthesia payment completely discount CRNAs long-standing initiative in improving quality and patient safety in the field of anesthesia.

The scale of these cumulative anesthesia reimbursement cuts compels us to underscore our previous comments to the agency on this subject. As we stated in our comment to CMS dated August 21, 2006 on its July 29, 2006, proposed notice we are very concerned with the impact applying budget neutrality on such a large scale to pay for increased values for some evaluation and management (E/M) services will have on nurse anesthesia practice and Medicare beneficiaries' access to anesthesia services. *(71 FR 37170, 07/29/06 - Medicare*

[1] Kohn L, Corrigan J, Donaldson M, ed. To Err is Human. Institute of Medicine, *National Academy Press*, Washington DC, 2000.

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

We understand the importance of valuing healthcare services accurately. Accurate values allow providers to continue to provide Medicare beneficiaries with access to a wide range of necessary services. However, the CMS' imposition of such a drastic, unprecedented and unjustified budget neutrality adjustor to pay for increasing the work value of some services over others would have exactly the opposite effect, and threatens wide-ranging and poorly understood negative impacts on patients' access to healthcare services.

With these work value cuts alone, Medicare payment for an average anesthesia service would lie far below its level in 1992, adjusting for inflation.[2] [3] At no other time has there been such a drastic cut in work values. In addition, CMS proposes to make these cuts without due consideration of the fact that Medicare already undervalues anesthesia services at 37 percent of market rates, while most physician services are reimbursed at about 80 percent of the market level.

CMS' proposed cut would cause an unprecedented shift in payment from certain groups of providers to other providers. Such a momentous shift calls for a thorough understanding of the effects this would have on Medicare beneficiaries' access to *all* healthcare services. A comprehensive assessment of this impact on patient access remains absent from CMS' equations.

CRNA Continued Contribution to Pay for Performance Initiatives

We are also acutely aware that CMS and Congress are rapidly moving forward with plans to promote provider-level quality performance measures and institute a Pay for Performance payment system. We understand that under Pay for Performance proposals Medicare Part B providers would be paid according to the quality and efficiency of the services they provide.

[2] An average anesthesia service is 12 units, times the mean Medicare anesthesia conversion factor for that year. The mean anesthesia CF in 1992 was $15.75; in 2006, $17.76; and for 2007 it would be $15.68.
[3] CMS Medicare Carrier Manual Transmittal 1766, Aug 29 2002, http://www.cms.hhs.gov/transmittals/downloads/R1766B3.pdf#search=%221992%20anesthesia%20conversion%20factor%20cms%22.

We appreciate Congress' and CMS' efforts to seek the expertise of all professional provider associations in developing quality measures for each specialty. To date, our work on this initiative has been multifaceted. In the policy arena, we have worked with members and committees of Congress to review and promote Pay-for-Performance provisions that place CRNAs and other healthcare providers who are not physicians on an equal footing with one another, and communicated our work and interest in the subject with senior CMS staff. In 2006, we hosted CMS' Dr. Thomas Valuck at a major AANA federal policy conference in Washington, DC, to discuss pay-for-performance systems. In related clinical and policy development venues, the AANA has played a partnership role with the Centers for Disease Control & Prevention's (CDC's) Surgical Care Improvement Project (SCIP) in the development and vetting of performance measures. AANA continues to play an active role in the National Quality Forum (NQF), where it was the first major national anesthesia professional organization to serve as a member. At the suggestion of CMS staff, the AANA has been an active participant in the deliberations and decisions made by the AMA Physician Consortium on Performance Improvement (AMA-PCPI) Perioperative Work Group and more recently with its Anesthesia Work Group. Thus, CRNAs and the nurse anesthesia profession continue to play a leadership role in shaping legislation and in developing performance measures specific to anesthesia services. The 36,000 members of the AANA look forward to continued opportunities to extend to CMS our profession's longstanding commitment to improving anesthesia patient safety.

Addendum C – Codes for Which We Received PERC Recommendations on PE Direct Cost Inputs

- **AMA-RUC, PERC Process Should Be Transparent, Represent All Specialties**

Addendum C in the proposed rule lists approximately 270 anesthesia codes that have received AMA Relative Value Update Committee (AMA-RUC) Practice Expense Review Committee (PERC) recommendations for changes on these codes' practice expense (PE) direct cost inputs. *(71 Fed. Reg. 48982, 49236-49237)* Separately, the American Society of Anesthesiologists (ASA) has stated, "In the proposed rule, CMS accepted an ASA-led recommendation from the Practice Expense Review Committee (PERC) to assign eight minutes to each existing anesthesia code for the scheduling and assignment of anesthesia

cases. ASA estimates this change to be worth approximately $30 million for anesthesiologists each year. ASA representatives to the AMA/Specialty Society RVS Update Committee (RUC) successfully presented the proposal to the PERC earlier this year."[4] To the extent that such changes equivalently and favorably impact anesthesiologists and nurse anesthetists' reimbursement, we would concur.

Unfortunately, neither the proposed rule nor the suggested internet links listed in the proposed rule clearly explain what if any value changes are being made to these codes, why recommendations were made by the PERC for these codes, what is the extent of these changes, and what the process was for determining recommended changes. For example, the "Practice Expense Per Hour" chart does not specify the methodology by which CMS has developed this data. The "Physician Time" chart describing mean times for services billed to certain CPT codes likewise is absent a methodology. In effect, this portion of the proposed rule preamble does not provide CMS' customary level of transparency to the public that the agency generally provides on other topics included in its proposed rules, notices and final rules. All Part B providers including CRNAs should be able to readily discern from CMS' statements in the *Federal Register*, or from CMS' clearly indicated internet links where applicable, the rationale and process behind any code changes proposed by CMS that would affect practitioners' payment and practice. Without this crucial information the AANA cannot fully, fairly and dispassionately comment on the Addendum C recommendations of the PERC. We therefore request that CMS clarify the rationale, process and impact on anesthesia services referenced in Addendum C. We would welcome the opportunity to comment on the Addendum C PERC recommendations at a later date.

Much of the transparency problem for CRNAs in the area of Medicare payment stems from the fact that the vast majority of the payment changes CMS makes are based on recommendations from the American Medical Association Specialty Society Relative Value Update Committee (AMA-RUC) – a committee in which CRNAs are excluded from directly participating. AMA-RUC is charged by CMS with representing all healthcare specialties in

[4] CMS proposed rule for 2007 Physician Fee Schedule slashes payments to physicians," ASA website, http://www.asahq.org/news/asanews81006.htm, Sept. 5, 2006, uploaded Oct. 4, 2006.

making recommendations to CMS on Relative Value Units (RVUs) for new and revised CPT codes. While CRNAs continue to be directly involved in providing some 27 million anesthesia services in the United States annually and can bill Medicare directly for 100 percent of the value of their services, CRNAs are excluded from directly participating in AMA-RUC activities and initiatives based on the fact that CRNAs are not physicians. Changes in these codes and their values directly impact CRNA practice and payment. Without fair representation by all specialties that bill Part B directly, CMS' reliance on the AMA-RUC as representing the professional views and knowledge of all healthcare specialties is deeply flawed. The AMA-RUC and CMS are missing out on the long-standing knowledge and experience in anesthesia and in related healthcare services that CRNAs could bring to the AMA-RUC table. For CMS to conclude that CRNA viewpoints are fairly represented by coming under the "umbrella" of representation of the American Society of Anesthesiologists (ASA) or the American Nurses Association (ANA) is inadequate. The AMA-RUC is not representative of all specialties because its system of governance excludes providers such as CRNAs who have an equal stake in the success of the healthcare system.

In its March 2006 Report to Congress and its August 17, 2006, comment letter to CMS, the Medicare Payment Advisory Commission (MedPAC) raised similar concerns about CMS' relatively unchecked reliance on the AMA-RUC. In its comment letter, MedPAC stated that "CMS itself must take a more central role in identifying potentially misvalued services...We recommended that CMS reduce its reliance on physician specialty societies by establishing a standing panel that would provide expertise in addition to that provided by the RUC."

Should CMS decided to establish a standing panel as recommended by MedPAC we request that CRNAs have an opportunity to be active participants and members of this standing panel. In addition, we also request that CMS encourage and persuade the AMA-RUC to provide CRNAs with an opportunity to have meaningful and direct representation on the AMA-RUC and related committees such as the Health Care Professionals Advisory Committee (HCPAC) and on the PERC.

CRITERIA FOR NATIONAL CERTIFYING BODIES - ADVANCED PRACTICE NURSES

According to the proposed rule, CMS is soliciting public comments on criteria or standards that CMS could use to determine whether an organization is an appropriate national certifying body for advanced practice nurses. The proposed rule points to the federal regulations and Medicare Benefit Policy Manual Chapter 15 entries with respect to nurse practitioners (NPs) and clinical nurse specialists (CNSs). We welcome the opportunity to inform and update CMS about the Council on Certification of Nurse Anesthetists (CCNA) and the Council on Recertification of Nurse Anesthetists (COR), so that these bodies continue to be listed in all the relevant CMS references as recognized and approved national certifying bodies for the certification and recertification of CRNAs as they and their predecessors have been since the inception of the Medicare program.

Currently, CMS regulations recognize the CCNA and COR when defining CRNAs. 42 CFR §410.69 states (with underline added by us):

> *Certified registered nurse anesthetist* means a registered nurse who:
> (1) Is licensed as a registered professional nurse by the State in which the nurse practices;
>
> (2) Meets any licensure requirements the State imposes with respect to non-physician anesthetists;
>
> (3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and
>
> (4) Meets the following criteria:
>
> > (i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or
> >
> > (ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

Additionally, according to the Medicare Claims Processing Manual, CMS already relies on the CCNA when it provides to all Medicare carriers on an annual basis a list of all CRNAs who are certified by the CCNA.[5]

Council on Certification of Nurse Anesthetists (CCNA)

The Council on Certification of Nurse Anesthetists (CCNA) is charged with protecting and serving the public by assuring that individuals who are credentialed have met predetermined qualifications or standards for providing nurse anesthesia services. The CCNA is an autonomous, multidisciplinary body and is responsible for the certification of registered nurse anesthetists who have fulfilled educational and other criteria for the practice of nurse anesthesia.

The primary purposes of the CCNA are to:

1. Formulate and adopt requirements for eligibility for admission to the Certification Examination and for certification of registered nurse anesthetists;

2. Formulate, adopt and administer the Certification Examination to those registered nurse anesthetists who have met all requirements for examination and have been found eligible by the CCNA;

3. Evaluate candidates' performance on the Certification Examination; and

4. Grant initial certification to those candidates who pass the Certification Examination and fulfill all other requirements for certification.

Credentialing provides assurances to the public that certified individuals have met objective, predetermined qualifications for providing nurse anesthesia services. While state licensure provides the legal credential for the practice of professional nursing, private voluntary

[5] Medicare Claims Processing Manual, Chapter 12 – Physicians/Nonphysician Practitioners. (Rev. 792, 12-23-05) 140.1.1 Issuance of UPINs, (Rev. 704, Issued: 10-07-0, Effective: 11-07-05, Implementation: 11-07-05)

certification indicates compliance with the professional standards for practice in this clinical nursing specialty. The certification credential for nurse anesthetists has been institutionalized in many position descriptions as a practice requirement or as the standard for demonstrating equivalency. It has been recognized through malpractice litigation, selected State Nurse Practice Acts, and state rules and regulations.

The certification program for nurse anesthetists was introduced by the AANA in 1945. In 1975, the AANA approved the establishment of autonomous Councils for the accreditation and certification processes and the CCNA assumed the responsibility for the Certification Examination. By this action, the profession recognized that credentialing mechanisms, which include examination and certification, function to protect and benefit the public. It is accepted that the profession, with broad input from the community of interest, has the expertise to set standards.

CCNA membership consists of eleven representatives appointed by the CCNA: seven CRNAs (three practitioners and four educators), two anesthesiologists, one public member, and one student currently enrolled in an accredited nurse anesthesia educational program.

Council on Recertification

The Council on Recertification is an autonomous body, with multidisciplinary and public representation, that is responsible for the recertification of CRNAs. The Council's purposes are to:

1. Recertify qualified CRNAs on a biennial basis;

2. Formulate, adopt and continuously evaluate the criteria for recertification of CRNAs;

3. Formulate, adopt and continuously evaluate the criteria for approval of continuing education (CE) activities;

4. Develop and maintain appellate mechanisms for CRNAs who have been denied recertification; and

in 1991, the ABNS is a national peer review program for specialty nursing certification bodies. ABNS serves as the national umbrella organization for nursing specialty certification boards authorized and recognized to certify nurse specialists in the United States. It promotes the highest quality of specialty nursing practice through the establishment of standards of professional specialty nursing certification

We thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

Terry C. Wicks, CRNA, MHS
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Senior Director of Federal Government Affairs

Submitter : **Dr. Dwight Reynolds** **Date: 10/10/2006**

Organization : **Heart Rhythm Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-851-Attach-1.DOC

#851

Heart Rhythm Society

October 10, 2006

Leslie Norwalk
Interim Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., SW
Washington, DC 20201

Dear Ms. Norwalk:

The Heart Rhythm Society (HRS) welcomes the opportunity to comment on proposed rule CMS 1321-P entitled Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B published in the August 22, 2006 *Federal Register*.

HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS is the preeminent professional group representing more than 3,700 specialists in cardiac pacing and electrophysiology, known as electrophysiologists or heart rhythm specialists. HRS' members perform electrophysiology (EP) studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who have indications for these life-saving devices. After device implantation, heart rhythm specialists then monitor these patients and their implanted devices.

Provisions – Cardiac Monitoring Services

HRS is encouraged that CMS has requested practice expense data for remote cardiac monitoring services as these services fall outside of the typical payment model used for physician services. Based on the proposed revisions to the practice expense methodology, payment for

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The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders.

Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards.

1400 K Street NW, Suite 500 | Washington, DC 20005 | USA | Phone: 202-464-3400 | Fax: 202-464-3401 | info@HRSonline.org | www.HRSonline.org

many cardiac monitoring services will experience severe reductions, and for some codes payment will fall to zero, by 2010. These reductions will occur because the codes have few or no practice expense inputs. HRS is very concerned about the potential negative impact on patient access to care if these reductions are implemented.

Therefore, HRS looks forward to working with CMS and the AMA to develop accurate inputs so that cardiac monitoring services are reimbursed appropriately. Currently, HRS and the American College of Cardiology (ACC) have a Cardiac Monitoring Task Force that is reviewing the current codes for cardiac monitoring services and is working to develop a revised coding structure that more accurately reflects current services and technology. The Task Force would welcome the opportunity to work with CMS and the AMA to provide PE input data related to number and type of transmissions, frequency of services, clinical staff, and supplies and equipment necessary for performing the services.

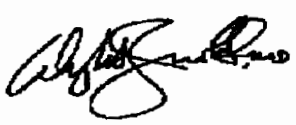
Finally, HRS would like to request that CMS add code 93236 for 24-hour electrocardiographic monitoring to the list of codes in immediate need of PE input data as it falls within the scope of cardiac monitoring services.

IDTF Issues

HRS supports implementation of the fourteen standards outlined in the proposed rule for independent diagnostic testing facilities (IDTFs). We agree that it is important for there to be quality assurance standards in IDTFs. However, HRS urges CMS to ensure that any standards will not negatively impact patients' access to medically necessary and appropriate care.

HRS appreciates the opportunity to provide input on Medicare payment policy and thanks CMS for your consideration of our comments. We look forward to continuing to work together to maintain access to medical services for Medicare beneficiaries. If you have any questions about HRS' comments, please contact Allison Waxler, Director, Reimbursement and Regulatory Affairs, at awaxler@hrsonline.org or 202.464.3433.

Sincerely,



Dwight Reynolds, MD, FHRS
President
Heart Rhythm Society

Submitter : **Ms. Donna Fiorentino** **Date: 10/10/2006**

Organization : **International Society of Clinical Densitometry**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

See Attachment

CMS-1321-P-852-Attach-1.PDF

CMS-1321-P-852-Attach-2.PDF

CMS-1321-P-852-Attach-3.PDF

CMS-1321-P-852-Attach-4.PDF

#852-1

ISCD
The International Society For Clinical Densitometry

342 North Main Street
West Hartford, CT 06117
Ph: 860.586.7563
Fax: 860.586.7550
www.ISCD.org

October 10, 2006

Mark McClellan MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1321-P Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule

Comments:

- **PROVISIONS:**
  - **BONE MASS MEASUREMENT TESTS**
  - **DRA PROPOSALS**
- **IMPACT:**
  - **Addendum B: Relative Value Units and Related Information Used in Determining Medicare Payments for 2007**
  - **Addendum C: Codes to Which We Received PERC Recommendations on PE Direct Cost**

Dear Dr. McClellan:

OVERVIEW

Osteoporosis is a major health care problem in the United States with annual costs of more than $18 billion dollars. Currently 300,000 Americans are hospitalized annually for hip fractures with one in five (20%) dying within the first year following fracture. Given population demographics, osteoporotic fractures are projected to increase for the foreseeable future emphasizing the importance of effective prevention and treatment strategies. To this end, the Centers for Medicare & Medicaid Services (CMS) is to be commended for establishing bone density testing as a key preventive service available for Medicare beneficiaries and highlighting the role of axial DXA (dual energy x-ray absorptiometry) in diagnosis and monitoring response to therapy. Despite this, bone density screening remains underutilized. **Efforts to increase screening rates for axial DXA above the current level of 20% require a different approach within the existing framework that values access over efficiency.** Importantly, it is necessary to appropriately value osteoporosis screening procedures such as axial DXA and VFA (Vertebral Fracture Assessment) which are increasingly being performed by primary care physicians in their offices. Unfortunately, if the currently proposed Medicare Physician Fee Schedule is enacted for axial DXA and/or Section 5102(b) of the Deficit Reduction Act takes effect on January 1, 2007, axial DXA testing will disappear from the non-facility setting as physicians' operating costs will be greater than reimbursement for the tests. **These regulatory and legislative actions will severely restrict patient access to bone density testing thereby undermining the effort by CMS to effectively screen Medicare beneficiaries for osteoporosis.**

These same regulatory and legislative actions will further curtail appropriate identification of individuals in need of fracture prevention efforts by reducing reimbursement for densitometric VFA. In addition to the

76% decline in reimbursement for axial DXA, VFA reimbursement will decline by 40%. As with axial DXA, the profound drop in reimbursement for VFA will lead to its disappearance from the non-facility setting, further impairing physicians' ability to optimally target osteoporosis care.

INTRODUCTION

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the recent CMS proposal **1321-P: Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule**. Specifically, we would like to address CPT codes 76075 (DXA bone density, axial) and 76077 (Vertebral Fracture Assessment or VFA). We have previously commented on CMS proposal 1512-PN: Five Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology as it relates to DXA and VFA. In this letter we will expand on the importance of successful promotion of high quality screening for key preventive services in the primary care setting. We will also comment on new provisions that will impact skeletal health assessment; specifically revisions to "Medicare Coverage of and Payment for Bone Mass Measurements" (63 FR 34320) and Section 5102(b) of the Deficit Reduction Act.

The ISCD is a multidisciplinary, non-profit organization with 6,365 members, 93% of whom practice in the United States. Approximately 60% of our members are physicians and 40% are densitometry technologists. The membership is diverse spanning over 20 disciplines including 43% in Primary Care (Internal Medicine, Family Practice, Gynecology, Pediatrics, Geriatrics) with the remainder in subspecialty Internal Medicine (Rheumatology, Endocrinology, Nephrology), Orthopedics, and Radiology.

The mission of the ISCD is to promote excellence in the assessment of skeletal health. We offer a four-hour introductory course in osteoporosis for those just beginning in the field, a twelve-hour intensive educational course in bone densitometry and a five-hour course in vertebral fracture assessment. These courses are given throughout the United States as well as internationally and use a standardized syllabus that is continuously updated by a scientific advisory committee. Faculty selection is highly competitive. Physicians who successfully pass a written certification exam are designated as Certified Clinical Densitometrists (CCD) while technologists are designated as Certified Densitometric Technologists (CDT). In the United States there are currently 7,058 physicians and 3,759 technologists with ISCD certification.

To further promote quality standards in osteoporosis assessment, the ISCD has developed, and is currently beta testing, a bone densitometry accreditation program that will ensure DXA centers meet specific criteria for the high quality performance and interpretation of bone densitometry according to accepted standards of practice in the United States. We anticipate that this will be available by the end of the 2006 calendar year.

Moreover, as the field of osteoporosis is rapidly evolving, questions often arise as to the appropriate indications and limitations of new and existing technologies, software enhancements, reference databases, and reporting methodologies. To address such issues and enhance standardization, the ISCD has held Position Development Conferences (PDCs) in 2001 (Denver), 2003 (Cincinnati) and 2005 (Vancouver). Preparations are underway for the 2007 PDC (Lansdowne, VA) and the first Children PDC (June 2007, Montreal, Canada). At these PDCs, select panels of international experts review and make recommendations after presentations by ISCD PDC task forces, public comment and internal discussion. PDC recommendations that are subsequently approved by the ISCD Board of Directors become Official Positions of the ISCD. These Official Positions promote uniformity in DXA and VFA performance, thereby enhancing patient care. A copy of the most recent Official Positions is amended to this report (Appendix A).

PROVISIONS: BONE MASS MEASUREMENT TEST

The ISCD is in agreement with the revisions made to the 1998 Balanced Budget Act 42 CFR 410.31 (Bone Mass Measurement: Conditions for Coverage and Frequency Standards). Specifically, we laud CMS for introducing the important concept of quality and standardization in axial DXA testing and reporting. *"As there are many sources of variability in the measurement of BMD, a quality control system related to both the methodology and reporting of test results is important to ensure the validity of DXA analysis."* Axial DXA is also cited for its superior accuracy and precision as it compares to older technologies. As such, the ISCD agrees with the CMS recommendation to restrict monitoring over time to axial DXA technology; *"DXA is precise, safe and low in radiation exposure and permits more accurate and reliable monitoring of individuals over time."* We share the CMS concern that to ensure accurate and reproducible bone density measurement, DXA centers must perform a precision assessment on their equipment and patients be followed over time on the same machine to determine if a true change in BMD has occurred. We note that this will be disrupted if physicians in non-hospital practice settings are forced to abandon axial DXA testing.

We also are in agreement with the CMS decision to lower the cut point for DXA testing in patients on glucocorticoids from less than or equal to 7.5 mg for at least 3 months to less than or equal to 5 mg a day for at least 3 months. This change is supported by the current literature and brings the CMS recommendations for a qualified individual into line with those of the American College of Rheumatology (Arthritis Rheum. 2001;44(7):1496-1503).

PROVISIONS: DEFICIT REDUCTION ACT

Section 5102(b) of the Deficit Reduction Act (DRA) enacted by Congress on February 28, 2006 would have a substantial impact on reimbursement of DXA and would further undermine CMS attempts to improve the percentage of Medicare beneficiaries screened for osteoporosis. Under this provision, the Medicare payment for the technical component of an imaging service would be set at the Hospital Outpatient Department (HOPD) payment rate, if the HOPD rate is lower than the Medicare Physician Fee Service (PFS) payment rate. Both axial DXA and VFA are listed in Addendum F of CMS 1321-P as imaging codes affected by Section 5102(b).

Due only to the regulatory changes proposed in the Medicare Physician Fee Schedule, axial DXA reimbursement would decline from $139.46 in 2006 to $110.29 in 2007. Application of an additional 10% reduction in the work RVU to maintain budget neutrality reduces this further to $109.53. The additional application of the changes legislated by Section 5102(b) of the DRA will reduce axial DXA reimbursement further to $84.50. The calculations leading to this conclusion are as follows: applying the changes legislated by Section 5102(b) in 2007 when the HOPD technical component (TC) for axial DXA is $73.89 the non-facility TC component would have an RVU of 2.65 and using the $37.90 conversion factor the TC fee would be $100.44. As this is greater than the HOPD of $73.89, the HOPD would apply, dropping the total payment for axial DXA (76075-TC + 76075-26) to $84.50 ($73.89 + [.28 x $37.90]). Thus the drop in total non-facility payment for 76075 from $139.46 in 2006 to $84.50 in 2007 would amount to a decline of 39.4% instead of the 21% without the DRA. While the intent of CMS was to phase in changes to the Medicare Physician Fee Schedule over 4 years, this drastic drop would have an immediate effect on access to bone density testing as we anticipate physician operating costs per axial DXA would be greater than the reimbursement rate (see below).

Medicare physician reimbursement for VFA would not be altered by Section 5102(b) of the DRA as the technical component of 76077 in 2007 at $26.90 would be lower than the HOPD TC of $44.78. It should be noted that the non-facility reimbursement for the technical component of VFA is 60% of the HOPD technical component for the same service and underscores flaws in the current system.

IMPACT

In CMS 1321-P Addendum B: Relative Value Units and Related Information Used in Determining Medicare Payments for 2007, the Practice Expense RVU for axial DXA (CPT code 76075) is further reduced from 0.67 to 0.61 (the RVU listed in CMS 1512-PN). In our earlier comments to CMS 1512-PN, we documented our concerns about the marked decline in RVU assigned to axial DXA and the chilling effect this would have on physicians' ability to identify and treat the millions of Americans with osteoporosis. We detailed flaws in input for the physician work and practice expense RVUs and a resultant rank order anomaly when axial DXA was compared to peripheral DXA. We also presented the results of an ISCD sponsored clinical society survey nearly identical in format and content to the 2005 American College of Radiology (ACR) Relative Value Update Committee (RUC) survey used to determine physician work value. As the reimbursement for axial DXA has now been further reduced in the current proposal, we would like to take this opportunity to expand on our earlier comments.

The ISCD remains gravely concerned about the current proposed Medicare Physician Fee Schedule which would decrease payment for axial DXA (76075) by 76% and VFA (76077) by 40% when the additional reduction in the PE RVU for DXA and the 10% adjustment for budget neutrality are factored into final payments for both axial DXA and VFA. We will provide an estimated range of operating costs incurred for axial DXA in the non-facility setting in the United States to demonstrate that such reductions in reimbursement will lead most physicians in private practice to abandon axial DXA testing.

Over 10 million Americans have osteoporosis and 34 million more have low bone mass and are at risk for future fracture. Appropriately, CMS has recognized the dramatic impact that osteoporosis has on the health of Medicare beneficiaries and osteoporosis screening is now a key preventive service that is provided at the time of the first exam and covered at least once every 24 months thereafter. Although axial DXA testing has increased significantly in the last decade as evidenced by 77,133 claims in 1994, 1.265 million in 1999 and 2.43 million in 2004, this still represents less than 20% of Medicare beneficiaries who have been tested. In comparison, mammography screening rates were approximately 68% in 2000. This was considered "suboptimal" by CMS which recently embarked on the national Medicare Mammography Campaign *"to improve beneficiaries' knowledge of breast cancer screening and awareness of Medicare's annual screening mammography benefit."* The campaign also targets health care providers to encourage them to promote screening mammography to their patients. (http://www.cms.hhs.gov/mammography/)

The ISCD suggests that in order for CMS to be successful in raising screening rates for osteoporosis several assumptions must be made.

- Unlike other diagnostic imaging services, axial DXA and VFA as screening technologies need to be performed by primary care physicians throughout the country in rural, suburban and urban settings.
- Screening services by their very nature are not efficient; if one demands efficiency one will sacrifice access.
- The work involved to screen greater segments of the population increases incrementally as the percentage of patients screened increases.
- Quality cannot be sacrificed. Therefore, physicians need to invest in certification, continuing education and facility accreditation programs.

Given these assumptions, osteoporosis screening differs from other diagnostic imaging services.

Consistent with axial DXA being a screening tool and differing from other diagnostic imaging services that have seen recent rapid growth, Medicare claims data (which we presented in our letter of August 18, 2006; copy enclosed) demonstrates that the percentage of DXA studies being done by primary care (now at 30%) has rapidly increased over the last decade. In contrast, the proportion of DXA studies done by radiology has remained constant (40%) while the percentage performed by specialists (endocrinology

and rheumatology) has declined. Appropriately, primary care uptake needs to be actively promoted to improve current screening rates.

Unlike other procedures where an increase in volume is assumed to lead to increased efficiency and less work, this does not appear to be the case for DXA. In the ACR RUC survey of 51 radiologists, 59% of the radiology respondents felt that the complexity of DXA had increased within the last 5 years. Similarly, in the ISCD sponsored clinical society survey of 453 physicians from multiple specialties (30% of whom were primary care), 61% felt that complexity had increased. Only 12% of radiologists and 19% of the clinical society survey respondents felt that DXA had become "more familiar" (less work). These results are at odds with the RUC subgroup that rejected the recommendations of the ACR and ruled that the physician work RVU for axial DXA should be reduced from 0.3 to 0.2 because the procedure was felt to be "less intense and more mechanical than the ACR survey results would indicate." To our knowledge, data to support this contention does not exist.

The analysis and interpretation of an axial DXA study is complex. Specifically, an appropriate study involves reviewing images of the spine, hip and/or forearm for optimal positioning, placement of bone and soft tissue markers and regions of interest. Artifacts, degenerative changes and other abnormalities are noted and specific sites are excluded from evaluation when necessary. The accepted physician interpretation of an initial study includes comments on diagnosis using the World Health Organization (WHO) criteria where applicable, estimation of fracture risk, consideration of secondary causes, treatment recommendations, and if/when the test should be repeated. The ability to provide an appropriate interpretation requires the physician to be aware of the patient's history either from their own medical records or a patient questionnaire containing past medical history, family history, medications, and a directed review of systems. Review of previous radiographs and other medical records may also be necessary. Given the above noted complexity of axial DXA performance, it is not surprising that Lewiecki et. al., found that errors in analysis and interpretation of DXA studies are not uncommon. (Lewiecki EM, Binkley N, Petak SM. Impact of DXA quality on patient care: clinician and technologist perceptions. J Bone Miner Res. 2006;21(Suppl 1):S354)

The ISCD is committed to establishing standards for both DXA and VFA. Our educational courses, certification exam, Position Development Conference (PDC) Official Positions and facility accreditation programs are all integral parts of this effort which involve both physicians and technologists. We have championed the importance of precision assessment in DXA analysis and offer a tool to calculate precision on our website. Quality axial DXA and VFA performance takes time, requires extra work and adds to the complexity and intensity of both procedures.

Moreover, as more patients are identified as being at high fracture risk and are started on pharmacologic therapy, the interpretation and reporting for follow-up bone density studies substantially increases the complexity of DXA interpretation. Comparison of two or more DXA studies must be performed with the same attention to analysis detail as noted above to ensure study comparability. Additionally, use of the same or a cross-calibrated densitometer and performance of precision assessment is essential to determine if a significant BMD change over time has occurred. Physician interpretations may include recommendations on further therapy, possible secondary causes of osteoporosis or other causes of drug therapy failure.

Viewed in this way, the axial DXA report has many elements of an E/M visit. As such, it is not surprising that in the ISCD clinical society survey, the key reference codes selected most often were 99213 (19.9% of respondents), followed by 99212 (16.3%) and 99214 (15.9%) with RVUs of 0.67, 0.45 and 1.10 respectively. The ISCD clinical society survey also demonstrated internal consistency in that the median estimated work RVU for axial DXA was 0.5 (with 25th percentile of 0.35 and 75th percentile of 1.00).

Consistent with an E/M type approach being taken by clinicians, a substantial difference was seen between the ACR RUC survey and the ISCD sponsored clinical society survey in physician work time. As we previously reported, the median physician work time for a DXA study was 25 minutes (5 minutes pre-service, 10 minutes intra-service, and 10 minutes post-service). For radiologists who were surveyed in

the ACR RUC survey, the median physician work time was either 6 or 8 minutes[1] (1-2 minutes pre-service, 4 minutes intra-service, and 1-2 minutes post-service). **Such differences in physician work time could in part be explained by what are considered "essential elements" of an axial DXA report. If the report were to only provide a densitometric diagnosis without reviewing the patient's history, risk factors and providing broad treatment recommendations, the work time would be anticipated to be substantially less.**

In our earlier letter, we demonstrated other apparent flaws in the input and assumptions used to determine physician work and practice expense. The ISCD sponsored clinical society survey also underscores some of those key points as follows:

1. 93% of respondents have a fan-beam axial DXA system which is valued at $85,000. Only 7% currently use an older pencil-beam system valued at $41,000. The Practice Expense survey used a pencil beam densitometer at $41,000 for calculation of machine costs.
2. Utilization rates across all locations in the ISCD sponsored clinical society survey were calculated to approximate 21%. This is vastly different than the 50% utilization rate used in the Practice Expense methodology for all procedures. Rates of 50% and often higher are more typically seen in large diagnostic imaging centers where patients are referred and devices are used for multiple disease states.
3. Median service contracts of $5,000, software upgrades of $2,000 per year and phantom costs were listed by the ISCD clinical society survey respondents. None of these expenses were included in the Practice Expense survey.

Additionally, it is important to recognize that osteoporosis care in the United States, and worldwide, is on the verge of a WHO driven paradigm shift based on international consensus that optimal targeting of individuals for receipt of pharmacologic intervention should be determined using an estimate of absolute 10-year hip fracture risk. The National Osteoporosis Foundation (NOF) is developing a United States-specific absolute fracture risk WHO prediction model that will identify the fracture probability at which treatment intervention becomes cost effective. This model will specifically input femoral neck BMD (necessitating axial DXA) and specific risk factors including history of prior fracture after age 50 for calculation of fracture probability and thus need for pharmacologic intervention. VFA can be performed at the same time and location as an axial DXA study, providing information about prior vertebral fractures. This will provide clinicians with essential point-of-care information for appropriate assessment of need for therapeutic intervention. Thus, the future of osteoporosis care in the United States will be based on present day axial DXA equipment, upgraded with special software provided by the WHO and NOF (following FDA approval) that will automatically link the patient's BMD and prior fracture status (as well as the other risk factors) into the aforementioned NOF cost effectiveness model that will be reported by axial DXA equipment.

Given the importance of axial DXA and VFA screening as key preventive services, one could argue that not only do the services need to be appropriately valued compared to other CPT codes, but that value could be set higher to further increase incentives and improve the proportion of beneficiaries screened. MEDPAC in their report to Congress in March 2006 outlined the dangers of undervaluing a service noting that physicians may opt not to provide the service, thereby threatening access to care. Additionally, Medicare would not be spending taxpayer money wisely by not paying enough for the undervalued service.

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[1] The ISCD identified two ACR physician work survey documents with different results for the time involved (enclosed). The first survey done before final RUC input listed pre-service time of 2 minutes, intra-service time of 4 minutes and post-service time of 2 minutes for a total time of 8 minutes. The second survey identified included the RUC work value of 0.2 and listed pre-service time as 1 minute, intra-service time of 4 minutes and post-service time of 1 minute for a total time of 6 minutes.

What is an appropriate reimbursement for axial DXA?

We have begun to explore the operating costs per axial DXA study for physicians in the non-facility setting realizing that costs may vary for each of the specific inputs identified. We have taken a range of fixed and variable costs incorporating input from a number of different practices in the United States (Table 1).

Table 1: Estimation of DXA Cost

Fixed costs		
Depreciation of axial DXA	$85,000/ 5years	$17,000
Interest on loan	6% for 5 yrs	$2,600
Maintenance contracts		$6,000 – $9,000
Space	150 sq ft @ $16 – $30/sq ft.	$2,400 – $4,500
Overhead		$10,000 – $40,000
	Total fixed costs	**$38,000 – $73,100**
Variable costs		
Technologist salary + fringe	$50,000 – $70,000 x 30 min.	$12.02 – $16.83
Receptionist salary + fringe	$30,000 – $40,000 x 20 min.	$4.88 – $6.51
Billing salary + fringe	$50,000 – $70,000 x 15 min.	$6.01 – $8.41
MD salary + fringe [interpretation]	$150,000 – $250,000 x 25 min.	**$30.00 – $49.28**
	Variable costs per DXA	**$52.91 – $81.03**

Assumptions:

- Fan beam DXA at $85,000
- Work calculated on 2080 hrs/year
- Overhead calculated as percent of total clinic overhead that is associated with DXA. Percent is derived from DXA revenue/ total clinic revenues
- Physician time of 25 minutes is based on ISCD clinical society survey
- Divide number of DXA studies done/year in to total fixed costs to determine total fixed costs/ DXA then add that to total variable costs/DXA for total expenses/DXA

We then examined the effect of varying the number of axial DXA studies performed over the range of operating costs (Table 2)

Table 2: Estimated Costs per DXA Study Based on Number Performed

# studies / mo	# studies / yr	Cost / DXA (low)	Cost/DXA (high)
10	120	$369.58	$690.20
20	240	$211.24	$385.61
30	360	$158.47	$284.09
36	432	$139.87	$250.24
40	480	$132.08	$233.32
50	600	$116.24	$202.86
60	720	$105.69	$182.56
70	840	$98.15	$168.05
80	960	$92.49	$157.18
100	1200	$84.58	$141.95
102	1224	$83.96	$140.75
120	1440	$79.30	$131.79
2030	24,366	$54.47	$84.03

We estimate that at the current reimbursement rate for axial DXA of $139.46 (not factoring in the Geographic Adjustment Factor), to meet operating costs a practice would need to perform approximately 36 studies per month (432 studies per year) at the low end of operating costs and 102 studies per month (1224 per year) at the high end of operating costs. Once the projected reimbursement rate of $84.50 for axial DXA takes effect on January 1, 2007, (applying the MPFS and Section 5102(b) of the DRA but not SGR) the number of studies that would have to be performed to meet operating costs would nearly triple to 100 studies per month (1200 per year) at the low end and increase 200 fold to 2,030 studies per month or 24,366 per year at the high end.

From the ISCD clinical society survey we obtained the median number of axial DXA studies performed per month in varying locations and practice types. Using the corresponding range of operating costs as estimated above, we then examined how practices would fare given the current reimbursement of $139.46 per axial DXA study, the projected reimbursement of $84.50 to take effect on January 1, 2007, and the anticipated reimbursement of $33.73 that would apply on January 1, 2010, after the 4 year incremental phase in (Table 3).

Table 3: Range of Estimated Operating Costs per DXA Based on Practice Location and Type

Practice location	Median number of studies per month	Low Operating Costs per DXA	High Operating Costs per DXA
Rural	50	$116.24	$202.86
Suburban	60	$105.69	$182.56
Urban	80	$92.49	$157.18
Practice type			
Solo	35	$143.39	$255.08
Single specialty	60	$105.69	$182.56
Multi-specialty	90	$88.10	$148.72
Med school faculty	120	$79.30	$131.79

As one might predict, axial DXA utilization rates are lower in rural locations and solo practice settings and highest in urban locations, multi-specialty and medical school faculty settings. The greater the number of studies performed, the lower the expense per study. At current reimbursement rates and even allowing for low operating costs, solo practitioners are currently just covering their costs. At the high end of operating costs, only medical school faculty are performing enough studies to avoid losing money.

If one now looks at **the anticipated reimbursement of $84.50** that would take effect on January 1, 2007 (excluding the effects of the SGR), only medical school faculty using low operating cost assumptions would be able to avoid a loss. All practice models, in all locations, under any reasonable operating cost assumption will lose money when the reimbursement drops to $33.73 in 2010. The reimbursement rate in 2008 of $83.76 and $59.12 in 2009 are equally onerous. The results of the ISCD clinical society survey coupled with our operating cost analysis unequivocally demonstrates that DXA testing would be abandoned by almost all practitioners in all settings if the proposed changes take effect in January 2007.

As CMS is interested in a successful screening program for osteoporosis, an increasing number of physicians in solo practice and rural settings will have to be added; work and complexity will increase and quality will need to be maintained. Viewed in this way one must conclude that the reimbursement for axial DXA will have to increase above the current rate of $139.46.

What are the potential consequences of profoundly undervaluing DXA?

Physicians in non-facility/private practice settings will abandon axial DXA testing if the current Medicare Physician Fee Schedule is enacted as reimbursement in 2007 will be less than the operating cost to perform the study. Enactment of Section 5102(b) of the Deficit Reduction Act alone would also accomplish the same result. With removal of bone density measurement capability from physicians' offices, osteoporosis screening will be curtailed; the personal and societal expense of osteoporotic fractures would be expected to increase.

Although current screening rates of 20% are low, the dramatic increase in claims over the last 10 years implies significant potential for improvement, but only if the service is appropriately valued. By their very nature, screening services are less efficient than diagnostic procedures. Identifying patients not yet tested will require extra time and work. If screening services are to be successful, it seems reasonable that the total number of DXA units must increase, not decrease as seems certain will occur if the above noted regulatory and legislative changes are adopted.

Physician office-based axial DXA and VFA centers presently perform 71% of the total number of DXA studies for Medicare beneficiaries. Physician offices (non-facility) performed 1.7 million DXA examinations in 2004 (latest figures available) of which 46% were completed by primary care physicians. Hospital outpatient facilities are unable to handle the additional number of patients required to increase screening rates above the current level of 20%. Patient access will be further restricted and long waits for an appointment will discourage many. Additionally, by shifting patients to the hospital outpatient setting, the ability to measure response to current therapy will be lost.

Optimal patient care may be compromised. A Medicare patient who has their axial DXA performed in their doctor's office has an important advantage over general radiological facilities in that their DXA study may be done the same day as they see their physician, thus improving convenience. Additionally, their study is either interpreted by their personal physician or by other physicians in the same clinic that have their medical records available for review. Personal knowledge of the patient's medical history, or access to such data in the medical record, provides the bone density interpreter with important information that may directly influence study interpretation. The difference in time spent performing and interpreting a DXA study between the ACR survey (6-8 minutes) and the ISCD clinical society survey (25 minutes) suggests there are substantial differences in the interpretation and reporting of bone density examinations in clinician's offices.

With enactment of the CMS reductions in reimbursement, bone density assessment and VFA will be severely undervalued. DXA centers that do elect to continue offering these services are unlikely to offer their physicians and technologists the additional education that is necessary for continued performance of high quality testing. Additional expenses such as service contracts will not likely be extended and software upgrades not purchased.

With the loss of physician office-based axial DXA availability, future osteoporosis care in the United States will become a two-tiered system of the haves and have nots. Individuals having sufficient personal financial resources to pay up front for bone densitometry will do so at their physician's central DXA center, if still operational. In contrast, the vast majority of patients will have to wait for an appointment and travel to a hospital to have a bone density assessment performed without the benefit of having their physician's clinical expertise integrated into the final interpretation. This two-tiered Medicare system is contrary to present Federal directives as iterated by the United States Preventive Services Task Force recommendations of 2002, the Surgeons General's 2004 report on Osteoporosis and Bone Health, and the Balanced Budget Act of 1998.

Summary of input errors in the physician work and practice expense surveys for axial DXA

The ISCD stated in its initial comments to CMS (August 18, 2006, see enclosed copy) and have again reiterated in the aforementioned text that significant flaws exist in the input data that was used in calculation of the work and practice expense RVU for axial DXA. CMS agreed with the AMA RUC that axial DXA work RVU should be 0.20 which is contrary to the specialty society survey (ACR) work RVU of 0.30 and the clinical society survey work RVU of 0.50. The work RVU of 0.20 for axial DXA will now be identical to another imaging densitometric procedure called radiographic absorptiometry (RA), CPT code 76078. However, axial DXA requires substantial depth of knowledge, meticulous attention to detail, appreciation of published standards and guidelines, regular updates of one's skills and a proficiency of skeletal health assessment at the DXA center itself (facility accreditation) that can only be attained through additional and ongoing post graduate medical education and financial expenditure. This should be contrasted with radiographic absorptiometry that uses a simple digitized x-ray to measure finger density in comparison to an aluminum wedge and reports "RA" units rather than BMD. RA cannot be used for diagnosing osteoporosis or monitoring patients on therapy. Either we accept the opinion of the RUC that these two technologies are identical, which is unrealistic, or the RUC analysis of the ACR survey is flawed resulting in a significant rank order anomaly that cannot be reconciled in its present form. The axial DXA work RVU of 0.50 supported by the clinical society work survey should be considered as the true physician work related to this imaging procedure.

Additionally, the practice expense RVU as calculated by CMS in their "bottom up" methodology contains flawed data input. Present day central DXA equipment, called fan beam DXA, costs $85,000 instead of older pencil beam instruments costing $41,000 that were included in the CMS calculations. Moreover, the additional expense associated with service contracts, software upgrades, quality control phantoms, initial training and continuing medical education of technologists, axial DXA certification and future facility accreditation were not included in the CMS calculations. Lastly, inappropriate DXA machine utilization rates of 50% were used by CMS in their calculations instead of "single disease state" imaging procedure utilization rates of 15-20% for axial DXA and VFA performed by primary care physicians, rheumatologists, and endocrinologists as a point-of-care service.

The case for VFA

The ISCD is aware that VFA is currently not considered a preventive service by CMS. Moreover, since VFA was only recently assigned a CPT code, we do not have claims data to review. However, given the CMS commitment to screening patients for osteoporosis and treating those at highest risk, incorporating VFA into current benefits has much to recommend. VFA is an attractive alternative to standard radiography for vertebral fracture identification in that radiation exposure is low; only 3-8 microsieverts compared to 700-800 microsieverts for a lateral radiograph of the lumbar and thoracic spine. Additionally,

VFA has the added convenience of being done at the same time and location as a DXA study, thus allowing immediate integration of bone density and fracture knowledge into an estimation of the individual's risk for future fracture. Importantly, VFA has comparable accuracy to plain radiography in the identification of moderate and severe fractures in post-menopausal women being evaluated for osteoporosis, including those with low bone mass (osteopenia).

Unlike many other imaging techniques, which are expensive and of unproven benefit in altering outcomes, multiple clinical trials have demonstrated that knowledge of bone density and/or vertebral fracture status can reduce fracture risk when drug therapy is initiated. VFA also offers advantages above and beyond those of DXA. For example, 14-20% of Medicare beneficiaries with osteopenia by WHO criteria, who might not be otherwise treated, have vertebral fractures on VFA and have a clinical diagnosis of osteoporosis. Such individuals are at substantially increased risk for fracture and require pharmacologic therapy. However, since two-thirds of vertebral fractures are clinically unappreciated, neither the patient nor their physician would be aware of their increased fracture risk. Therefore, VFA combined with DXA has the capability to identify those at greatest fracture risk allowing improved targeting of pharmacologic therapy. VFA will play an even more critical role in patient care with release of the NOF United States-specific absolute fracture risk WHO prediction model that will identify the fracture probability at which treatment intervention becomes cost effective based on axial DXA hip BMD and the presence of VFA documented prevalent spine fragility fractures as noted above.

As VFA is a software addition to current fan-beam axial densitometers, this allows primary care physicians who lack access to plain spine radiography in their office the ability to screen for vertebral fractures. This allows more appropriate targeting of treatment in the primary care setting to Medicare beneficiaries who are at highest risk for osteoporotic fractures. CMS 1321-P did not address the work RVU for VFA (76077) but reduced the Practice Expense RVU from 0.81 to 0.41, thereby reducing reimbursement by 40% over the next four years when the 10% adjustment for budget neutrality is applied to the physician work RVU. The current reimbursement of $39.41 would be reduced to $23.61 by 2010. We note that the HOPPS reimbursement would be $53.50, thus the non-facility reimbursement for the technical component of VFA would be 60% of the HOPD technical component for the same service. ISCD recommends that CMS consider VFA as a screening tool and apply special resource considerations that will appropriately value this service.

CONCLUSION

CMS has identified osteoporosis as a major health care concern in the United States. Moreover, CMS has designated axial DXA as the key diagnostic tool for the screening of Medicare beneficiaries and for monitoring response in patients on pharmacologic therapy. Efforts to increase axial DXA screening rates above the current level of 20% will require a different approach within the existing framework that values access over efficiency and assigns an appropriate value to a screening procedure increasingly performed by primary care physicians in the office (non-facility setting).

Unfortunately, if the current proposed Medicare Physician Fee Schedule is enacted for axial DXA and/or Section 5102(b) of the Deficit Reduction Act takes effect on January 1, 2007, axial DXA testing will disappear from the non-facility setting as physicians operating costs will be greater than reimbursement for the test. Enactment of this policy will result in severe limitations in patient access to skeletal health assessment and will undermine the CMS initiative to screen beneficiaries for osteoporosis and monitor their response to medical therapy.

We encourage CMS to re-examine the input data and assumptions used to determine reimbursement for central DXA and VFA and have offered suggestions for changes in the data used to determine work and PE RVUs. Accordingly, the ISCD urges CMS to review the proposed cuts and at the very least keep reimbursement at the current levels. Moreover, based on the ISCD clinical society survey, the ISCD cost analysis and the CMS initiative to attain 100% screening of Medicare beneficiaries, an increase in axial DXA and VFA reimbursement is warranted. Finally, the ISCD proposes that special resource

considerations are necessary for both DXA and VFA to ensure widespread availability, and enhance utilization of high quality osteoporosis screening in the United States.

The ISCD appreciates this opportunity to comment on the proposed changes to the Medicare Physician Fee Schedule. We welcome any further dialogue with the Centers for Medicare and Medicaid Services regarding the issues we have outlined in this letter. If you have any questions concerning ISCD's comments, please contact Donna Fiorentino (Manager Public Policy Affairs) at 860.586.7563 Ext. 553 or at dfiorentino@iscd.org.

Sincerely,

Neil Binkley, MD, CCD
President, ISCD

Sanford Baim, MD, FACR, CCD
Vice-President, ISCD

Andrew Laster, MD, FACR, CCD
Chair Public Policy, ISCD

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ISCD
The International Society For Clinical Densitometry

342 North Main Street
West Hartford, CT 06117
Phone: 860.586.7563
Fax: 860.586.7550
www.iscd.org

August 18, 2006

Mark McClellan MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1512-PN: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

Comments:

- **Work RVU 76075 (Dual Energy X-ray Absorptiometry)**
- **Practice Expense 76075 (Dual Energy X-ray Absorptiometry); 76077 (Vertebral Fracture Assessment)**
- **Regulatory Impact Analysis 76075 and 76077**

Dear Dr. McClellan:

Summary

Osteoporosis is a major health care issue in the United States. DXA (dual energy x-ray absorptiometry) and VFA (vertebral fracture assessment) are crucial for the detection of osteoporosis and identification of those at highest fracture risk. Federal initiatives to identify patients with osteoporosis have led to the increased utilization of DXA and VFA; however, the vast majority of affected individuals continue to remain undiagnosed and untreated. The proposed changes in the physician fee schedule would reduce DXA reimbursement from approximately $140 to $40 and VFA from $40 to $25. These reductions will force physicians to discontinue offering these vital services, resulting in a severe limitation of patient access to high quality bone densitometry and vertebral fracture assessment. In this letter, the ISCD enumerates flaws in data input, data omission and erroneous assumptions that have contributed to these reductions in reimbursement. In view of these flaws, we request that CMS review the proposed cuts, and, at the very least, keep reimbursement at the current levels. This approach would resolve the inconsistency with the agency's preventive health care mission. In doing so,

we suggest that special resource considerations are necessary for DXA and VFA to assure the widespread availability of high-quality screening in the United States.

Introduction

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the **CMS-1512-PN: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology**. Specifically, we would like to address CPT codes 76075 (DXA) and 76077 (Vertebral Fracture Assessment or VFA).

The ISCD is a multidisciplinary, nonprofit organization founded in 1993 that provides a central resource for scientific disciplines with an interest in bone mass measurement. Presently, the ISCD has 6,392 members in 56 countries. 93% of our members practice within the United States; 60% are physicians and 40% are densitometry technologists. Our membership spans more than 20 health care disciplines including Endocrinology, Family Practice, Gynecology, Internal Medicine, Nephrology, Orthopedics, Radiology, and Rheumatology.

The mission of the ISCD is to promote excellence in the assessment of skeletal health. As such, the ISCD provides approximately 25 comprehensive bone densitometry educational courses and 8 vertebral fracture assessment courses annually in the United States as well as certification in DXA performance and interpretation for technologists and physicians. Physicians who successfully pass the certification exam are designated Certified Clinical Densitometrists (CCD), while technologists are designated Certified Densitometry Technologists (CDT). Currently in the United States there are 5,750 physicians and 3,160 technologists with ISCD certification.

With the evolution in the field of bone densitometry, differences in technologies, acquisition techniques, reference databases, reporting methods, and terminology have developed. These differences may have adverse effects on patient care and the exchange of scientific information. To address these issues, the ISCD periodically holds Position Development Conferences (PDCs), a process whereby an international panel of experts makes recommendations after reviewing scientific literature presented by ISCD PDC Task Forces. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD. A copy of the most recent Official Positions is amended to this report (Appendix A). These Official Positions promote uniformity in DXA and VFA performance, thereby enhancing clinical care.

Consistent with our goal of promoting excellence in skeletal health assessment, the ISCD has developed, and is currently beta-testing, a bone densitometry facility accreditation program that will soon be available. We anticipate this ISCD Facility Accreditation Program will assure patients, health care providers, CMS, and other health care payers that patients will receive high-quality bone density measurement nation-wide.

VFA are essential to the clinical identification and monitoring of people at risk for osteoporotic fracture.

Previous Health Care Policy and Effect on Bone Density Measurement

Despite the above noted impact of osteoporotic fracture on health care outcomes, this disease continues to be substantially under-recognized by patients and health care providers alike. In fact, 95% of people who suffer an osteoporotic fracture are never evaluated or treated for this disease.[19]

In appreciation of the importance, but under-recognition, of osteoporosis as a major health care problem, a number of initiatives at the Federal level have been introduced during the last decade. The Balanced Budget Act of 1997 established DXA testing for qualified Medicare beneficiaries for both the diagnosis and monitoring response to therapy. In 2002 the United States Preventive Services Task Force recommended routine DXA testing for all women aged 65 and older and for women aged 60 and older if certain risk factors were present.[20] In 2004 the Surgeon General's Report on Bone Health and Osteoporosis called on health care professionals to proactively assess, diagnose and treat patients at risk for osteoporosis.[1] The Surgeon General hailed development of non-invasive tools to measure bone density as "one of the most significant advances in the last quarter century... Thanks to the development of bone mineral density testing, fractures need not be the first sign of poor health. It is now possible to detect osteoporosis early and to intervene before a fracture occurs."[1] Recognizing the necessity of bone density measurement, the Health Plan Employer Data and Information Set (HEDIS) now tracks the percentage of women aged 67 and older who have had a bone density test or started medical therapy within six months of sustaining an osteoporotic fracture.[21] Finally, bone mass measurement is one of the preventive services offered by Medicare and was recently highlighted as part of the Initial Preventive Physical Examination (IPPE) ("Welcome to Medicare" Physical Exam).[22] The Medicare Learning Network dedicates one of its six brochures on Medicare Preventive Services to bone mass measurement.[23] Thus, the importance of osteoporosis and its diagnosis has been clearly recognized at the Federal level. Ideally, such Federal recognition of a societal health problem would translate to alteration of clinical care, in this case to improved availability and use of bone mass measurement technology.

A review of CMS claims filed for central DXA (CPT codes 76075 and 76075-26) demonstrates that improved availability and increased use has occurred. Specifically, the number of DXA claims has increased from 77,133 in 1994 to 1,331,271 in 1999 and 2,555,727 in 2004 (Table 1). Unlike other imaging studies whose volume increases have been driven by single specialty society use, increases in DXA testing result from multiple specialties (Figure 1). Importantly, there have been major increases in DXA use by primary care specialties (Family Practice, Internal Medicine, and Gynecology), while Radiology has remained constant and the Rheumatology and Endocrinology proportion has declined (Figure 2). *Driven by the patient-based Federal initiatives listed above, these increases can be seen to be appropriate and not an over-utilization of services.*

Despite these increases there is evidence that DXA testing still remains under-utilized. In a recent study of a random sample of a representative Medicare population of 43,802 women eligible for osteoporosis screening, only 23% were tested between 1999 and 2001. Of greater concern, among women at highest fracture risk due to advancing age, BMD testing declined by 4-6% for each 5-year age increment after age 75.[24] Data from HEDIS in 2003 indicated that only 18% of female Medicare beneficiaries who had a fracture received either a BMD or prescription for drug therapy within 6 months of the date of the fracture. In 2004, that number had increased to 19%.[25] In summary, though progress has been made with an increase in the number of people tested, this disease continues to be neglected in most individuals at high risk for fracture.

Proposed Changes: Effect on Access and Quality of Care

With the above as background, *the ISCD is seriously concerned about the revised Medicare Physician Fee Schedule that would decrease payment for DXA (76075) by 71%* (current payment of $139.46, 2010 payment of $39.80) *and VFA by 37%* (current payment of $39.41, 2010 payment of $24.64) assuming a constant conversion factor. [Note that potential further reductions factoring in the proposed 10% decrease in physician work RVU to preserve budget neutrality and Section 5102 of the Deficit Reduction Act of 2005 for non-facility services are not included in these calculations.] In reviewing the proposed changes in RVUs for DXA and VFA (see Table 2) we note a 30% decline in work RVU and a 79% decline in Practice Expense (PE) RVU for DXA. For VFA, we note a 48% decline in PE RVU. (Department of Health and Human Services; Centers for Medicare and Medicaid Services. Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Notice. (CMS-1512-PN, RIN 0938-AO22) Federal Register. Vol 71, No. 125. Thursday, June 26, 2006. p 37170-37430. **http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1512pn.pdf**)

The ISCD is concerned that this will markedly reduce the availability of high quality bone mass measurement and thus have a profound adverse impact on patient access to appropriate skeletal health care. We believe that many physicians will discontinue performing these essential services, as it will not be fiscally viable to continue doing so either with existing equipment or by replacing aging machines. Moreover, despite the under-utilization noted above, physicians who are contemplating adding DXA and VFA capabilities to their practice will now be dissuaded from doing so. This reduction of access could be expected to be of greatest consequence in rural areas.

In addition to reducing access, the proposed changes seem destined to lower the quality of measurements performed. As noted above, a major focus of the ISCD is to promote excellence in skeletal health assessment through education, certification and standardization. We recognize that quality bone mass measurement requires specific education and expertise for both the physician and technologist. It is essential that densitometers are appropriately maintained and that physician and technologist skills be continually updated. With inadequate reimbursement, such quality measures, continuing professional development, and ultimately patient care, seem destined to suffer.

Analysis of the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology

The ISCD extensively reviewed the current Work surveys for DXA and VFA and the Practice Expense data for DXA and VFA and has identified specific flaws in data input and important data omissions, which when combined with use of other CMS methodology for calculation of the PE, results in the aforementioned severe reductions in DXA and VFA reimbursement.

The ISCD respectfully submits that flaws exist in the calculation of the Practice Expense RVU component for DXA (76075) and VFA (76077). Specific areas of concern are as follows:

- **Inappropriate application of equipment costs.** While the equipment cost is appropriately listed for VFA using current fan beam densitometers at $85,000, in contrast, DXA is assigned a cost of $41,000 based on pencil beam instrumentation. Of the two largest United States manufacturers of DXA instruments, one no longer produces pencil beam machines and for the other such low-end instruments comprises less than 20% of sales. Thus, fan beam densitometers make up the vast majority of densitometers currently available in practice, and therefore the ISCD would argue that the equipment cost for DXA should be listed at $85,000.
- **Inappropriate utilization rates**. Utilization rates for DXA and VFA are listed at 50%. This rate has been applied to all procedures, despite the fact that "single disease state" imaging procedures such as DXA and VFA have utilization rates that have been estimated at 15-20%. Unlike other high volume procedures where patients are referred to dedicated imaging centers, DXA and VFA are frequently obtained by primary care physicians, rheumatologists and endocrinologists and offered as point-of-care service. Based on 2002 Medicare data, 70% of DXA studies are performed in office (30% in hospital settings) and 60% are performed by non-radiologists.
- **Other densitometry costs are omitted**. For example, the cost of phantoms, necessary service contracts/software upgrades and office upgrades to allow digital image transmission are not included.

The ISCD also believes that flaws exist in determination of the physician work RVU component for DXA (76075). Specific areas of concern are as follows:

- **RUC subcommittee decreases work RVU.** The American College of Radiology (ACR) polled a broad range of radiologists to perform the physician work survey and recommended that the work RVU remain at 0.3. However, subsequently, a working group comprised of six RUC members recommended that the value be reduced to 0.2 (the 25th percentile of the ACR survey) stating that *"... the (RUC) workgroup believed that the actual work is less intense and more mechanical*

than the specialty society's description of the work." It is worth noting that this RUC subcommittee was comprised of a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, psychiatrist, and a family practitioner. Only one of these physicians could be expected to be knowledgeable about DXA interpretation. We believe this reduction to be inappropriate in that DXA reporting is not simple mechanical reporting of data generated by the DXA machine software. Rather, the optimal reporting of DXA data requires specialized knowledge and expertise. That the need for such expertise is often unappreciated is emphasized by a recent survey of over 700 physicians conducted by the ISCD in which 71% of physicians reported finding incorrect DXA interpretations at least once per month and 98% reporting that poor quality DXA reports were harmful to patient care.[26] Moreover, the RUC recommendation to reduce the physician work RVU places DXA in a unique group of only 29 other codes (out of a total of approximately 500) which the RUC recommended for cutbacks.

- **Clinical vignette.** A clinical vignette of a typical patient is provided to assist in assigning an appropriate value to the average physician work effort. A series of questions references this vignette in assigning a value to complexity/intensity, mental effort/judgment, technical skill/physical effort, and psychological stress. The 2005 survey was compared to the original survey in 1994 to determine if the work value differed (under or over-valued). Strikingly, "the typical patient" listed in both surveys was not the same. In 1994 it was "*a 55 year old menopausal woman presents with a family history of osteoporosis and is considering estrogen therapy.*" In 2005 the "typical patient" is "*A 66 year old woman (who) had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.*" Since the survey vignettes are substantially different, a comparison of work involved in DXA interpretation using this vignette with the prior survey vignette is problematic.

This flawed methodology leads to inappropriate rankings of procedures sometimes known as a "Rank Order Anomaly." Physician work in terms of corresponding RVUs can be ranked from least to greatest intensity. The greater degree of physician work, the higher the RVU. Examples include physicians work reading an EKG is 0.17 versus reading a series of lumbar spine radiographs is 0.36. This would imply that reading lumbar spine radiographs has over twice the physician work related to that activity compared to reading an EKG. A rank order anomaly would be defined as a CPT code that, despite having greater amount of physician work, is ranked below one in which less work is involved. The summation of the aforementioned flaws in accuracy of data input, important data omissions and use of the CMS designed bottom-up methodology for calculation of the PE taken together result in such a "Rank Order Anomaly" in which tests that are clearly less intensive than DXA are more highly valued. Specifically, peripheral DXA studies (CPT 76076) would carry a greater physician work RVU (0.22) than central DXA (CPT 76075) (0.20) despite the fact that central DXA is clearly more labor intensive and of greater complexity.

Clinical Society Survey Results

We appreciate that CMS did request input on CPT code 76075 for review by all interested societies and that the current ACR survey results for DXA and VFA were based on 51 completed surveys sent to 240 radiologists. However, we believe that clinical societies were remiss by not participating in the prior survey. As such, the ISCD, in cooperation with the American Society for Bone and Mineral Research (ASBMR), the American Association of Clinical Endocrinologists (AACE), The Endocrine Society (TES), the North American Menopause Society (NAMS), and the American College of Rheumatology (ACR – Rheum) completed an independent Work and PE RVU survey almost identical to the 2005 ACR RUC survey to provide additional clinical perspective. We were kindly assisted by the ACR in this process. As such, an electronic survey was created by an ISCD task force and distributed to all physician members of the aforementioned societies. A summation of these results follows.

The ISCD received a total of 453 surveys completed by physicians. Respondents identified themselves as practicing in the following medical specialty areas:

Specialty	% of total respondents
Rheumatology	36.7%
Endocrinology	22.2%
Internal Medicine	11.2%
OB/GYN	9.2%
Family Practice	6.9%
Radiology	4.7%
Other	9.2%

Of responding physicians, 16% identified their practice location as rural, 42% suburban and 42% urban. Additionally, they identified their practice type as 28% solo practice, 39% single specialty group, 24% multispecialty group, and 9% medical school faculty.

The ISCD welcomes the opportunity to share the full results of this survey with CMS. Several key survey questions and their results are as follows:

Clinical Society Physician Work Survey Results

Time Question:
"How much of your own time (day of procedure) is required per patient treated for each of the following steps in patient care related to this procedure? Indicate your time (in minutes) for DXA CPT code 76075. (Record time in minutes.)"

Time in Minutes

	Low	25th %	Median	75th %	High	Mean
Pre-Service	0	2	5	10	60	6
Intra-Service	0	5	10	15	90	9.8
Post-Service	0	5	10	12	37	9.2

It is apparent that the time required per patient for DXA CPT code 76075 is substantially higher than recorded in the ACR survey, which noted a median **intra-service time** of 4 minutes and a 25th percentile of 2 minutes.

Work RVU Question:
"Based on your review of all previous steps, please provide your estimated physician work RVU for the DXA CPT code 76075."

	Low	25th %	Median	75th %	High	Mean
DXA 76075	.17	.35	.50	1.00	3.68	.76

The work RVU values for DXA CPT code 76075 are substantially higher than that recorded in the ACR survey, which noted a median work RVU of 0.3 and a 25th percentile of 0.2.

Thus, for both the physician time component and the physician work RVU, substantially higher values were obtained when 453 physicians from multiple disciplines were surveyed in contrast to 51 physicians from a single specialty (radiology).

Clinical Society Practice Expense Survey Results

- **Equipment costs**: Although we did not ask for invoice cost of DXA machines, we did survey for the type of machine used. 93% of the machines utilized were fan beam and only 7% were pencil beam. This corroborates our earlier statement that the vast majority of densitometers in clinical practice are fan-beam technology, to which CMS has previously assigned a value of $85,000.
- **Utilization rates**. The following questions were asked to determine utilization rates:
  - "Number of DXA procedures done in an average month per machine?"
  - "Number of hours per week that practice (where machine is located) is open for operation?"
  - "Average number of days per month (where machine is located) is open for operation?"

  A median of 60 DXA procedures were performed in an average month at a median intra-service time for non-facility and facility of 34 minutes per procedure. The median hours per week were 40 and the median number of days per month 20, to arrive at a utilization rate of 21%. This is in line with previous estimates for single-disease state imaging of 15-20% and vastly different from the 50% utilization rate used in the original PE calculation. It is important to note that the 50% utilization rate was not surveyed, but provided as an estimate by consultants to CMS.
- **Additional costs**: Our survey identified median service contract costs of $5,000 per year and median software upgrades of $2,000 per year documenting the additional costs associated with DXA performance which were not previously accounted for.

In summary, this larger survey supports our premise that specific flaws were present in data input and data omissions in calculation of the physician work and practice expense RVUs.

Conclusion:

In view of the aforementioned flaws used to capture and calculate work and practice expense RVU, the resultant rank order anomaly, and the discordance of results from this larger specialty society survey, **the ISCD respectfully requests that that CMS review the proposed cuts, and, at the very least, keep reimbursement at the current levels for DXA (CPT code 76075) and VFA (CPT code 76077).** This approach would resolve the inconsistency with the agency's preventive health care mission. As noted above, osteoporosis is a major health care issue in this country. Federal initiatives to detect this disease using DXA and VFA, and appropriately treat individuals at high risk, are crucial. CMS claims data indicates that testing is increasing, however it still remains vastly under utilized. Our survey data underscores the additional time involved in the performance of DXA and VFA studies that has not been captured by prior survey methods. Moreover, additional costs associated with machine upgrades, phantoms for quality control and continuing education of technologists and physicians are required to assure that this essential service is performed optimally. As such, we propose that special resource considerations are necessary, for both DXA and VFA, to assure widespread availability of high-quality screening in the United States.

We strongly believe that if the new RVUs are enacted, the very same initiatives that CMS has championed to increase the diagnosis and treatment of osteoporosis will be severely undermined. Reducing DXA reimbursement from approximately $140 to $40 and VFA from $40 to $25 will force primary care physicians and specialists to abandon testing and limit future purchases by other health care providers. Limited access to DXA and VFA testing will be particularly severe in rural areas where there are fewer facilities and distances to travel are greater.

We appreciate that the problems in the field of health care are complex. However, testing for osteoporosis using DXA and VFA are low cost options that can be incorporated into the primary care setting. Coupled with increased knowledge of non-pharmacologic approaches to fracture prevention and an expanding array of medications for osteoporosis prevention and treatment, these tests are of proven benefit in reducing future fractures and improving the quality of life for our patients. The Surgeon General's report on Bone Health and Osteoporosis calls on the Federal government to play a "vital leadership role...in promoting bone health. To play this role effectively, elected policymakers and other government leaders need to recognize the long-term financial and social costs of the status quo (less than optimal bone health status) and appreciate the potential to reduce these costs and improve quality of life through prevention, early detection and early treatment."[1] President Bush has declared 2002-2011 as the "Decade of the Bone and Joint." The ultimate irony would be to honor this by limiting the availability of DXA and VFA in the United States.

We are sensitive to economic concerns that try to preserve budget neutrality for medical care to Medicare beneficiaries. However, reducing DXA and VFA payments appears to be short-sighted. Given the increasing age of the United States population, coupled with the anticipated further limits on osteoporosis testing one can only expect dramatic increases in fracture-related health care costs above the current levels of $12-17 billion per year.

The ISCD appreciates this opportunity to comment on the proposed changes to the Medicare Physician Fee Schedule. We welcome any further dialogue with the Center for Medicare and Medicaid Services regarding the issues we have outlined in this letter. If you have any questions concerning ISCD's comments, please contact Donna Fiorentino (Manager Public Policy Affairs) at 860.586.7563 Ext. 553 or at dfiorentino@iscd.org.

Sincerely,

Neil Binkley, MD, CCD
President, ISCD

Sanford Baim, MD, FACR, CCD
Vice-President, ISCD

Andrew Laster, MD, FACR, CCD
Chair Public Policy, ISCD

Nelson B. Watts, MD, FACP, MACE, CCD
Past-President, ISCD

Table 1: Claims to CMS for DXA (Provided by the AMA)

CPT Code	Year		
	1994	1999	2004
76075	61,862	853,144	1,593,796
76075-26	15,271	412,352	832,565
76075-TC	3,129	65,775	129,366
Total	80,262	1,331,271	2,555,727
76075 and 26	77,133	1,265,496	2,426,361

Note: 76075-26 = professional component only; 76075-TC = technical component only

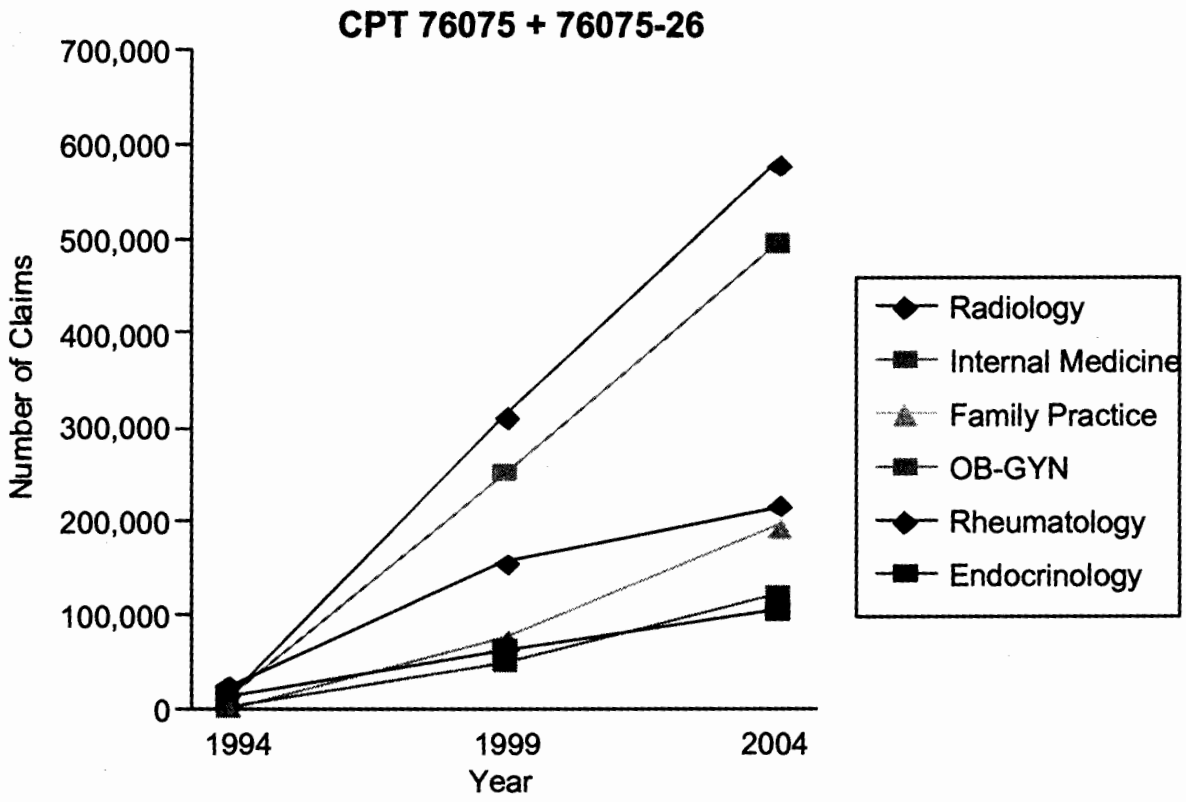
Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

Table 2: Proposed Changes in RVUs for DXA and VFA

76076	(Total)						
Year	Work	Non-Facility PE	(Office) Liability	Total	Conversion		Payment
2006	0.3	3.2	0.18	3.68	$37.90		$139.46
2007	0.2	2.57	0.18	2.95	($37.90)		$111.81
2008	0.2	1.9	0.18	2.28	($37.90)		$86.41
2009	0.2	1.3	0.18	1.68	($37.90)		$63.67
2010	0.2	0.67	0.18	1.05	($37.90)		$39.80
	(Professional)						
2006	0.3	0.1	0.01	0.41	$37.90		$15.54
2007	0.2	0.09	0.01	0.3	($37.90)		$11.37
2008	0.2	0.08	0.01	0.29	($37.90)		$10.99
2009	0.2	0.07	0.01	0.28	($37.90)		$10.61
2010	0.2	0.06	0.01	0.27	($37.90)		$10.23
	(Technical)						
2006	0	3.1	0.17	3.27	$37.90		$123.92
2007	0	2.48	0.17	2.65	($37.90)		$100.44
2008	0	1.86	0.17	2.03	($37.90)		$76.94
2009	0	1.23	0.17	1.4	($37.90)		$53.06
2010	0	0.61	0.17	0.78	($37.90)		$29.56
76077	(Total)						
2006	0.17	0.81	0.06	1.04	$37.90		$39.41
2007	0.17	0.71	0.06	0.94	($37.90)		$35.63
2008	0.17	0.61	0.06	0.84	($37.90)		$31.84
2009	0.17	0.52	0.06	0.75	($37.90)		$28.43
2010	0.17	0.42	0.06	0.65	($37.90)		$24.64
	(Professional)						
2006	0.17	0.08	0.01	0.24	$37.90		$9.10
2007	0.17	0.07	0.01	0.24	($37.90)		$9.01
2008	0.17	0.07	0.01	0.23	($37.90)		$8.91
2009	0.17	0.06	0.01	0.23	($37.90)		$8.82
2010	0.17	0.05	0.01	0.23	($37.90)		$8.72
	(Technical)						
2006	0	0.75	0.05	0.8	$37.90		$30.52
2007	0	0.66	0.05	0.71	($37.90)		$26.91
2008	0	0.56	0.05	0.61	($37.90)		$23.12
2009	0	0.47	0.05	0.52	($37.90)		$19.71
2010	0	0.37	0.05	0.42	($37.90)		$15.92

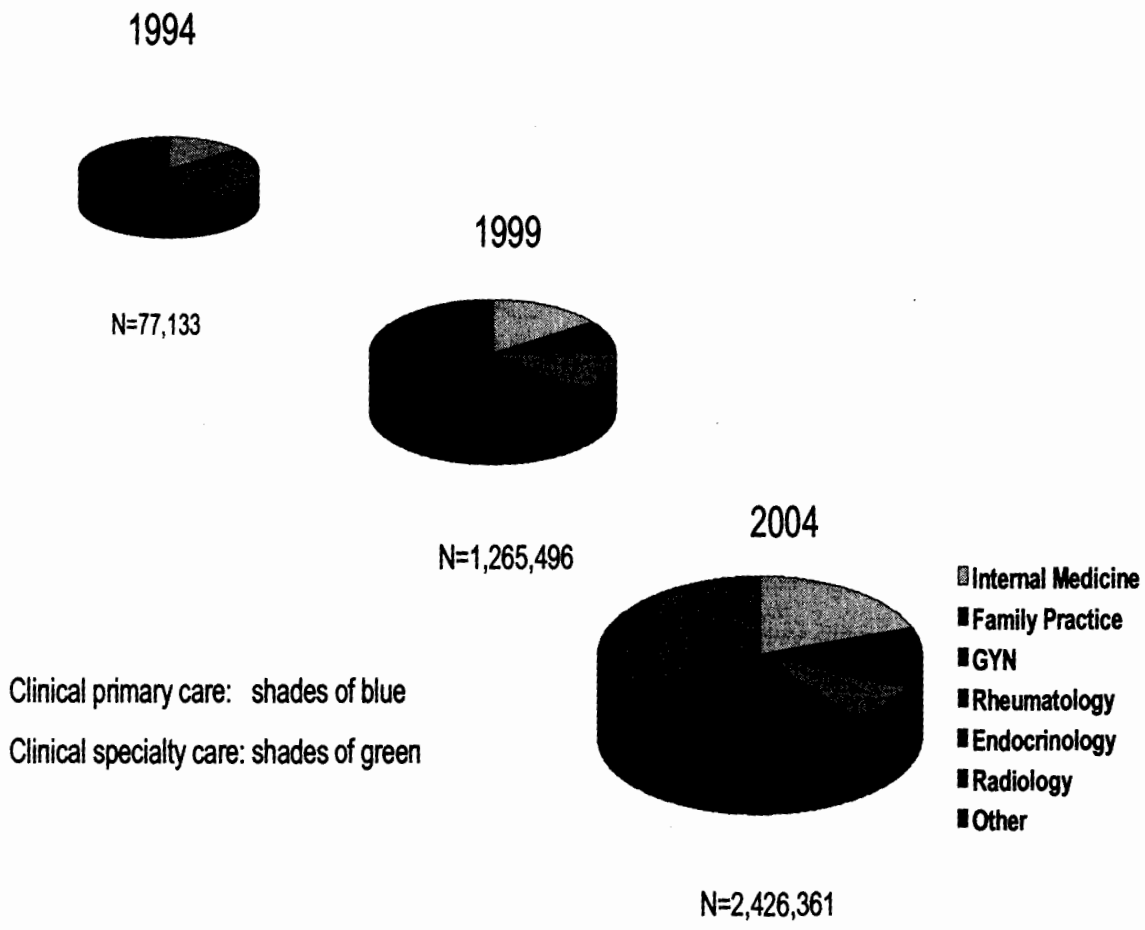
Data from Medicare Physician Fee Schedule 2006 and 2010

Figure 1: Increase in DXA testing over time



Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

Figure 2: Change in DXA Usage by Specialty Based on Claims to CMS



Excerpted from claims data provided by the AMA's Department of Physician Payment Policy and Systems

Appendix A: Official Positions of the International Society for Clinical Densitometry

The International Society for Clinical Densitometry (ISCD) is a not-for-profit multidisciplinary professional society with a mission to enhance knowledge and quality of bone densitometry among healthcare professionals, educate clinicians and technologists, increase patient awareness and access to bone densitometry, and support clinical and scientific advances in the field.

With the evolution of bone densitometry, differences in technologies, acquisition techniques, reference databases, reporting methods, and terminology have developed. These differences may have adverse effects on patient care and the exchange of scientific information. To address these issues, the ISCD periodically holds Position Development Conferences, a process whereby an international panel of experts makes recommendations based on reviews of the scientific literature by the ISCD's Scientific Advisory Committee. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD.

All ISCD Official Positions are for worldwide application except where otherwise noted.
These are the Official Positions of the ISCD as updated in 2005. **The Official Positions that are new or revised since 2003 are in bold type.** These Official Positions may also be viewed and downloaded as a text file or PowerPoint presentation from the ISCD Web site at www.ISCD.org.

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INDICATIONS FOR BONE MINERAL DENSITY (BMD) TESTING

- Women aged 65 and older.
- Postmenopausal women under age 65 with risk factors.
- Men aged 70 and older.
- Adults with a fragility fracture.
- Adults with a disease or condition associated with low bone mass or bone loss.
- Adults taking medications associated with low bone mass or bone loss.
- Anyone being considered for pharmacologic therapy.
- Anyone being treated, to monitor treatment effect.
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.

Women discontinuing estrogen should be considered for bone density testing according to the indications listed above.

REFERENCE DATABASE FOR T-SCORES

- Use a uniform Caucasian (non-race adjusted) female normative database for women of all ethnic groups.*
- Use a uniform Caucasian (non-race adjusted) male normative database for men of all ethnic groups.*
- **The NHANES III database should be used for T-score derivation at the hip regions.**

*Note: Application of recommendation may vary according to local requirements.

CENTRAL DXA FOR DIAGNOSIS

- **The WHO international reference standard for osteoporosis diagnosis is a T-score of -2.5 or less at the femoral neck.**
  - **The reference standard from which the T-score is calculated is the female, white, age 20-29 years NHANES III database.**
- **Osteoporosis may be diagnosed in postmenopausal women and in men age 50 and older if the T-score of the lumbar spine, total hip or femoral neck is -2.5 or less:***
  - **In certain circumstances the 33% radius (also called 1/3 radius) may be utilized.**

***Note: Other hip regions of interest, including Ward's area and the greater trochanter, should not be used for diagnosis. Application of recommendation may vary according to local requirements.**

- Skeletal sites to measure
  - Measure BMD at both the PA spine and hip in all patients.
  - Forearm BMD should be measured under the following circumstances:
    - Hip and/or spine cannot be measured or interpreted.
    - Hyperparathyroidism.
    - Very obese patients (over the weight limit for DXA table).

- Spine Region of Interest
  - Use PA L1-L4 for spine BMD measurement.
  - Use all evaluable vertebrae and only exclude vertebrae that are affected by local structural change or artifact. Use three vertebrae if four cannot be used and two if three cannot be used.
  - **BMD based diagnostic classification should not be made using a single vertebra.**
  - **If only one evaluable vertebra remains after excluding other vertebrae, diagnosis should be based on a different valid skeletal site.**
  - **Anatomically abnormal vertebrae may be excluded from analysis if:**
    - **They are clearly abnormal and non-assessable within the resolution of the system; or**
    - **There is more than a 1.0 T-score difference between the vertebra in question and adjacent vertebrae.**
  - **When vertebrae are excluded, the BMD of the remaining vertebrae is used to derive the T-score.**
  - Lateral spine should not be used for diagnosis, but may have a role in monitoring.

- Hip Region of Interest
  - **Use femoral neck or total proximal femur, whichever is lowest.**
  - BMD may be measured at either hip.
  - There are insufficient data to determine whether mean T-scores for bilateral hip BMD can be used for diagnosis.
  - The mean hip BMD can be used for monitoring, with total hip being preferred.

- Forearm Region of Interest
  - Use 33% radius (sometimes called one-third radius) of the non-dominant forearm for diagnosis. Other forearm regions of interest are not recommended.

FRACTURE RISK ASSESSMENT

- **A distinction is made between diagnostic classification and the use of BMD for fracture risk assessment.**
- **For fracture risk assessment any well-validated technique can be used, including measurements of more than one site, where this has been shown to improve the assessment of risk.**

USE OF THE TERM "OSTEOPENIA"

- **The term "osteopenia" is retained, but "low bone mass" or "low bone density" is preferred.**
- **People with low bone mass or density are not necessarily at high fracture risk.**

PERIPHERAL BONE DENSITOMETRY

- The World Health Organization (WHO) criteria for diagnosis of osteoporosis and osteopenia should not be used with peripheral BMD measurement other than 33% radius.
  - Peripheral measurements:
    - Are useful for assessment of fracture risk.

- Theoretically can be used to identify patients unlikely to have osteoporosis and identify patients who should be treated; however, this cannot be applied in clinical practice until device-specific cut-points are established.
- Should not be used for monitoring.

BMD REPORTING IN POSTMENOPAUSAL WOMEN AND IN MEN AGE 50 and OLDER

- **T-scores are preferred.**
- **The WHO densitometric classification is applicable.**

BMD REPORTING IN FEMALES PRIOR TO MENOPAUSE AND IN MALES YOUNGER THAN AGE 50

- **Z-scores, not T-scores, are preferred. This is particularly important in children.**
- **A Z-score of -2.0 or lower is defined as "below the expected range for age" and a Z-score above -2.0 is "within the expected range for age."**

Z-SCORE REFERENCE DATABASE

- **Z-scores should be population specific where adequate reference data exist. For the purpose of Z-score calculation, the patient's self-reported ethnicity should be used.**

DIAGNOSIS IN CHILDREN (MALES OR FEMALES LESS THAN AGE 20)

- T-scores should not be used in children; Z-scores should be used instead.
- T-scores should not appear in reports or on DXA printouts in children.
- The diagnosis of osteoporosis in children should not be made on the basis of densitometric criteria alone.
- Terminology such as "low bone density for chronologic age" or "below the expected range for age" may be used if the Z-score is below -2.0.
- Z-scores must be interpreted in the light of the best available pediatric databases of age-matched controls. The reference database should be cited in the report.
- Spine and total body are the preferred skeletal sites for measurement.
- The value of BMD to predict fractures in children is not clearly determined.
- There is no agreement on standards for adjusting BMD or bone mineral content (BMC) for factors such as bone size, pubertal stage, skeletal maturity, and body composition. If adjustments are made, they should be clearly stated in the report.
- Serial BMD studies should be done on the same machine using the same scanning mode, software and analysis when appropriate. Changes may be required with growth of the child.
- Any deviation from standard adult acquisition protocols, such as use of low-density software and manual adjustment of region of interest, should be stated in the report.

SERIAL BMD MEASUREMENT

- Serial BMD testing can be used to determine whether treatment should be started on untreated patients, because significant loss may be an indication for treatment.
- Serial BMD testing can monitor response to therapy by finding an increase or stability of bone density.
- Serial BMD testing can evaluate individuals for non-response by finding loss of bone density, suggesting the need for reevaluation of treatment and evaluation for secondary causes of osteoporosis.
- Follow-up BMD testing should be done when the expected change in BMD equals or exceeds the least significant change (LSC).
- Intervals between BMD testing should be determined according to each patient's clinical status. Typically one year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate.

- **Calculate the average BMD relationship and least significant change between the initial and new machine using the ISCD Cross Calibration Tool.**
- **Use this least significant change for comparison between previous and new system. Inter-system quantitative comparisons can only be made if cross calibration is performed on each skeletal site commonly measured.**
- **Once a new precision assessment has been performed on the new system, all future scans should be compared to scans performed on the new system using the newly established intra-system least significant change.**

- **If a cross-calibration assessment is not performed, no quantitative comparison to the prior machine can be made. Consequently, a new baseline BMD and intra-system LSC should be established.**

BMD COMPARISON BETWEEN FACILITIES

- **It is not possible to quantitatively compare BMD or to calculate a least significant change between facilities without cross-calibration.**

VERTEBRAL FRACTURE ASSESSMENT NOMENCLATURE

- **Vertebral Fracture Assessment (VFA) is the correct term to denote densitometric spine imaging performed for the purpose of detecting vertebral fractures.**

INDICATIONS FOR VFA

- **Consider VFA when the results may influence clinical management.**
- **When BMD measurement is indicated, performance of VFA should be considered in clinical situations that may be associated with vertebral fractures. Examples include:**
  - **Documented height loss of greater than 2 cm (0.75 in) or historical height loss greater than 4 cm (1.5 in) since young adult.**
  - **History of fracture after age 50.**
  - **Commitment to long-term oral or parenteral glucocorticoid therapy.**
  - **History and/or findings suggestive of vertebral fracture not documented by prior radiologic study.**

METHOD FOR DEFINING AND REPORTING FRACTURES ON VFA

- **The methodology utilized for vertebral fracture identification should be similar to standard radiological approaches and be provided in the report.**
- **Fracture diagnosis should be based on visual evaluation and include assessment of grade/severity. Morphometry alone is not recommended because it is unreliable for diagnosis.**
- **The severity of vertebral fractures may be determined using the semiquantitative (SQ) assessment criteria developed by Genant. [Genant HK et al. J Bone Miner Res. 1993;8:1137-1148] Severity of deformity may be confirmed by morphometric measurement if desired.**

INDICATIONS FOR FOLLOWING VFA WITH ANOTHER IMAGING MODALITY

- **The decision to perform additional imaging must be based on each patient's overall clinical picture including the VFA result.**
- **Consider additional imaging when there are:**
  - **Equivocal fractures.**
  - **Unidentifiable vertebrae between T7-L4.**
  - **Sclerotic or lytic changes or findings suggestive of conditions other than osteoporosis.**

Note: VFA is designed to detect vertebral fractures and not other abnormalities.

BASELINE DXA REPORT: MINIMUM REQUIREMENTS

- Demographics (name, medical record identifying number, date of birth, sex).
- Requesting provider.
- Indications for the test.

#852-3

CPT Code:

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:76075 Global Period: XXX

Recommended Work Relative Value
Specialty Society RVU: **0.30**
RUC RVU: **0.20**

CPT Descriptor: Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (eg, hips, pelvis, spine)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

(Note: 76077 Vertebral fracture assessment when ordered and performed is coded separately)

Percentage of Survey Respondents who found Vignette to be Typical: 93%

Is conscious sedation inherent to this procedure? No Percent of survey respondents who stated it is typical? 0%

Is conscious sedation inherent in your reference code? No

Description of Pre-Service Work:

- Review the reason for the exam and any pertinent clinical history
- Review any prior DXA studies

Description of Intra-Service Work:

- Review scout images to assure scanning technique was satisfactory
- Interpret the DXA scan data and compare to established norms
- Compare the results of the DXA scan to previous studies
- Dictate report for the medical record

Description of Post-Service Work:

- Review and sign final report
- Discuss findings with referring physician

SURVEY DATA

RUC Meeting Date (mm/yyyy)	08/2005					
Presenter(s):	Bibb Allen, Jr., M.D. and Jonathan Berlin, M. D.					
Specialty(s):	American College of Radiology					
CPT Code:	76075					
Sample Size:	240	**Resp n:** 51		**Response:** 0.00 %		
Sample Type:	Random					
		Low	**25th pctl**	**Median***	**75th pctl**	**High**
Survey RVW:		0.05	0.20	**0.30**	0.45	0.92
Pre-Service Evaluation Time:				**1.0**		
Pre-Service Positioning Time:				**0.0**		
Pre-Service Scrub, Dress, Wait Time:				**0.0**		
Intra-Service Time:		1.00	2.00	**4.00**	5.00	15.00

Post-Service	**Total Min****	**CPT code / # of visits**
Immed. Post-time:	**1.00**	
Critical Care time/visit(s):	**0.0**	99291x **0.0** 99292x **0.0**
Other Hospital time/visit(s):	**0.0**	99231x **0.0** 99232x **0.0** 99233x **0.0**
Discharge Day Mgmt:	**0.0**	99238x **0.00** 99239x **0.00**
Office time/visit(s):	**0.0**	99211x **0.0** 12x **0.0** 13x **0.0** 14x **0.0** 15x **0.0**

**Physician standard total minutes per E/M visit: 99291 (63); 99292 (32); 99233 (41); 99232 (30); 99231 (19); 99238 (36); 99215 (59); 99214 (38); 99213 (23); 99212 (15); 99211 (7).

CPT Code:

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU
72050	XXX	0.31

CPT Descriptor Radiologic examination, spine, cervical; minimum of four views

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU
73560	XXX	0.17

CPT Descriptor 1 Radiologic examination, knee; one or two views

MPC CPT Code 2	Global	Work RVU
74400	XXX	0.49

CPT Descriptor 2 Urography (pyelography), intravenous, with or without KUB, with or without tomography

Other Reference CPT Code	Global	Work RVU

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 12 **% of respondents:** 23.5 **%**

TIME ESTIMATES (Median)

	CPT Code: 76075	**Key Reference CPT Code: 72050**
Median Pre-Service Time	1.00	0.00
Median Intra-Service Time	4.00	0.00
Median Immediate Post-service Time	1.00	0.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Median Total Time	**6.00**	**0.00**
Other time if appropriate		8.00

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgment (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	1.42	2.82

		CPT Code:
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	2.17	2.64
Urgency of medical decision making	1.25	2.73

Technical Skill/Physical Effort (Mean)

Technical skill required	1.67	2.09
Physical effort required	1.33	1.45

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	1.50	2.91
Outcome depends on the skill and judgment of physician	1.67	3.09
Estimated risk of malpractice suit with poor outcome	1.42	3.27

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1

Time Segments (Mean)

Pre-Service intensity/complexity	1.60	1.78
Intra-Service intensity/complexity	2.08	2.70
Post-Service intensity/complexity	1.82	2.10

COMPELLING EVIDENCE RATIONALE (Required to be Completed)

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The ACR RUC Committee reviewed the survey data and concluded there is no compelling evidence to change the work RVU for this service. Rationale for the no change recommendation includes:

1. The RUC Committee considered the intensity of 76075 to be similar to the plain radiograph family of codes.
2. Time data is consistent with other XXX codes with similar RVU values. (For example, the work value and survey time for DXA is consistent with that obtained for code 74022 (Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest) in this Five Year Review.
3. Comparison to 73560 (Radiologic examination knee; one or two views) on the MPC A List with:
   Work RVU: 0.17 RVU
   Pre-service Time: 0 minutes
   Intra-service Time: 3 minutes
   Post Service Time: 0 minutes
4. Intensity/complexity measures are similar to the reference service.

CPT Code:

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

Five-Year Review Specific Questions:

Please indicate the number of survey respondent percentages responding to each of the following questions (for example 0.05 =5%):

Has the work of performing this service changed in the past 5 years? Yes 33% No 67%

A. This service represents new technology that has become more familiar (i.e., less work):
   I agree 12% I do not agree 88%
B. Patients requiring this service are now:
   more complex (more work) 59% less complex (less work) no change 41%
C. The usual site-of-service has changed:
   from outpatient to inpatient from inpatient to outpatient 18% no change 82%

Addendum to RUC Summary of Recommendation Form
Five-Year Review of Physician Work
Resulting Practice Expense Direct Input Modifications

CPT Code: N/A

Current Time Data *(2005 Medicare Physician Payment Schedule – Utilize Report Provided by AMA Staff with Survey Packet)*

Complete if Code is priced in the non-facility:			
Physician Intra-Service Time:			
Clinical Staff #1	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time
Clinical Staff #2	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time
Complete if the global period is 010, or 090			
Discharge Day (none, ½, or full)		99238:	
Number and Level of Office Visits:		99211:	
		99212:	
		99213:	
		99214:	
		99215:	

Revised Time Data *(Base physician time data on new survey data and recommendations; use current staff type and ratios from above to compute new clinical staff intra assist physician time. The change in staff intra-assist physician time is the difference between the current and revised intra-assist physician time)*

Complete if Code is priced in the non-facility:			
Physician Intra-Service Time:			
Clinical Staff #1	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time **Change: In Time**
Clinical Staff #2	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time **Change: In Time**
Complete if the global period is 010, or 090			
Discharge Day (none, ½, or full)		**99238:**	
Number and Level of Office Visits:		**99211:**	
		99212:	
		99213:	
		99214:	
		99215:	

#853-4

CPT Code:

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

Recommended Work Relative Value

CPT Code:76075 Global Period: XXX Specialty Society RVU: **0.30**
RUC RVU:

CPT Descriptor: Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (eg, hips, pelvis, spine)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

(Note: 76077 Vertebral fracture assessment when ordered and performed is coded separately)

Percentage of Survey Respondents who found Vignette to be Typical: 93%

Is conscious sedation inherent to this procedure? No Percent of survey respondents who stated it is typical? 0%

Is conscious sedation inherent in your reference code? No

Description of Pre-Service Work:

- Review the reason for the exam and any pertinent clinical history
- Review any prior DXA studies

Description of Intra-Service Work:

- Review scout images to assure scanning technique was satisfactory
- Interpret the DXA scan data and compare to established norms
- Compare the results of the DXA scan to previous studies
- Dictate report for the medical record

Description of Post-Service Work:

- Review and sign final report
- Discuss findings with referring physician

CPT Code:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	08/2005					
Presenter(s):	Bibb Allen, Jr., M.D. and Jonathan Berlin, M. D.					
Specialty(s):	American College of Radiology					
CPT Code:	76075					
Sample Size: 240	**Resp n:** 51	**Response:** 0.00 %				
Sample Type:	Random					
	Low	**25th pctl**	**Median***	**75th pctl**	**High**	
Survey RVW:	0.05	0.20	**0.30**	0.45	0.92	
Pre-Service Evaluation Time:			**2.0**			
Pre-Service Positioning Time:			**0.0**			
Pre-Service Scrub, Dress, Wait Time:			**0.0**			
Intra-Service Time:	1.00	2.00	**4.00**	5.00	15.00	

Post-Service	**Total Min****	**CPT code / # of visits**
Immed. Post-time:	**2.00**	
Critical Care time/visit(s):	**0.0**	99291x **0.0** 99292x **0.0**
Other Hospital time/visit(s):	**0.0**	99231x **0.0** 99232x **0.0** 99233x **0.0**
Discharge Day Mgmt:	**0.0**	99238x **0.00** 99239x **0.00**
Office time/visit(s):	**0.0**	99211x **0.0** 12x **0.0** 13x **0.0** 14x **0.0** 15x **0.0**

**Physician standard total minutes per E/M visit: 99291 (63); 99292 (32); 99233 (41); 99232 (30); 99231 (19); 99238 (36); 99215 (59); 99214 (38); 99213 (23); 99212 (15); 99211 (7).

CPT Code:

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU
72050	XXX	0.31

CPT Descriptor Radiologic examination, spine, cervical; minimum of four views

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU
73560	XXX	0.17

CPT Descriptor 1 Radiologic examination, knee; one or two views

MPC CPT Code 2	Global	Work RVU
74400	XXX	0.49

CPT Descriptor 2 Urography (pyelography), intravenous, with or without KUB, with or without tomography

Other Reference CPT Code	Global	Work RVU

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 12 **% of respondents:** 23.5 **%**

TIME ESTIMATES (Median)

	CPT Code: 76075	Key Reference CPT Code: 72050
Median Pre-Service Time	2.00	0.00
Median Intra-Service Time	4.00	0.00
Median Immediate Post-service Time	2.00	0.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Median Total Time	**8.00**	**0.00**
Other time if appropriate		8.00

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgment (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	1.42	2.82

		CPT Code:
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	2.17	2.64
Urgency of medical decision making	1.25	2.73
Technical Skill/Physical Effort (Mean)		
Technical skill required	1.67	2.09
Physical effort required	1.33	1.45
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	1.50	2.91
Outcome depends on the skill and judgment of physician	1.67	3.09
Estimated risk of malpractice suit with poor outcome	1.42	3.27

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	1.60	1.78
Intra-Service intensity/complexity	2.08	2.70
Post-Service intensity/complexity	1.82	2.10

COMPELLING EVIDENCE RATIONALE (Required to be Completed)

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The ACR RUC Committee reviewed the survey data and concluded there is no compelling evidence to change the work RVU for this service. Rationale for the no change recommendation includes:

1. The RUC Committee considered the intensity of 76075 to be similar to the plain radiograph family of codes.
2. Time data is consistent with other XXX codes with similar RVU values. (For example, the work value and survey time for DXA is consistent with that obtained for code 74022 (Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest) in this Five Year Review.
3. Comparison to 73560 (Radiologic examination knee; one or two views) on the MPC A List with:
   Work RVU: 0.17 RVU
   Pre-service Time: 0 minutes
   Intra-service Time: 3 minutes
   Post Service Time: 0 minutes
4. Intensity/complexity measures are similar to the reference service.

CPT Code:

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

Five-Year Review Specific Questions:

Please indicate the number of survey respondent percentages responding to each of the following questions (for example 0.05 =5%):

Has the work of performing this service changed in the past 5 years? Yes 33% No 67%

A. This service represents new technology that has become more familiar (i.e., less work):
   I agree 12% I do not agree 88%
B. Patients requiring this service are now:
   more complex (more work) 59% less complex (less work) no change 41%
C. The usual site-of-service has changed:
   from outpatient to inpatient from inpatient to outpatient 18% no change 82%

Addendum to RUC Summary of Recommendation Form
Five-Year Review of Physician Work
Resulting Practice Expense Direct Input Modifications

CPT Code: N/A

Current Time Data *(2005 Medicare Physician Payment Schedule – Utilize Report Provided by AMA Staff with Survey Packet)*

Complete if Code is priced in the non-facility:			
Physician Intra-Service Time:			
Clinical Staff #1	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time
Clinical Staff #2	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time
Complete if the global period is 010, or 090			
Discharge Day (none, ½, or full)		99238:	
Number and Level of Office Visits:		99211:	
		99212:	
		99213:	
		99214:	
		99215:	

Revised Time Data *(Base physician time data on new survey data and recommendations; use current staff type and ratios from above to compute new clinical staff intra assist physician time. The change in staff intra-assist physician time is the difference between the current and revised intra-assist physician time)*

Complete if Code is priced in the non-facility:			
Physician Intra-Service Time:			
Clinical Staff #1	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time **Change: In Time**
Clinical Staff #2	Staff Type:	Intra Assist Physician Time:	Staff % of Physician time **Change: In Time**
Complete if the global period is 010, or 090			
Discharge Day (none, ½, or full)		**99238:**	
Number and Level of Office Visits:		**99211:**	
		99212:	
		99213:	
		99214:	
		99215:	

Submitter : **Mr. John Outlaw** **Date: 10/10/2006**

Organization : **Pathology Service Associates, LLC**

Category : **Laboratory Industry**

Issue Areas/Comments

GENERAL

GENERAL

RE: REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

SUMMARY: POD labs and the like will continue to thrive despite attempts to erect technical barriers as long as the financial incentive to profit from self-referrals remains in place. Therefore, we believe that the most effective means of addressing the fraud and abuse threat posed by the pod lab model is to exclude anatomic pathology services from the in-office ancillary services exception.

See Attachment.

CMS-1321-P-853-Attach-1.PDF

#833

PSA
Pathology Service Associates, LLC

181 East Evans Street • Suite 301 • Florence, SC 29506
P.O. Box 100559 • Florence, SC 29501-0559

843-664-4300 • 800-832-5270 • Fax 843-664-4322
psapath@psapath.com • www.psapath.com

9 October 2006

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

RE: REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

Dear Dr. McClellan:

Pathology Service Associates, LLC (PSA) wishes to offer the following comments on changes to the Medicare reassignment and physician self-referral rules as proposed in the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B", CMS-1321-P (71 Fed. Reg. 48982, August 22, 2006). PSA is a business support service company for independent practices of pathology, providing billing and other back-office solutions for some 380 pathologists in 24 states. Unfortunately, we have seen that very independence which we seek to preserve as a highly-valued and necessary element in providing high-quality patient care threatened in recent years. A variety of schemes have been carefully crafted to subvert the intent of Medicare policy by circumventing the very laws, rules and regulations meant to constrain them. Therefore, we applaud CMS' latest proposed changes designed specifically to curb the recent growth of these so-called "pod" or "condo" laboratories.

Perhaps more important, however, we encourage CMS to take aggressive action now to fend off a newer, and perhaps larger, threat to the truly independent practice of pathology, which has appeared recently in the form of in-office (POL) anatomic pathology labs. These labs are a result of the various warnings and prohibitions against the pod labs, crafted specifically to achieve "technical" compliance with the in-office ancillary exception and other Medicare laws, rules and regulations. These anatomic POL's still pose the same threat in the form of economic incentives and therefore the potential for abuse in the increased utilization of anatomic pathology services.

While we are generally supportive of CMS' efforts to restrict the various contractual joint ventures which threaten independence of the pathology industry, we believe that continuing to address this issue through various technical requirements, however well-thought and intended, will have little practical long-term impact. As long as anatomic

pathology services continue to be viewed as a potential new source of revenue for certain specialty physician practices, permitting them to profit from their own self-referrals, they will find a way to circumvent the technical requirements of the law.

For that reason, we believe that the most effective means of addressing this threat is to **exclude anatomic pathology services from the in-office ancillary services exception.** We believe this will effectively eliminate the financial incentives that create the most significant threat of fraud and abuse in the program, while preserving the ability of physicians to provide these necessary services for the care of their patients, as purchased services under existing regulations. To that end, we ask CMS to work with the College of American Pathologists (CAP) to develop appropriate regulatory language that will deal more directly with the root cause of the current abuse in the pod and anatomic POL schemes by removing the financial incentive currently associated with the self-referral for anatomic pathology services.

Thank you for the opportunity to provide these comments.

Respectfully,

John R. Outlaw, CHC
Chief Compliance Officer
Pathology Service Associates, LLC
PO Box 100559
Florence, SC 29501-0559

Submitter : Dr. Steven Nissen **Date:** 10/10/2006

Organization : American College of Cardiology

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-830-Attach-1.PDF

CMS-1321-P-830-Attach-2.PDF

#830-1

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Heart House
2400 N St., NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

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Steven E. Nissen, M.D., F.A.C.C.

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Kim Allan Williams, M.D., F.A.C.C.
Michael J. Wolk, M.D., M.A.C.C.
Janet S. Wright, M.D., F.A.C.C.
William A. Zoghbi, M.D., F.A.C.C.
*ex officio

Interim Chief Staff Officer and General Counsel
Thomas E. Arend, Jr.

October 10, 2006

Leslie V. Norwalk, Esquire
Acting 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 21244-8018

Dear Ms. Norwalk:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS 1321-P)** published in the *Federal Register* on August 22, 2006. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

DRA Proposals

Section 5102 Multiple imaging procedures

The ACC supports CMS's proposal to maintain the payment reduction for the technical component of certain multiple imaging procedures at 25 percent for the second and any subsequent procedures instead of the previously proposed 50 percent. As we noted in comments submitted previously, we recognize that physician practices may achieve some savings in practice expenses when multiple imaging procedures are performed on contiguous body parts during

the same patient care session. However, the ACC disagreed that the data on direct practice expense inputs supported a reduction of 50 percent. We are pleased that CMS has responded favorably.

As a result of the savings from the multiple imaging procedure payment reduction, CMS increased the 2006 practice expense RVUs by 0.3 percent. The proposed rule notes that this increase will be removed from the 2007 practice expense RVUs to comply with the Deficit Reduction Act (DRA) requirement that the multiple imaging procedure payment reduction be exempted from the budget neutrality requirement. The ACC understands that CMS is merely complying with the statute in making this change. We must note, however, our strong objection to singling out one type of physician service to achieve savings in overall Medicare physician payments.

Section 5102 Limit on payment for technical component of imaging procedures

The ACC strongly opposes the DRA provision limiting payment for the technical component of imaging services to the lesser of the payment amount under the Medicare physician fee schedule or the payment amount under the hospital outpatient prospective payment system (OPPS). We object to the process through which it was enacted without full discussion and public debate, to the precedent it sets of targeting imaging services to achieve savings in physician payment, and to the invalid comparison it makes between two fundamentally different payment systems. We recognize, nevertheless, that CMS must implement the statutory requirement. ACC's comments on several aspects CMS's proposal for implementing this DRA provision follow.

Definition of imaging services

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the OPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS proposes to define imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We believe this proposed definition is overly broad and, theoretically, could even apply to open surgical techniques. We recommend the following definition of imaging for purposes of implementing the DRA:

Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization, or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the

absence of minimally invasive diagnostic procedures and interventions; and without this type of imaging only open surgical procedures would be possible.

The ACC does not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors. We believe that these services should not be subject to the DRA reimbursement cap.

Services included in Addendum F

The preamble to the proposed rule states "We excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap." However, Addendum F includes 93555 and 93556 (Imaging, cardiac catheterization). Under OPPS imaging guidance is bundled into the payment for cardiac catheterization, so there is no separate OPPS payment corresponding to either 93555 or 93556. We believe CMS included these two codes in error and we urge that they be removed from Addendum F.

The ACC also recommends that CMS exclude Category III CPT codes from the list of procedures subject to the DRA cap on payments for the technical component of imaging services. By definition, Category III codes describe emerging technology. Thus, no RVUs have been assigned to reflect costs in the physician office setting and OPPS payment rates do not reflect the costs of providing these procedures in the hospital outpatient setting. Therefore, the ACC believes it is inappropriate to apply the DRA payment limitation to emerging technology services currently identified by Category III CPT codes.

Services subject to both the DRA cap and the multiple procedure payment reduction

The ACC supports CMS's decision to apply the multiple procedure payment reduction first for those services subject to both the cap on the technical component payment and the multiple imaging procedure payment reduction.

Resource Based Practice Expense RVU Proposals for 2007

The ACC's comments on the June 29, 2006 proposed rule included a discussion of our concerns about the significant decreases in practice expense RVUs proposed for cardiac catheterization services performed in the non-facility setting (CPT 93510 - 93533). As we noted, we believe that the magnitude of the proposed cuts for these services reflects, in large measure, weaknesses in data used for establishing both the direct and indirect cost portions of the RVUs.

In the August proposed rule, CMS proposed carrier pricing for these codes. We agree that the data problems affecting these codes are so significant that even the proposed first year

transition values are probably inappropriate and could adversely affect patient access. We believe, though, that carrier pricing is not the most appropriate strategy for establishing 2007 values. It is our understanding that other commenters will be submitting to CMS data on direct expenses. The ACC has not yet reviewed these data. We plan to work closely with all affected stakeholders to review existing data, gather any additional data needed, and request prompt review by the PERC. Until the ACC and the PERC can complete this review, we recommend that CMS use the 2006 non-facility RVUs for CPT 93510 - 93533 as interim values for 2007.

Cardiac monitoring

The ACC remains concerned that the significantly reduced practice expense RVUs proposed for remote cardiac monitoring services could threaten patient access to these important services. We are pleased that CMS has requested additional practice expense data for these procedures. We note that CPT 93236 (24 hour electrocardiographic monitoring) should be added to the list. The ACC concurs with CMS's assessment that remote cardiac monitoring services do not fit the typical physician service model for purposes of developing direct practice expense inputs. Consequently, the current direct practice expense inputs do not capture all practice expenses required to provide remote cardiac monitoring services. We look forward to working with CMS and remote cardiac monitoring services providers to gather and review the necessary data.

Supply and equipment information

Tables 1 and 2 in the preamble to the proposed rule identified several supply and equipment items for which CMS needs of current price information. Following is ACC's response to this request.

Table 1 Supply items needing specialty input for pricing			
Code	Description	New price	Source
SK 105	Blood pressure recording form	NA	
This item can be deleted. The ambulatory blood pressure monitoring system for which we are providing new price information generates the form, so separate pricing is not necessary.			
SD 140	Pressure bag	$95.00 per 5 unit box	McKesson
SD 213	Tubing, sterile, non-vented (fluid administration)	$47.46 per 50 unit box	McKesson
Table 2 Equipment items needing specialty input for pricing			
Code	Description	New price	Source
EQ 269	Ambulatory blood pressure monitor	$1920	Tiba Medical
EQ 008	ECG signal averaging system	$17,900	GE
System includes ECG cart ($12,500), software for late potential QRS ($3,200), and software for P-wave measurement which is less common ($2,200).			

We have forwarded this information, along with documentation of the prices to the responsible CMS staff.

PLI RVUs

Currently, CMS assigns professional liability insurance (PLI) RVUs to the professional and technical components of codes by allocating the PLI RVUs for the global code on the basis of the division of practice expense RVUs between the two components. The ACC believes that in the case of imaging services, this approach results in PLI RVUs that do not accurately reflect the relative professional liability costs associated with the professional and technical components. Although the technical performance of an imaging service does entail some professional liability risk, the liability risk associated with the physician interpretation of the imaging service is much greater. We urge CMS to develop a more accurate method for distributing the PLI RVUS between professional and technical components. Development of such a method may not be accomplished quickly. In the short term, therefore, we recommend that CMS reverse the current assignment of PLI RVUs between technical and professional components.

Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

The ACC has strongly and consistently supported efforts to eliminate or severely reduce opportunities for fraud and abuse in the Medicare program. The proposed rule revisions to the physician self-referral rules appear to target apparent abuses within pathology services. The ACC, therefore, recommends that CMS strictly limit the application of these changes—if adopted—to the field of pathology at the present time.

We believe this is the most appropriate course of action for CMS to pursue at this time, as it is our understanding that the medical societies representing pathologists initiated the development of these proposed rule changes with the agency out of concern for the specific practices emerging in that field (i.e. "pod-labs."). Further, we also understand that the proposed revisions are the product of a collaborative effort between CMS and those pathologist groups, and that the revisions generally meet with the pathology groups' approval. The ACC commends CMS for taking this collaborative approach to rulemaking.

As noted by the preamble itself, CMS is seeking comments on whether the proposed changes should apply strictly to pathology services, or if they should also extend to diagnostic imaging and other services beyond pathology (71 Fed. Reg. 49056; August 22, 2006).At the present time, we believe that the impact of these proposed regulations on diagnostic imaging and other non-pathology services cannot be accurately studied within the relatively short timeframe afforded by the comment period for the proposed 2007 Medicare Physician Fee Schedule. Among possible ACC concerns requiring additional study:

- The proposed conditions of permissible billing for technical and/or professional components (TC/PC, respectively) of testing services may significantly interfere

with physician group practices' flexibility in legitimately contracting with independent physicians, thereby potentially increasing costs to the Medicare program; and

- The proposed changes to the reassignment rules, along with the modifications to the "centralized building" requirements may also significantly impede the incorporation of certain diagnostic imaging services into (non-radiology) physician group practice settings—potentially closing opportunities to reduce costs and inefficiencies in the delivery of these critical services to Medicare beneficiaries.

To ensure that such rules with potentially wide-ranging and disruptive effects on the quality of care are adequately studied prior to adoption, the ACC reiterates its strong recommendation that CMS limit the application of these proposed revisions strictly to pathology services (e.g. pod-labs, etc.), and that the agency engage with the ACC and other stakeholder groups to study and develop solutions to potential fraud and abuse concerns in other areas of care. The ACC remains eager to work with CMS on such an endeavor.

Independent Diagnostic Testing Facility (IDTF) Issues

With regard to the application of the proposed standards to IDTFs, the ACC recommends that CMS carefully evaluate whether, as currently written, they should apply uniformly to the diverse array of services provided by these entities. We also encourage CMS to consider accreditation status as an alternative mechanism for compliance with the proposed standards. Specifically, we suggest that entities that have been accredited by a nationally recognized accreditation body, such as the Intersocietal Accreditation Commission, could be deemed to be in compliance with Medicare's IDTF standards. In the alternative, the ACC urges CMS to work with IDTFs and other stakeholders to ensure that the proposed standards properly target questionable practices while not impeding the provision of legitimate and beneficial services for Medicare beneficiaries.

Promoting Effective Use of Health Information Technology (HIT)

The ACC strongly supports the incorporation of health information technology (HIT) into the practice of medicine and throughout the health care industry in general, out of recognition for both the potentially significant improvements to the quality of care provided to patients and the administrative cost savings involved.

We agree with CMS' conclusion that the selection and promotion of voluntary data and systems standards is key to achieving effective HIT implementation among providers and payers. It is critical to the success of HIT implementation that the process for developing standards must include thorough consideration by HHS/CMS of the input from all stakeholders.

#830-2

Helping Cardiovascular Professionals Learn. Advance. Heal.

Heart House
2400 N St., NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

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President-Elect
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**ex officio*

Interim Chief Staff Officer and General Counsel
Thomas E. Arend, Jr.

October 10, 2006

Leslie V. Norwalk, Esquire
Acting 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 21244-8018

Dear Ms. Norwalk:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS 1321-P)** published in the *Federal Register* on August 22, 2006. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

DRA Proposals

Section 5102 Multiple imaging procedures

The ACC supports CMS's proposal to maintain the payment reduction for the technical component of certain multiple imaging procedures at 25 percent for the second and any subsequent procedures instead of the previously proposed 50 percent. As we noted in comments submitted previously, we recognize that physician practices may achieve some savings in practice expenses when multiple imaging procedures are performed on contiguous body parts during

the same patient care session. However, the ACC disagreed that the data on direct practice expense inputs supported a reduction of 50 percent. We are pleased that CMS has responded favorably.

As a result of the savings from the multiple imaging procedure payment reduction, CMS increased the 2006 practice expense RVUs by 0.3 percent. The proposed rule notes that this increase will be removed from the 2007 practice expense RVUs to comply with the Deficit Reduction Act (DRA) requirement that the multiple imaging procedure payment reduction be exempted from the budget neutrality requirement. The ACC understands that CMS is merely complying with the statute in making this change. We must note, however, our strong objection to singling out one type of physician service to achieve savings in overall Medicare physician payments.

Section 5102 Limit on payment for technical component of imaging procedures

The ACC strongly opposes the DRA provision limiting payment for the technical component of imaging services to the lesser of the payment amount under the Medicare physician fee schedule or the payment amount under the hospital outpatient prospective payment system (OPPS). We object to the process through which it was enacted without full discussion and public debate, to the precedent it sets of targeting imaging services to achieve savings in physician payment, and to the invalid comparison it makes between two fundamentally different payment systems. We recognize, nevertheless, that CMS must implement the statutory requirement. ACC's comments on several aspects CMS's proposal for implementing this DRA provision follow.

Definition of imaging services

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the OPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS proposes to define imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We believe this proposed definition is overly broad and, theoretically, could even apply to open surgical techniques. We recommend the following definition of imaging for purposes of implementing the DRA:

Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization, or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the

transition values are probably inappropriate and could adversely affect patient access. We believe, though, that carrier pricing is not the most appropriate strategy for establishing 2007 values. It is our understanding that other commenters will be submitting to CMS data on direct expenses. The ACC has not yet reviewed these data. We plan to work closely with all affected stakeholders to review existing data, gather any additional data needed, and request prompt review by the PERC. Until the ACC and the PERC can complete this review, we recommend that CMS use the 2006 non-facility RVUs for CPT 93510 - 93533 as interim values for 2007.

Cardiac monitoring

The ACC remains concerned that the significantly reduced practice expense RVUs proposed for remote cardiac monitoring services could threaten patient access to these important services. We are pleased that CMS has requested additional practice expense data for these procedures. We note that CPT 93236 (24 hour electrocardiographic monitoring) should be added to the list. The ACC concurs with CMS's assessment that remote cardiac monitoring services do not fit the typical physician service model for purposes of developing direct practice expense inputs. Consequently, the current direct practice expense inputs do not capture all practice expenses required to provide remote cardiac monitoring services. We look forward to working with CMS and remote cardiac monitoring services providers to gather and review the necessary data.

Supply and equipment information

Tables 1 and 2 in the preamble to the proposed rule identified several supply and equipment items for which CMS needs of current price information. Following is ACC's response to this request.

Table 1 Supply items needing specialty input for pricing			
Code	Description	New price	Source
SK 105	Blood pressure recording form	NA	
This item can be deleted. The ambulatory blood pressure monitoring system for which we are providing new price information generates the form, so separate pricing is not necessary.			
SD 140	Pressure bag	$95.00 per 5 unit box	McKesson
SD 213	Tubing, sterile, non-vented (fluid administration)	$47.46 per 50 unit box	McKesson
Table 2 Equipment items needing specialty input for pricing			
Code	Description	New price	Source
EQ 269	Ambulatory blood pressure monitor	$1920	Tiba Medical
EQ 008	ECG signal averaging system	$17,900	GE
System includes ECG cart ($12,500), software for late potential QRS ($3,200), and software for P-wave measurement which is less common ($2,200).			

We have forwarded this information, along with documentation of the prices to the responsible CMS staff.

PLI RVUs

Currently, CMS assigns professional liability insurance (PLI) RVUs to the professional and technical components of codes by allocating the PLI RVUs for the global code on the basis of the division of practice expense RVUs between the two components. The ACC believes that in the case of imaging services, this approach results in PLI RVUs that do not accurately reflect the relative professional liability costs associated with the professional and technical components. Although the technical performance of an imaging service does entail some professional liability risk, the liability risk associated with the physician interpretation of the imaging service is much greater. We urge CMS to develop a more accurate method for distributing the PLI RVUS between professional and technical components. Development of such a method may not be accomplished quickly. In the short term, therefore, we recommend that CMS reverse the current assignment of PLI RVUs between technical and professional components.

Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

The ACC has strongly and consistently supported efforts to eliminate or severely reduce opportunities for fraud and abuse in the Medicare program. The proposed rule revisions to the physician self-referral rules appear to target apparent abuses within pathology services. The ACC, therefore, recommends that CMS strictly limit the application of these changes—if adopted—to the field of pathology at the present time.

We believe this is the most appropriate course of action for CMS to pursue at this time, as it is our understanding that the medical societies representing pathologists initiated the development of these proposed rule changes with the agency out of concern for the specific practices emerging in that field (i.e. "pod-labs."). Further, we also understand that the proposed revisions are the product of a collaborative effort between CMS and those pathologist groups, and that the revisions generally meet with the pathology groups' approval. The ACC commends CMS for taking this collaborative approach to rulemaking.

As noted by the preamble itself, CMS is seeking comments on whether the proposed changes should apply strictly to pathology services, or if they should also extend to diagnostic imaging and other services beyond pathology (71 Fed. Reg. 49056; August 22, 2006).At the present time, we believe that the impact of these proposed regulations on diagnostic imaging and other non-pathology services cannot be accurately studied within the relatively short timeframe afforded by the comment period for the proposed 2007 Medicare Physician Fee Schedule. Among possible ACC concerns requiring additional study:

- The proposed conditions of permissible billing for technical and/or professional components (TC/PC, respectively) of testing services may significantly interfere

with physician group practices' flexibility in legitimately contracting with independent physicians, thereby potentially increasing costs to the Medicare program; and

- The proposed changes to the reassignment rules, along with the modifications to the "centralized building" requirements may also significantly impede the incorporation of certain diagnostic imaging services into (non-radiology) physician group practice settings—potentially closing opportunities to reduce costs and inefficiencies in the delivery of these critical services to Medicare beneficiaries.

To ensure that such rules with potentially wide-ranging and disruptive effects on the quality of care are adequately studied prior to adoption, the ACC reiterates its strong recommendation that CMS limit the application of these proposed revisions strictly to pathology services (e.g. pod-labs, etc.), and that the agency engage with the ACC and other stakeholder groups to study and develop solutions to potential fraud and abuse concerns in other areas of care. The ACC remains eager to work with CMS on such an endeavor.

Independent Diagnostic Testing Facility (IDTF) Issues

With regard to the application of the proposed standards to IDTFs, the ACC recommends that CMS carefully evaluate whether, as currently written, they should apply uniformly to the diverse array of services provided by these entities. We also encourage CMS to consider accreditation status as an alternative mechanism for compliance with the proposed standards. Specifically, we suggest that entities that have been accredited by a nationally recognized accreditation body, such as the Intersocietal Accreditation Commission, could be deemed to be in compliance with Medicare's IDTF standards. In the alternative, the ACC urges CMS to work with IDTFs and other stakeholders to ensure that the proposed standards properly target questionable practices while not impeding the provision of legitimate and beneficial services for Medicare beneficiaries.

Promoting Effective Use of Health Information Technology (HIT)

The ACC strongly supports the incorporation of health information technology (HIT) into the practice of medicine and throughout the health care industry in general, out of recognition for both the potentially significant improvements to the quality of care provided to patients and the administrative cost savings involved.

We agree with CMS' conclusion that the selection and promotion of voluntary data and systems standards is key to achieving effective HIT implementation among providers and payers. It is critical to the success of HIT implementation that the process for developing standards must include thorough consideration by HHS/CMS of the input from all stakeholders.

For these reasons, the ACC recommends that CMS continue to collaborate with all stakeholders in the process of developing HIT standards and implementation timeframes, only establishing and promoting such standards after carefully considering such input.

Health Care Information Transparency Initiative

The ACC shares with CMS concerns regarding rapidly escalating health care costs and expenditures, and recognizes the need to implement reforms aimed at introducing cost efficiencies while also improving the quality of care provided. While "transparency" of costs and prices may indeed have an important role to play in helping to curb the growth of health care costs, we have concerns regarding possible misrepresentations or misinterpretations of such data, particularly in the latter example by patients. To ensure complete and accurate data is assembled for these consumer resources, we urge CMS not to rely exclusively on claims data, and instead incorporate information from a variety of sources.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,

Steven E. Nissen, MD, FACC
President

Submitter : **Mr. Rob Foreman** **Date: 10/10/2006**

Organization : **Kidney Care Council**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-1321-P-854-Attach-1.PDF

CMS-1321-P-854-Attach-2.PDF

#854-1

KIDNEY CARE COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

October 10, 2006

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

Re: **CMS 1321-P:** Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Administrator McClellan,

I am writing on behalf of the Kidney Care Council (Council), formerly known as the Renal Leadership Council, to provide you with our members' comments regarding the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2007 (Proposed Rule). As you may know, the Council is a coalition representing the nation's dialysis providers who collectively provide life-saving care to more than 70 percent of the dialysis population.[1] We welcome the opportunity to comment on the Proposed Rule. We also appreciate the collaborative relationship that has developed over the years with Centers for Medicare and Medicaid Services (CMS), and we look forward to working with the CMS staff to ensure access to quality dialysis services for Medicare beneficiaries.

Overall, the Council is generally supportive of the ESRD-related provisions included in the Proposed Rule. It is apparent from the Proposed Rule provisions and the accompanying preamble explanation that CMS has taken into consideration many of the issues the kidney care community has encountered in years past. We appreciate the Agency's willingness to work with the community to ensure that its policies result in efficient and high quality care for patients with kidney failure.

Although generally pleased, we do have some concerns about the transparency of the methodology underlying the Proposed Rule. Specifically, we encourage the Agency to:

- Clarify the methodology it used in updating the drug add-on adjustment and ensure that the price and utilization estimates are based on accurate data or are indexed appropriately;

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[1]See Attachment A for a list of the members of the Council.

- Clarify that separately billed drugs for CY 2007 will be reimbursed at Average Sales Price (ASP) +6 percent;

- Outline the methods used to develop the budget neutrality calculation for the geographic wage index; and

- Implement the MedPAC recommendation to equalize the payments between hospital-based and independent dialysis facilities.

I. ESRD PROVISIONS: The Council agrees that the drug add-on adjustment should be updated using a standard index, but is concerned about the methodology used to determine price and utilization.

The Council is pleased that CMS proposes using an index to update the drug add-on adjustment, consistent with the requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The use of an index will provide a stable estimate of the increases that influence the update of the drug add-on adjustment. However, based upon the limited amount of information provided in the Proposed Rule, we are concerned that the proposed methodology is not based upon a reliable data series and may, in particular, result in an inaccurate assessment of the utilization of drugs that will affect the calculation of the update. Therefore, we urge the Agency to work closely with the kidney care community to develop an appropriate proxy that can be used until CMS has accurate price and utilization data. In addition, we strongly urge CMS to perform an adjustment to account for any forecasting error until CMS has stable data as it does with other reimbursement programs, such as the managed care program, to ensure that if estimates are not consistent with the actual price or utilization changes, there is a process to account for the differences and to ensure that facilities receive the appropriate reimbursement payments.

A. CMS Should Clarify How It Arrived at the Proposed Producer Price Index of 4.9 Percent for Drug Prices

As a threshold matter, the Council is concerned about how the growth in drug prices is estimated in the calculation of the update to the drug add-on adjustment. We agree that the Producer Price Index (PPI) could potentially provide a stable and accurate estimate of price changes. However, the Proposed Rule states that CMS estimates the PPI to be 4.9 percent. We understand that CMS uses an outside consultant to forecast the PPI. Even so, we are concerned that the forecast of 4.9 percent does not appear to be consistent with other data. For example, the reported PPI 2006 through September is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If these figures were used, there would be significant differences in the update to the drug add-on adjustment. We encourage CMS to work with the Council to evaluate the differences between the figures in the Proposed Rule and independent data sources to ensure that the appropriate price forecasting method is used in calculating the update to the drug add-on adjustment.

B. CMS Should Clarify the Utilization Estimate

A second important factor in calculating the drug add-on adjustment is estimating the utilization changes. In this regard, the Council also has questions about the data and methodology CMS proposes to use to determine this estimate. We appreciate the Agency's need to estimate utilization because its current volume data based on Medicare claims is unstable and not suitable for purposes of calculating the update to the drug add-on adjustment. However, the methodology CMS uses to determine this estimate is not transparent. Given the importance of the utilization to the calculation of the update for the drug add-on adjustment, we encourage CMS to review the analysis provided by The Moran Company, which concludes that utilization rose modestly in 2005 over 2004.

The Moran Company, using the most recent data available from CMS, has reviewed the Proposed Rule and determined there is a minor discrepancy between the two analyses. However, even small differences have a significant impact on provider payments ultimately for the kidney care community. For example, when member companies of the Council estimated the change in price and utilization using their own internal data, they found a decrease in price of 13.2 percent and an increase in utilization of 1.8 percent. With these slightly different figures, the resulting drug add-on adjustment would be approximately 15.46 percent. A different data set would lead to different results as well.

Additionally, we are concerned about the Agency's conclusion that the new EPO Monitoring Policy (EMP) will decrease utilization of that biologic. As we have discussed with CMS previously, dialysis facilities do not prescribe EPO and, therefore, cannot control its utilization. However, our concern in this instance is that CMS is assuming the decrease in utilization without having actual data to support the conclusion. We urge CMS to examine the impact of the policy closely and to avoid basing payment policies on assumptions about how it may or may not change behavior.

If the pricing change is consistent with the assessment of The Moran Company, then the utilization is not flat and should result in a slightly higher update to the drug add-on adjustment. As these examples demonstrate, small changes result in important differences in the ultimate update to the drug add-on adjustment. Therefore, as described below, the Council urges CMS to adopt a more stable estimate by using a proxy for CY 2007. However, if CMS follows this approach it should, at a minimum, use the most recent data set available.

C. CMS Should Work with the Council To Develop a Stable Utilization Estimate for CY 2007 and Establish a Mechanism to Allow for Forecasting Error Adjustments

Because of the difficulties associated with the estimates in the Proposed Rule, The Moran Company suggests that in the Final Rule CMS should (1) adopt an appropriate proxy of both price and utilization and (2) establish a mechanism to adjust for forecasting error in prior estimates before calculating subsequent years' updates.

For CY 2007, the Council seeks to work with CMS to develop an appropriate proxy to establish a utilization estimate until volume trends stabilize. As described in The Moran Company report, we suggest using the Agency's own NHE projection for prescription drugs to ensure an accurate update to the drug add-on adjustment. The NHE is superior to the PPI because it includes both price and utilization. As The Moran Company indicates, although there are concerns about the NHE aggregate trend projection being prejudiced by Part D drug utilization, it is possible for the CMS Actuary to separate the Part B and Part D forecasts and use the Part B utilization as an index for the growth in ESRD drugs. Historically, ESRD and part B annual drug utilization changes have tracked closely. This proxy would be useful until CMS has credible ESRD trend data for both price and utilization. We encourage the Agency to work with The Moran Company and the Council to assess the possibility of using this index or another proxy that would ensure stable and reliable data *until* CMS's volume data is more stable and reliable and the Agency has addressed the data concerns related to the methodology of the Proposed Rule.

Regardless of the estimate or proxy CMS ultimately adopts, the Final Rule should contain a mechanism that would adjust for forecasting error adjustments of prior year estimates until the Agency has stable data. If either the price or utilization forecasts are incorrect, then CMS can take the correct numbers and use them to recalculate the volume or price before projecting for 2008. This mechanism should only need to be employed for one or two years until CMS has accurate utilization data.

As The Moran Company report notes and the discussion of the price and utilization estimates demonstrates, there are significant data difficulties that make forecasting price and utilization for ESRD drugs problematic. Because of these data problems, there is not a clear methodology that would allow CMS to construct accurate estimates for at least the next few years. Until the data regarding ESRD drugs stabilizes, it is important that CMS ensures that price and utilization are corrected on a prospective basis. As you know and as MedPAC has repeatedly recognized, Medicare margins for dialysis payment, including separately billable drugs, remain negative. Small changes in reimbursement rates have significant implications for the community. This fact coupled with the Agency's conservative indexing practices could lead to inappropriate long-term implications for the payment system if adjustments are not made. Again, we envision that this mechanism should be focused on correcting errors on a prospective basis and would be needed only until CMS has accurate volume data, most likely one or two years. For example, if the NHE estimate were not representative of the actual trend, CMS could fix it in the base. We strongly urge CMS to allow for forecasting error adjustment for this limited period, as it has done for managed care payments to health plans and other programs. Therefore, it seems appropriate for CMS to adopt a mechanism that would allow it to adjust for forecasting errors in prior price and utilization estimates before calculating the next year's update to assure that any incorrect estimating problems do not accumulate.

D. CMS Should Incorporate Hospital Utilization Data in Its Calculation of the Drug Add-on Adjustment

Finally, the Council encourages CMS to collect cost data from hospital-based providers to enable accurate estimates of the costs of separately billable drugs in that setting. The Agency

acknowledged the importance of collecting this data in the Final Rule published last November. "We agree that the ideal approach would be to collect data from hospital-based facilities... We intend to pursue options for obtaining additional data to more accurately compute and update the drug add-on adjustment."[2] This approach is also consistent with MedPAC's recommendations.[3] This data will allow CMS to estimate the true drug add-on adjustment amount and the appropriate updates by incorporating the hospital-based provider data into the analysis as well. Therefore, we urge CMS to describe its data collection activities and how the data affect the calculation of the update to the drug add-on adjustment.

II. ESRD PROVISIONS: CMS Should Provide More Transparency on the Calculation of the Budget Neutrality Factor for the Geographic Wage Index.

The Council continues to support the revisions to the geographic wage index. Yet once again, we are concerned with the lack of transparency in terms of the data and methodology used. Without this information, it is impossible to assess the accuracy of the budget neutrality calculation for the wage index calculation. Calculation of budget neutrality for the geographic wage index methodology proposal is a process that is subject to a number of possible variables. However, it is difficult to understand the methodology CMS has employed because the Proposed Rule does not explain the Agency's approach. Therefore, the Council encourages CMS to provide the data and methodology it used to calculate the budget neutrality factor in the Final Rule.

III. ASP ISSUES: The Final Rule Should Explicitly State that CMS Will Reimburse Separately Billed Drugs at ASP+6 Percent.

In describing the reimbursement for separately billed drugs, the Proposed Rule states that drugs will be reimbursed "based on section 1847A of the Act." 71 *Fed. Reg.* at 49004. The text is clearer and states the reimbursement will be at 106 percent of ASP. We encourage the Agency to provide a clear, concise statement of the reimbursement rate in the preamble as well to ensure that there is no confusion because of the different wording.

IV. ESRD PROVISIONS: CMS Should Implement the Medicare Payment Advisory Commission's Recommendation that the Composite Rate Be Equalized between Hospital-Based and Independent Dialysis Facilities.

The Proposed Rule notes the continued application of an approximate $4.00 differential in composite rate payments that favor hospital-based providers.[4] Consistent with our previous comments, the Council strongly urges CMS to follow the MedPAC recommendation to equalize payments between hospital-based providers and independent dialysis facilities. As MedPAC notes, the difference is the result of the Omnibus Budget Reconciliation Act of 1981, which "mandated

[2] 70 *Fed. Reg.* 70116, 70163 (Nov. 21, 2005).
[3] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program" 96 (June 2005).
[4] 71 *Fed. Reg.* at 49005.

separate rates for the two types of facilities."[5] Initially, "the Secretary attributed this $4 difference to overhead, not to patient complexity or case mix."[6] MedPAC concludes:

> The current payment method is not consistent with the Commission's principle of paying the costs incurred by efficient providers who furnish appropriate care, regardless of the care setting. Consequently, we reiterate our recommendation that the Congress eliminate differences in payment for composite rate services between freestanding and hospital-based facilities.[7]

As MedPAC recognizes, there is no longer a legitimate reason to pay hospital-based providers more than independent dialysis facilities. We appreciate that CMS would prefer to have Congress explicitly indicate that it supports this change as well. However, we continue to believe the existing statutory language provides sufficient authority to allow CMS to implement this change in the Final Rule. Specifically, Section 1395rr(b)(7) states that the Secretary must develop a composite rate payment system that, among other things:

> *differentiate*[s] between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, *will more effectively encourage the more efficient delivery of dialysis services.*

(emphasis added). The language does not mandate that CMS provide a higher composite rate to hospital-based providers. Instead, it instructs the Secretary to engage in a "detailed analysis" that will ensure that the payment methodology encourages the more efficient use of dialysis services. As MedPAC has noted, the $4 differential payment does not appear to meet the efficiency requirement of the statute.

Without this change, CMS is sending mixed signals to providers by rewarding less efficient hospital-based providers, while simultaneously trying to develop programs that reward efficiency and the delivery of high quality care. The Council again strongly encourages CMS to follow MedPAC's recommendation and establish reimbursement parity among hospital-based providers and independent facilities.

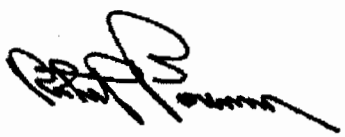
V. Conclusion

The Council appreciates the on-going collaborative relationship between CMS and the Council and we look forward to the opportunity to work with you and your staff to ensure the appropriate implementation of ESRD reimbursement policies. On behalf of the Council, I would like to thank you for your willingness to consider our perspective on these reimbursement changes that significantly affect the clinical settings in which dialysis care is rendered and for the opportunity

[5] MedPAC, "Report to the Congress: Medicare Payment Policy" 121 (March 2006).
[6] *Id.*
[7] *Id.*

to comment on the Proposed Rule. We hope to continue working with the Agency staff to ensure that effective and high-quality dialysis services are accessible for Medicare beneficiaries. Please do not hesitate to contact Rob Foreman (202) 756-3578 if you have comments or questions.

Sincerely,



Rob Foreman
President

Appendix A

THE KIDNEY CARE COUNCIL

American Renal Associates, Inc.

Centers for Dialysis Care

DaVita, Inc.

Fresenius Medical Care North America

Northwest Kidney Centers

Renal Advantage, Inc.

Satellite Healthcare, Inc.

U.S. Renal Care, Inc.

#854-2

The Proposed End Stage Renal Disease Prospective Payment System Update for 2007:

Evaluating Technical Options for Improved Payment Accuracy

October 5, 2006

THE MORAN COMPANY

The Proposed End Stage Renal Disease Prospective Payment System Update for 2007:

Evaluating Technical Options for Improved Payment Accuracy

As part of the Medicare Professional Fee Schedule rulemaking on August 22, 2006, the Centers for Medicare & Medicaid Services (CMS) proposed updates to the End Stage Renal Disease Prospective Payment System, which it has administered, since 2005, under the requirements of the Medicare Modernization Act of 2003[1] (MMA). Under that system, dialysis providers are paid for their services in two ways: they receive a prospective payment for each treatment, and they are separately reimbursed for drugs that are not explicitly "packaged" in the per treatment payment rate.

The prospective payment rate is itself composed of two components. The largest component, called the "composite rate," is fixed by statute, and provides for a $4 positive differential in payment for treatment in a hospital. A second component, which was implemented in 2005, is called the "drug spend add-on." This component, which is valued at $18.88 per treatment in 2006, is designed to hold dialysis providers harmless for reductions in pharmaceutical reimbursements mandated by the MMA.

In 2005 and 2006, CMS established the amount for these payments by projecting the expected volume of separately-reimbursable drugs likely to be used in the program year, and the reimbursement rates for each drug under both prior and current law. The aggregate drug spending "spread" between prior and current reimbursement policies was then divided by the projected number of dialysis treatments to establish a per treatment payment amount.

Citing the growing complexity of maintaining this estimation method in an environment of changing payment methodologies, CMS has proposed, for 2007, to simplify this calculation by indexing the 2006 drug spread add-on value to a two-part index.

The first part of the index would be a proxy for rising drug reimbursement rates under the current payment methodology. CMS is proposing to use a projection of the increase in the Producer Price Index (PPI) for pharmaceutical manufacturing as a proxy for this value. The projected PPI value they published for calendar year 2007 is 4.90%

The second part of the index would be a projection of the likely increase in drug volume consumed per dialysis beneficiary. In its proposed rule, CMS used data on reimbursement changes from 2004 to 2005 to estimate the year-over-year change in volume, which they then imputed to the 2006-2007 period. In the NPRM, the projected value of this component is proposed to be zero, i.e., the update would be limited to 4.9% of the 2006 drug spend add-on amount.

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[1] *Federal Register*, Vol. 71, No. 162, p. 49004ff.

The Moran Company was engaged by the Renal Leadership Council, a trade group of companies providing dialysis services, to evaluate the data CMS used and the methodology it employed to make this estimate, and to evaluate technical alternatives that could improve the accuracy of the projected payment update for 2007[2]. The highlights of our findings are as follows:

- Several aspects of the methodology CMS has proposed are not fully transparent based on the description of the methodology in the preamble.

- The volume growth projection is based on estimated values for "enrollment growth," the volume-weighted change in drug pricing, and the year-over-year change in drug reimbursements from 2004 to 2005.

- They estimate 3% "enrollment growth," but do not indicate what "enrollment" concept this value relates to. The actual growth in Part B enrollment, for example, was 1.7% from 2004 to 2005.

- They estimate a 12% decline in volume-weighted drug reimbursement rates from 2004 to 2005, based in part on a prior estimate of a 13% reduction from AWP-based reimbursement to reimbursement based on Average Acquisition Price.

- They estimate a 9% decline in total reimbursements for separately billable drugs between 2004 and 2005. We checked this estimate using data from the 2004 Outpatient Standard Analytical File, and from a new 2005 ESRD Limited Data Set (LDS) file. After working with CMS staff to resolve discrepancies between the documentation of the LDS and the data actually placed in the file, we obtain a slightly higher value for this ratio, which would increase CMS's volume projection by about 1%.

- Under the CMS methodology, however, the real issue is what the projected update would be once their formula is run through the values observed in the later claims data they will use for the final rule.

- The closer that value gets to the present projection of zero volume growth, the less likely it would be to serve as a valid proxy for volume growth *in 2007.*

- We believe that using the National Health Expenditures projection published by CMS each February, adjusted to restrict the projection to Part B drugs, would prove a better interim measure for 2007 than the index proposed.

- However this index is generated, it should be retrospectively rebased each year to prevent a permanent accumulation of conservative underestimates of ESRD drug spending growth.

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[2] During the course of this engagement, the RLC formally changed its name to the Kidney Care Council.

The CMS Volume Estimating Methodology

The methodology CMS chose to employ was, we believe, motivated by concerns about coding accuracy in ESRD claims data, particularly for erythropoietin (EPO), which comprises 70% of the drug volume billed by dialysis providers. The table below summarizes reported drug claims volumes, as measured by discrete claims lines, billed by dialysis providers over the 2001-2005 period[3].

Claims Lines Billed for Separately-Reimbursed Drugs

	2001	2002	2003	2004	2005
Epogen & Aranesp	2,496,480	2,697,620	2,820,000	5,183,120	6,319,323
Other Drugs	4,193,240	4,543,760	4,927,000	6,368,880	6,176,360
Total	6,689,720	7,241,380	7,747,000	11,552,000	12,495,683

As these data indicate, there was a sharp jump in reported claims lines in 2004, particularly for Epogen® . It is our understanding that this increase is due to a change in coding guidance. Prior to 2004, Medicare intermediaries apparently paid separately reimbursed drug claims for dialysis treatments without requiring accurate HCPCS coding, particularly for Epogen, as long as the claims had proper revenue codes. The claims counts in the table above for Epogen and Aranesp® were, in fact, generated by identifying claims by revenue code[4]. Since the claims line count more than doubled after the requirement for HCPCS coding was implemented, it is likely that many prior claims bundled billings for multiple days of EPO that are now being billed separately.

Given this trend, CMS reasonably concluded that it could not infer a volume trend directly from historical volume data. Instead, it elected to estimate volume by looking at the percentage change in reimbursement between 2004 and 2005, and then adjust for known changes in reimbursement rates between periods to back into the implied volume change. Their decision to impute the 2004-2005 experience to 2006-2007 implicitly suggests that they believe that the experience of the period prior to 2004 was likely to be atypical of trends going forward.

They based their calculation on three key data points:

- The increase in "enrollment" between 2004 and 2005.
- The change in drug reimbursements from 2004 (when they were based on prior payment policy) to 2005 (when they were based on Average Acquisition Price (AAP); and

[3] Throughout our analysis, the data for 2001-2004 are Moran Company estimates developed using the Outpatient 5% Standard Analytical Files for each of these years. The data for 2005 were extracted from the 2005 ESRD PPS Ratesetting Limited Data Set, which CMS released in the last week of September.

[4] Under the Uniform Bill revenue coding structure, EPO claims are billed with revenue codes 634(EPO < 10,000 units) or 635 (EPO >10,000 units). Fewer than 10% of these claims had accurate HCPCS codes for EPO in 2001-2003.

- The volume-weighted change in reimbursement rates from prior policy to AAP.

In the calculations presented on p. 49007 of the August 22, 2006 *Federal Register,* they show the following values:

"(.91 / (1.03 * .88) =1.00)"

Presumptively:

- The .91 factor is the assumed change in drug reimbursements between 2004 and 2005.
- The 1.03 factor is "enrollment growth"; and
- The .88 factor is the volume-weighted change in reimbursement rates.

This calculation is presented as the support for their conclusion that the adjustment for drug volume growth should be zero in 2007.

Discussing these values in reverse order:

Volume-Weighted Drug Reimbursement Rate Changes

The volume-weighted change in payment rates, applied to both EPO and non-EPO drugs, reflects the result of the calculation of this ratio in prior rules. CMS updated the 2004 reimbursement rates for non-EPO drugs to 2005 by applying the PPI (which they did not disclose, but which was 5.17% in 2005). They then applied the ratio of AAP to prior policy payment rates calculated in the Final Rule for 2005. This resulted in a determination that the ratio of AAP to prior payment rates was .88, which is then used in the denominator of the CMS formula to deflate the magnitude of the year-over-year declines in payment rates.

Refining this estimate would require more complete payment data for 2005, since the CMS factor of .88 is sensitive to assumptions about market share by product. As we indicate below, the best way to resolve uncertainties about this estimate would be to retrospectively rebase their calculated 2007 price and volume forecast using later data prior to developing their forecast of the 2008 index.

"Enrollment Growth"

The derivation of the enrollment growth factor used in the CMS methodology is unclear, since the term "enrollment" is undefined. If this is an attempt to estimate an increase in the prevalence of dialysis use, the source of the 3% factor is unclear. If it is intended as a measure of Part B enrollment growth, it is substantially too high, since the 2006 Trustees Report shows Part B enrollment growth of 1.7% in 2005 over 2004.

Because this factor appears in the denominator of the CMS volume estimating equation, lowering the enrollment factor would increase the estimated volume growth. Applying

actual Part B enrollment growth of 1.7% in lieu of the assumed 3% factor would increase the estimate from 1.0040 to 1.0168

Change in Drug Reimbursement

In the preamble, CMS did not directly present their estimate of year-over-year change in reimbursements for separately reimbursed dialysis drugs. They indicated that they started with twelve months of paid claims for services incurred in 2005, and adjusted upward by 13% to reflect the lack of claims run out[5]. In their formula, the value they enter is .91, implying that their adjusted reimbursement totals in 2005 were 9% below 2004.

We attempted to replicate this estimate. We used the data furnished in the new ESRD PPS Ratesetting Limited Data Set released at the end of September to tabulate 2005 values for drug reimbursements, compared to estimates of 2004 drug reimbursements generated using the 2004 Outpatient 5% Standard Analytical File.

Our initial attempt at replication was unsuccessful. In comparison to the CMS estimate of a -9.0% change from 2004 to 2005, we were computing a modest 1-2% increase in total drug payments between years. Since this is a substantial disparity, we shared our data with CMS staff. Upon analysis, it was determined that the disparity was the result of a mismatch between the data concepts used to create the file, and the description of the data concepts presented in the data dictionary accompanying the file. While the payment field was described in the documentation as comprising payments from intermediaries to providers excluding beneficiary cost sharing[6], the payment values actually contained in the file did contain the cost sharing amounts. When we corrected the data concept employed to tabulate the 2004 values using the same data concept, most of the disparity went away.

Here is the payment comparison prior to adjustment for differences in the duration of paid claims experience:

Reimbursements for Separately Billable Drugs

	2004	2005	2005/2004
EPO	$ 2,126,524,032	$ 1,915,636,264	0.9008
Other	$ 1,061,015,152	$ 679,171,618	0.6401
Total	$ 3,187,539,184	$ 2,594,807,883	0.8140

2004 Data from Outpatient 5% Standard Analytical File, as Paid through 6/30/05
2005 Data from ESRD PPS Ratesetting Limited Data Set as Paid Through 12/31/05

[5] For 2004, CMS had claims data for reflecting all payment adjustments made to these claims throughout 2005. For 2005 claims, by contrast, their data don't reflect payments or adjustments after December 31, 2005.

[6] It is our understanding that the CMS program staff had intended that the data concept described in the documentation would be used in creating the file.

The data in the table show total tabulated payments in both files, without trimming of outliers. As the data in the table indicate, claims incurred in 2005, as paid through December 31, 2005, were 18.6% below claims incurred in 2004, as paid through June 30, 2005. As CMS noted in the preamble, a significant part of this difference is attributable to the difference in the duration of paid claims history, since the claims set they used to compute the proposed rule values contained only twelve months of payment history for claims incurred in 2005. They used the relationship between 2004 incurred claims paid by June 30, 2005 to 2004 incurred claims paid through December 31, 2004 to calculate an adjustment factor for claims incurred but not paid of 13%. Lacking access to the detailed National Claims History, we cannot look behind this estimate.

Applying it, in unrounded form, we obtain a slightly different factor than does CMS for the adjusted year-over-year change:

$$.8140 * 1.13 = .9198$$

We note that the difference between our calculated factor and theirs is greater than could be explained solely by rounding of their 1.13 adjustment factor to two decimal places. It may be attributable to trimming of certain claims observations in their analysis – in combination with rounding. Given the large volume of ESRD drug claims in the 2004 5% sample, we would not expect estimating error to be material.

Alternative Adjustment Factor

Based on this analysis, we conclude that their estimate that the total volume change in 2005 over 2004 was zero is probably too conservative. In addition to the factors identified above, we believe that there are additional grounds to conclude that drug reimbursement volumes rose at least slightly in 2005 over 2004. In addition to anecdotal evidence from the provider companies that volume growth is decelerating but is not zero, we have the evidence of an observed year-over-year increase in claims lines for drugs, which may not be due solely to differences in coding practices. In all, we believe that when CMS recomputes this estimate using later data on 2005 volumes, their estimate of year-over-year volume growth is likely to rise – but is unlikely to reflect the double-digit volume growth observed in the 2001-2004 period.

Regardless of how these issues are resolved in the Final Rule, the foregoing discussion makes clear that the use of different data at different times can produce materially different estimates of ESRD drug volume growth. This reality creates substantial uncertainty about the likely accuracy of any forecast. When CMS recomputes their estimate using a longer claims run out, both CMS and the industry will have confidence that the new estimate of 2005 volume growth was better than the previous estimate, which was based earlier, less complete data. We would, however, still be without information on which to render a judgment regarding whether either of these estimates represented the best possible estimate of *likely volume growth between 2006 and 2007,*

which is the data concept actually required to implement the proposed CMS methodology.

The closer the value CMS estimates comes to the zero growth forecast presented in the proposed rule, the more difficult it will be to conclude that the 2005 experience represents a valid proxy for drug volume growth in 2007. Growth in the volume of drugs used to treat ESRD patients has been consistent for many years, as new drugs are added to the arsenal of treatments available to nephrologists to better manage care. While there are valid reasons for CMS to conclude that volume trends may be turbulent between 2004, when the previously-described coding changes were implemented, and 2006, when efforts to modify EPO dosing are being implemented, there is no reason to assume continued turbulence going forward from 2006 into 2007 and later years.

Until volume trends stabilize, therefore, CMS may find it useful to consider alternative proxies for price and volume change in ESRD drugs. Historically, the growth in drug pricing and volume in the ESRD program has been comparable to that observed for drug reimbursements under Part B generally. Since the CMS Office of the Actuary has traditionally forecast the Medicare share of growth in prescription drug expenditures as part of the annual National Health Expenditures (NHE) projection, CMS could easily link the update of the drug spend add-on to that forecast.

In the preamble to the proposed rule, CMS indicated that it considered this option, but rejected it due to the fact that, for 2006 and 2007, the NHE forecast of Medicare drug spending is heavily dominated by assumptions about the early trend under the new Medicare Part D drug program. While we are sympathetic to that concern about using the aggregate NHE trend projection, it would be possible for the Actuary to decompose that forecast into Part B and Part D forecasts, respectively, and use the former to index growth of the drug spend add-on until such time that it has credible trend data for price and volume growth under the ESRD program itself.

Retrospective Rebasing

Given the state of the data, we see no clearly superior methodology for improving this estimate. Accepting that reality, it strikes us as prudent to suggest that it would be in the interest of both the agency and the industry to adopt an update mechanism that makes provision for retrospective rebasing of prior estimates before calculating the subsequent year's update. Such rebasing should be for both pricing and volume effects. Whatever 2007 value CMS calculates under it final rule methodology for both price and volume, their methodology should provide for adjusting that value (up or down) to reflect known variations from the forecast trend (PPI +Volume or NHE) before projecting forward from that base to calculate the 2008 update.

In saying this, we are not endorsing a permanent policy of basing the drug spend add-on for a year on the assumption that volume growth in a year will be equal to the volume growth rate observed two years prior. Clearly, what CMS is doing now is a stopgap measure designed to bridge to a period when time series data on actual drug volumes can

be used to make this projection. Until that time, however, we believe it's important to have some ability to retrospectively adjust toward reality. Given CMS's fiduciary responsibility to be inherently conservative in indexing future program growth, failure to do so could accumulate a substantial payment deficit relative to the stated policy intent of making providers whole for the impact of changes in drug reimbursement policy.

Submitter : Dr. Patricia Gregg **Date:** 10/10/2006

Organization : Florida Society of Pathologists

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The Florida Society of Pathologists wishes to append this statement to our comments sent by overnight mail: We are aware of additional ideas which we believe are valuable, which came to our attention after our original comments were submitted, and which are in the comments by the College of American Pathologists, the Texas Society of Pathologists, and others. We therefore ask that CMS acknowledge that additional communication between interested parties may be needed in order to determine the optimal language for the final rule, in order to avoid penalizing any legitimate non-abusive arrangements while preventing the abusive ones.

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RE: REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

Submitter : **Mrs. Jacqueline Stewart** **Date: 10/10/2006**

Organization : **Board of Certification for Emergency Nursing**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Criteria for National Certifying Bodies-Advanced Practice Nurses
On behalf of the Board of Certification for Emergency Nursing, I would like to express my appreciation to CMS for addressing this issue. Our Board is interesting in responsing to you, however, due to the short interval of time allocated for responses, we respectfully request an additional 48 hours to form our thoughts and develop a recommendation.
Jacqueline Stewart RN, MSN, CEN
Board of Certification for Emergency Nursing

Submitter : Dr. Robert Zwolak **Date:** 10/10/2006

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on August 22, 2006. We will address multiple provisions under the DRA proposals, including proposed adjustment for payments to imaging services, the proposed addition of ultrasound screening for Abdominal Aortic Aneurysms (AAA), and the 2007 Medicare physician payment rate.

As stated in our August 21, 2006 comments, 2007 may be the year when vascular surgeons are forced to reduce access to Medicare beneficiaries. Our specialty is currently facing an intolerable 11% Medicare reimbursement reduction based on the Centers for Medicare and Medicaid Services (CMS) projections. This massive pay-cut represents the combination of -5% due to the SGR impact on the Conversion Factor, -5% due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies, and -1% related to changes in work RVUs and Practice Expense. Alone, the proposed 5% reduction in reimbursement for noninvasive diagnostic vascular laboratory studies may mean that 54% of those vascular surgeons with office-based vascular labs who responded to SVS survey regarding the impact of the DRA will no longer provide or reduce vascular lab services to Medicare beneficiaries. These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation s seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

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GENERAL

PLEASE SEE ENCLOSED MICROSOFT WORD FILE FOR COMPLETE TEXT OF SOCIETY FOR VASCULAR SURGERY COMMENT.

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The SVS comments will follow in this order:
1. DRA Proposals Section 5102 Proposed Adjustments for Payments for Imaging Services
2. DRA Proposals Section 5112 Proposed Addition of Ultrasound Screening for AAA
3. Medicare Physician Payment Rate for 2007

1. DRA Proposals - Section 5102 Proposed Adjustments for Payments for Imaging Services

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

" Non-invasive Diagnostic Vascular Studies that are Physiologic in Nature Do Not Include Imaging

Non-invasive diagnostic vascular studies ARE NOT included in the Radiology section of the CPT Book by intent because they are diagnostic tests used to identify and assess the severity of arterial and venous vascular diseases and disorders, either entirely or primarily through non-imaging modalities. Although these vascular diagnostic tests use ultrasound, they were invented as applications of Doppler ultrasound, which is NOT an imaging form of ultrasound. Doppler ultrasound measures the frequency shift of sound waves that bounce off moving red blood cells. Those frequency shifts undergo analysis by the electronics in the Doppler instrument and are plotted on paper or on a computer screen as graphs of velocity. These are NOT pictures or images of the tissue. The velocities determine if blood is flowing or not. For instance, in a patient with severe atherosclerosis plaque in the carotid artery, the high velocities of blood flowing through a very narrow artery correspond to a severe stenosis. The most accurate way to determine the severity of stenosis is based on these velocities, and NOT on a picture of the plaque. It is the visual display of blood flow velocity, not visual pictures, which are analyzed and interpreted when performing a non-invasive diagnostic vascular study. Thus, non-invasive diagnostic vascular studies are included in the Medicine section of the CPT book.

Over the years, the SVS has worked with the CPT Editorial Panel and others at the American Medical Association to construct a series of parenthetical notes to better describe the non-invasive diagnostic vascular studies to support the selection by physicians of the appropriate CPT codes to describe the study performed. Thus, we believe the CPT manual is very clear that non-invasive physiologic studies used to diagnose vascular disease are performed using equipment that is separate and distinct from the duplex scanner. In a vascular surgeon s practice, we perform physiologic studies on Medicare patients where there are signs and symptoms of peripheral arterial disease and we use physiologic vascular studies, CPT codes 93922, 93923 and 93924 to confirm presence of disease, assess the severity, allow prognostication regarding outcomes, and provide a measure of effectiveness of treatments including exercise programs, percutaneous intervention and bypass surgery. Because these codes do not contain imaging, CMS should remove them from the list of services included under the imaging provisions of the DRA in the Final Rule, just as it has done in the proposed rule for nuclear medicine services that are non-imaging diagnostic services and radiation oncology services that are not imaging services . Likewise, transcranial Doppler studies (93886, 93888, 93890, 93892, 93893) are Doppler velocity analyses that include either no imaging at all, or just enough imaging to identify vessel location. These 5 CPT codes should be excluded from provisions of the DRA.

PLEASE SEE ENCLOSED MICROSOFT WORD FILE FOR FULL SVS COMMENT

Submitter : **Barbara Peck** **Date: 10/10/2006**

Organization : **American College of Surgeons**

Category : **Health Care Industry**

Issue Areas/Comments

Background

Background

See Attachment

GENERAL

GENERAL

See Attachment

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See Attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Attachment

CMS-1321-P-858-Attach-1.PDF

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American College of Surgeons

Washington Office: 1640 Wisconsin Avenue, NW • Washington, DC 20007 • 202/337-2701 • FAX 202/337-4271
e-mail: postmaster@facs.org ACS Web site: http://www.facs.org

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October 10, 2006

Ms. Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: 1321-P
PO Box 8015
Baltimore, MD 21244-8015

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

Dear Ms. Norwalk:

On behalf of the 71,000 Fellows of the American College of Surgeons (College), I am pleased to submit the following comments on the Proposed Rule published in the *Federal Register* on August 22, 2006. We will discuss the 2007 conversion factor, direct practice expense inputs, DRA proposals, physician self-referral, and the promotion of health information technology.

I. Background

2007 Conversion Factor - Changes in the Medicare Economic Index (MEI)

The College strongly opposes the recently announced 0.5 percent reduction in the estimated Medicare Economic Index (MEI). We note that the changes causing this reduction were not discussed in the proposed rule. In fact, unlike previous proposed rules for the physician fee schedule, there was absolutely no discussion in the 2007 proposed rule of the update to the Medicare fee schedule for the coming year. Instead, the section of the proposed rule on the Regulatory Impact Analysis includes only the following single sentence: "Table 7 below shows the specialty level impact of section 5102 of the DRA and our most recent estimate (-5.1 percent) of the CY 2007 Medicare PFS update." This number was unexpected because it is larger than the estimate contained in the President's Budget for FY2007 and CMS' March letter to MedPAC.

To determine why the update to the conversion factor would be -5.1 percent instead of the -4.6 percent contained in the President's Budget, the public must read a separate Medicare News article that was released by the CMS on August 8, 2006. Unfortunately, as with the proposed rule itself, there was no explanation for the lower update other than the statement "The negative update is projected for 2007 because spending on physicians' services and other Part B services has been growing at a much faster rate than target spending." To find a partial explanation, the public must find and read a Fact Sheet on the Medicare Economic Index that accompanied the press release announcing the proposed rule. The fact sheet states that the lower MEI is due to the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and comments on the changes were not requested.

We believe that CMS is in violation of the spirit if not the letter of the Administrative Procedures Act (APA) which requires publication in the *Federal Register* of proposed changes in current policy (including revised estimates of the MEI) and provides for a period for public comment. When the MEI was rebased in 2004 – and for all previous rebasings as well – CMS thoroughly discussed the proposed changes in the applicable NPRM and invited public comment. In 2004, when CMS adopted the current 10-year multifactor productivity adjustment, CMS also held a 1-day meeting with an outside technical panel before deciding what changes to include in the proposed rule. To address the current problem, the College strongly urges CMS to continue to use the multifactor productivity estimates for 2003 and 2004 that were used to calculate the 2006 MEI and to begin a consultation process prior to proposing changes for the 2008 MEI.

Based on the impact table in the proposed rule that shows $75 billion of allowed charges under the physician fee schedule, a -0.5 percent reduction in the update would result in a $375 million cut in total physician payments in 2007. At least $225 million of this reduction is due to the change in the data used to calculate the multifactor productivity adjustment. As noted, this change that was not described in any detail nor were options presented for public comment.

The CMS fact sheet notes that the productivity adjustment since 2004 has been based on a 10-year moving average of private non-farm business multifactor (MFP), as calculated by the Bureau of Labor Statistics (BLS). It states that the BLS recently converted from the Standard Industrial Classification System-based measure of MFP, to the North American Industrial Classification System (NAICS)-based measure and that this new productivity data series replaces the previous data series. According to CMS, the previous series ended in 2002. For the MEI calculation for 2006, CMS used an estimate of MFP for 2003 and 2004. In March 2006, however, BLS released data for the new series. These data show substantially higher productivity gains than had been assumed in the estimates.

In fact, these productivity gains are much greater than in any other year in the 10-year series, as shown in the table below:

Year	Annual Multifactor Productivity Gain
Year	Annual
1994	0.9
1995	0.0
1996	1.4
1997	0.7
1998	1.5
1999	1.1
2000	1.2
2001	0.1
2002	1.7
2003	2.7
2004	2.9

Because the two most recent years' MFP rates were among the highest in recent history, their inclusion has a significant increase in the 10-year moving average MFP figure.

The College is concerned about the failure of the proposed rule to include a discussion of this change in the MEI because it prevents all affected parties from appropriate notice of the change and the opportunity to comment. Had we been given the opportunity to comment, we would have questioned the use of data that shows increased productivity in a year when the productivity of most physician practices has been reduced significantly by the need to counsel Medicare beneficiaries about the new prescription drug benefit and the availability of preventive services and to comply with the agency's requests related to the Physician Voluntary Reporting Program (PVRP). In addition, we would have pointed out that our patients are typically frailer, have multiple chronic conditions and cognitive impairments that increase the time and effort required for counseling and patient education.

We also believe that there are alternative measures of multifactor productivity using the extensive economic data available from BLS and the Census Bureau. CMS should identify and consider these alternatives and seek public comment before changing the data used to calculate the MEI.

II. Provisions

A. Direct Practice Expense Inputs

In the rule, CMS proposes to accept all of the American Medical Association/Specialty Society Relative Value Update Committee's (RUC) recommendations regarding the direct practice expense inputs for more than 2000 codes. We agree with this provision and thank CMS for supporting the work of the Practice Expense Review Committee.

III. DRA Proposals

A. Definition of Imaging Services

In the proposed rule, CMS states it must define "imaging services" in order to determine which services are affected by the Deficit Reduction Act of 2005 (DRA) limits. However, the DRA defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography." We believe this is the definition Congress intended CMS to use and believe CMS has not applied this definition correctly in several instances.

In the rule, CMS states "imaging services provide visual information regarding parts of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." In addition, CMS states it "excluded any service where the CPT code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is either included in the code whether or not it is used or is employed peripherally in the performance of the main procedure." CMS referenced codes 31622 (bronchoscopy with or without fluoroscopic guidance) and 43242 (upper gastrointestinal endoscopy with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy) as examples of when this exclusion would apply. We believe there are other codes that meet this criteria and were not properly excluded from the DRA reductions. Specifically, believe the following codes should be excluded from the DRA reductions because they included as part of a procedure:

75894 x-rays, transcath therapy
75896 x-rays, transcath therapy
75901 Remove cva device obstruction
75902 Remove cva lumen obstruction
75940 X-ray placement, vein filter
75945 Intravascular ultrasound
75952 Endovascular repair abdominal aorta
75954 Illiac aneurysm endovascular repair
75962 Repair arterial blockage
75966 Repair arterial blockage
75970 Vascular biopsy
75989 Abscess drainage, under x-ray
75992-75996 Atherectomy
76940 US guide, tissue ablation
76941 Echo guide for transfusion
76942 Echo guide for biopsy
76945 Echo guide, vilius sampling
76946 Echo guide for amniocentesis
76948 Echo guide ova aspiration
76095 Stereotactic breast biopsy
76942 Echo guide for biopsy

In all of the procedures listed above, an imaging modality is merely the way the physician gains visual access to the site in order to perform a procedure. We do not believe they are "imaging services" as intended by the DRA. If the DRA cuts are applied to these services, we fear there will be a shift in the site of service back to the hospital, or even a shift back toward traditional "open" procedure. We believe this is a step backward and not in the best interest of the Medicare program or its beneficiaries.

In addition, we also do not believe the vascular Doppler ultrasound codes are imaging services as defined by the DRA. The Doppler does not provide images of veins or arteries and, therefore, Doppler techniques do not meet CMS'definition for inclusion because these services do not provide "visual" information. In these codes, the ultrasound and the non-imaging Doppler velocity spectral data and Doppler color flow mapping cannot be separated out. In addition to the services listed above, we also ask that the following codes be excluded from the DRA provisions: 93922; 93923; 93924; 93880; 93882; 93925; 93926; 93930; 93975; 93976; 93978; 93979; and 93990.

IV. Reassignment and Physician Self-Referral

We agree with the agency's proposals regarding the Stark provisions related to reassignment and the definition of centralized building. We believe the minimum space and equipment requirements for a centralized building will limit the abusive situations described in the rule. At this point, we do not believe it is necessary to impose an additional requirement related to minimal nonphysician staff. Physicians groups are organized in a plethora of structures and we believe it is difficult to balance the need to prevent fraudulent activity with overly burdening physician groups and inhabiting legitimate structures. We believe the agency's proposals regarding minimum space and equipment should be implemented first and allowed to serve their purpose before CMS adds additional restrictions.

V. Promoting Effective Use of Health Information Technology (HIT)

We agree that the proliferation of health information technology would be beneficial to both the Medicare program and beneficiaries. However, in the rule CMS states "the Administration supports the adoption of HIT as part of the normal cost of doing business." First, we note that large scale adoption of HIT may save the Medicare program money, not individual providers. HIT companies often market these systems not as saving the provider money, but as a way to increase revenue through more accurate coding (a fact that will cost the Medicare program more money, not less). Second, in *CMS-1512-PN; Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*, it was noted that Medicare is only paying for 66 percent of direct expenses and 35 percent of indirect expenses. Given this fact, we do not believe the Administration's policy is realistic and will not lead to the large scale adoption of HIT.

Conclusion

The College appreciates the opportunity to comment on this important rule. We look forward to working with CMS to further improve the Medicare program.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

Submitter : **Mr. Frank Kiesner** **Date: 10/10/2006**

Organization : **Oncotech, Incorporated**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

"Independent Lab Billing"- attached

CMS-1321-P-859-Attach-1.DOC

#859

ONCOTECH
15501 Red Hill Ave., Tustin, CA 92780
(800) 576-6326 • (714) 566-0420
Fax (714) 566-0482 • www.oncotech.com

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1321-P Comments on the Medicare Physician Fee Schedule proposed rule for calendar year 2007 (the Proposed Rule).

Comment Topic: Independent Lab Billing and Clinical Diagnostic Lab Tests

To Whom It May Concern:

Background

These comments are submitted by Oncotech, Inc. We are an independent laboratory located in California which provides highly specialized laboratory testing for cancer patients. The main service we provide is generally categorized as chemoresponse testing. Our Extreme Drug Resistance (EDR) Assay identifies patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (< 1% as reported in published literature) to respond to specific drugs in a clinical setting. Physicians use this test to assist them in the management of their cancer patients. By utilizing the EDR Assay, both the patient and Medicare are spared the hardship and expense of ineffective chemotherapy. CMS has paid for this service through their Part B program for over ten years.

We are commenting on section II.M Independent Laboratory Billing and N.3.c. Other Lab Issues--Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens. These rules have led to confusion about whether chemoresponse testing is properly categorized as Part A or Part B Medicare service when a fresh tissue sample is obtained during an inpatient stay and some of the cells from the fresh tissue sample are later used in chemoresponse testing.

Chemoresponse testing has never been provided as a hospital inpatient service. This type of service is highly specialized and not provided by hospitals and therefore is has never been reflected in hospital costs. The prospective payment system for hospital inpatient services does not and has never accounted for this technology. A new policy that redefines chemoresponse testing as a hospital Part A service for the first time and does not create a new payment methodology will simply deny Medicare beneficiaries to this important technology. Hospitals do not have the incentive to pay for a service unrelated to the hospital course of treatment and for which they will not receive reimbursement. The new and unnecessary bundling with a Part A DRG will even prevent Medicare beneficiaries from requesting and obtaining service when it is declined by the hospital. With this new policy interpretation, Medicare will lose an important

advance in chemotherapy for cancer patients and Medicare beneficiaries will lose all choice in the matter.

Discussion

Our EDR assay requires fresh tumor tissue that is typically obtained from part of the surgical biopsy excised at the time of inpatient surgery. The tissue can not be archived or obtained at a later date, post discharge. This harvesting of the living tissue is the only service provided to a hospital inpatient. The test results from our assay are **not** related to the surgery or cancer diagnosis. Instead it provides information to the patient's oncologist about candidate drugs to personalize treatment for their patients. Our EDR test results in no way influence the inpatient care or treatment. Instead, it is post-discharge outpatient chemotherapy that is guided by our chemoresponse testing.

Medicare Part B covers many categories of benefits, including according to SSA § 1861(s) "medical and other health services." Among these medical and other health services are laboratory tests performed in an outpatient setting. Medicare contractors have paid for chemoresponse testing through Part B for over ten years. There are good reasons for why this has been the case:

- They are utilized for the post-hospital management of the patient
- The testing is unrelated to the underlying hospital stay
- They are provided by a provider different from the hospital
- They are not routinely performed for every patient (i.e. they are only used in particular cases)
- They are generally completed after discharge

The scientific requirements of chemoresponse testing are such that fresh tumor tissue is an absolute necessity. If the decision to hold the issue for possible testing is not made at the time of surgery, the opportunity for later testing is lost. This process is necessary because live tissue cannot be stored in the same way that paraffin-embedded specimens can be stored.

Recommendation

Current payment policy should remain in effect. Chemoresponse testing is properly defined as a Part B service when testing is done outside of the hospital and for purposes unrelated to hospital treatment. This policy interpretation has made chemoresponse testing available to Medicare beneficiaries for over a decade. We recommend CMS continue its current practice which makes chemoresponse testing available to Medicare beneficiaries as a Part B service.

We appreciate the opportunity to provide these comments and are eager to work with CMS to ensure that physicians and patients continue to realize the clinical benefits offered by chemoresponse testing. Please let us know if we can answer any further questions.

Sincerely,

Frank J. Kiesner
President and CEO

Submitter : **Steve Blades** **Date: 10/10/2006**

Organization : **Cardiovascular Outpatient Center Alliance**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-860-Attach-1.DOC

#860

COCA
CARDIOVASCULAR OUTPATIENT CENTER ALLIANCE
320 SEVEN SPRINGS WAY, SUITE 220, BRENTWOOD, TN 37027
Phone: 615-250-1706 Fax: 615-250-1644
www.cocaheart.org

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
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: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of the Cardiovascular Outpatient Center Alliance ("COCA")[1], we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. While we support the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"), we are concerned that the approach to developing standards does not reflect the diversity of the types of facilities in terms of the diagnostic services that are provided.

In the following sections, we provide a brief overview of outpatient diagnostic cardiac catheterizations and express our concerns related to the use of carrier pricing for these established procedures. Since we have previously identified the flaws in the relative values for cardiac catheterization procedures, we suggest a possible solution to ensure adequate national rates in 2007 that would be consistent with the Medicare statute. In addition, we express our support for the development of quality standards and suggest a process to facilitate the

[1] COCA is a non-profit organization representing over sixty U.S. cardiology practices and organizations and 1,000 cardiologists that own and operate non-hospital cardiac catheterization facilities.

development of standards that address the unique needs of outpatient cardiac catheterization centers that may be quite different from other IDTFs.

PROVISIONS: Outpatient Diagnostic Cardiac Catheterizations

Cardiac catheterizations are an important and sophisticated tool for diagnosing heart disease that were traditionally performed in hospitals. However, an increasing number of catheterizations are now performed in cardiovascular outpatient centers ("CVOCs") because they offer patients greater convenience, higher quality, and lower costs – factors that have lead payers, including CMS, to encourage their development. CVOCs can be organized as part of a cardiology group practice or an independent diagnostic testing facility. The cardiology group practice can bill a global fee for both the professional and technical component, while the IDTF bills only the technical component. Medicare's payments for the technical component, either as part of the global payment billed by the cardiology group or the separate technical component billed by an IDTF are intended to reimburse solely for the technological and other support services that enable physicians to perform catheterizations. Medicare calculates payments for the technical component through the same fee schedule methodology used to pay physicians. This methodology seeks to identify for each service a "relative value" that reflects the resources needed to provide that service. Because Medicare has been unable to capture complete cost information for the technical services associated with cardiac catheterizations, the program for several years has used a special estimation method to calculate values for these technical services, which involved the use of the non-physician work pool.

IMPACT

Medicare will pay for approximately 28,000 diagnostic catheterization procedures (CPT Code 93510 TC) and a comparable number of cardiac catheterization imaging procedures (CPT Code 93555 TC and CPT Code 93556 TC). CMS estimates that the 2006 allowed charges for the practice expense ("PE") portion of these claims would total approximately $58.6 million.[2] CMS's change to a bottom-up methodology for developing PE relative value units ("RVUs") would result in a 16 percent reduction in 2007 payments, compared to the 2006 level, resulting in Medicare spending of $49.3 million.[3]

PROVISIONS: Payment Method

In Addendum B of the proposed rule, CMS indicates that payment for several cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be

[2] Medicare Spending for 2006 is based on CMS Data from Town Hall Meeting on Practice Expense Methodology found at
http://www.cms.hhs.gov/apps/ama/license.asp?file=/physicianfeesched/downloads/pe_townhall_hcpcs_level.zip

[3] Medicare Spending for 2007 is based on a payment level that reflects the PE RVUs in June 29th Federal Register Notice and the 2006 Conversion Factor, which is applied to the 2006 utilization level, increased by the rate of growth for Part B enrollees projected in the 2006 Medicare Trustees Report

based on prices established by the Medicare contractors.[4] The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We recognize that carrier based pricing gives CMS some flexibility by exempting these codes from the fee schedule based on a bottom up approach to developing the PE RVUs and appreciate that it may appear to provide a reprieve from the inaccurate PE RVUs that were published in the June 29th Notice. That is not the case.

Instead, if carrier pricing were to be implemented, the carriers would look to CMS for guidance in establishing a price that purportedly reflects the resources needed to perform the procedures, consistent with the statute governing physician payment. Absent any CMS guidance that acknowledges the flaws in the PE RVUs for the cardiac catheterization procedure codes, the carriers would likely use the values in the June 29, 2006 Notice that changed the methodology for the development of PE RVUs. Therefore, we urge that CMS address the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component ("TC") can be billed separately.

An alternative would be for CMS to use cost estimates based on a COCA analysis of direct costs. The results, which are summarized in the chart below, indicate direct costs of $880 based on median values for each cost component. The comparable value from the Resource Utilization Committee ("RUC") for this procedure code is $500. This 48 percent underestimate of cost may account for the significant reduction in the PE RVUs in the June 29th Notice for this procedure code since the direct cost estimate is the starting point for the 19-step calculation of the PE RVU.

COCA Direct Cost Survey Estimates[5] for CPT code 93510 TC	
Cost Component	***Cost Estimate***
Clinical Labor	$323
Medical Supplies	$341
Medical Equipment	$216
Total	$880

The estimates are based on a COCA survey of its members who completed worksheets that were based on the same approach used by RUC. Specifically, each center identified the number of minutes for each type of clinical staff that was associated with a detailed list of activities related to patient care. Unlike the list of activities in the RUC template for this procedure code, the listing of activities was more complete and was based on actual clinical practice derived from a workflow analysis in CVOCs. Similarly, each center provided

[4] With the exception of Noridian's role as a new Medicare Administrative Contractor (MAC) all of the other contractors responsible for processing claims for these procedures are referred to as Medicare carriers.
[5] Based on median values; comparable value based on mean estimates is $1136.

information on the number, the probability of use and the unit cost of a standard list of supplies used as part of the cardiac catheterization procedure. While RUC's supply list was comprehensive, it did not include items if they are used for less than 51 percent of the procedures. The COCA analysis included all supplies. However, the cost estimate incorporates the probability that they are used. For example, if a supply item is used in only 20 percent of the patients, only 20 percent of the supply cost is included in the cost estimate. Similarly, each center provided information on the type of equipment used in cardiac catheterizations, including information about acquisition costs and useful life.

The COCA direct cost survey was managed by staff from Epstein Becker and Green, P.C. and the cost estimates are based on the median value reported for the clinical time in the pre-, intra-, and post- procedure phases of the procedure. The Bureau of Labor Statistics hourly compensation was used to calculate the clinical labor cost associated with each phase of activity. Therefore, the difference in cost compared to the RUC estimate reflects differences in the specificity of the activities for which time was allocated and the time estimate itself. It does not reflect any differences in wage rates by type of clinical labor. Similarly, the medical supplies and medical equipment costs reflect the median values. With regard to equipment, the cost estimate is based on the same assumptions regarding useful life, utilization rate and financing that CMS used in the June 29th Notice.

The study results suggest that the major problem associated with the RUC estimate of direct costs for cardiac catheterization is that the list of direct patient care activities that various clinical staff perform is inadequate and that the total estimates of clinical time are sufficiently low as not to be credible. COCA has learned that some of the under-reporting of time may be associated with an assumption that clinical staff can be performing services related to patients who are undergoing other procedures. As a result, the clinical labor time that should be associated with 93510 TC may be allocated to other procedures that the RUC evaluated. Allocation of time to other procedures is not appropriate in this case because CVOCs focus on diagnostic catheterizations and all of the clinical labor activities and time needs to be allocated to these procedures alone. We believe that the flaws identified for cardiac catheterization procedure codes are likely to be found in a comparable analysis of codes for other procedures performed in a CVOC.

While we are confident in the approach that has been taken to estimate direct costs, we readily acknowledge that the COCA study data would need to be evaluated with regard to methodological factors that could impact the precision of the results. Recognizing that developing an adequate solution will take time, COCA requests that CMS set the 2007 relative value units for the three cardiac catheterization related codes using the 2006 PE RVUs. The reasonableness of using the current 2006 RVUs can be justified by comparing the physician fee schedule ("PFS") rate for the three cardiac catheterization related CPT codes that comprise the APC for diagnostic catheterizations. In 2006, the PFS payment for these codes represents 94 percent of the 2007 APC rate. As a result of the 5.1 percent reduction in the conversion factor, the 2006 RVUs, when applied to the proposed conversion factor for 2007 would, result in a PFS payment that is approximately 90 percent of the APC rate. Therefore, the average payment for

CPT code 93510 TC in 2007 would be $1490, rather than the average rate of $1292 based on the PE RVUs in the June 29, 2006 Notice. The study results indicate that the $1490 rate is more appropriate given that the direct cost estimate that resulted in the $1292 estimate is 43 percent less than the RUC estimate, largely because RUC did not consider all of the direct patient care activities associated with this procedure, or allocated some of the time to other procedures which are not performed in CVOCs.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures because it is inappropriate for CMS to rely on Medicare carriers to price these services, which have a national utilization pattern and historically have been paid under the national fee schedule for physician services. By applying the 2006 PE RVUs for these procedures, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers as described above. The study results demonstrated that the 2006 PE RVUs would result in a more appropriate estimate of the average cost of providing these services. As a result, we do not believe that carrier pricing, which would represent a new payment methodology for these procedure codes, is necessary.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 result in overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterizations performed in CVOCs, are summarized below.

- *Incomplete Tabulation of Direct Costs* – Medicare determines key elements of payments to physicians based on the work of a Resource Utilization Committee, or "RUC" – an AMA body composed of representatives of physician specialty societies. For CVOC catheterization procedures, the CMS proposal assumes *less than one half* the amount of direct costs – the starting point for calculating payments – that were documented in data submitted to the RUC in 2004. COCA study results indicate that most of the deficiency is associated with RUC's use of an incomplete list of direct patient care activities that involve clinical labor and an inadequate approach to estimating supply costs.

- *Incomplete Composition of Direct Costs* – RUC limits its analysis to the marginal costs of labor – a measure that does not adequately account for the costly staffing required to support sophisticated cardiac catheterization procedures. COCA study results indicate that in addition to the incomplete listing of activities in the pre-, intra-, and post- procedure time, there are another set of activities that relate to patient care more generally which could add another ten percent to the clinical labor cost estimate.

- *Reliance on Inapplicable Cost Assumptions* – Two key determinants of CMS' proposed values for technical services is the ratio of direct costs to indirect costs and the average practice expense for each specialty relative to all specialties. For catheterization procedures, the proposal makes the assumption that the direct cost to indirect cost ratios that apply are those for services delivered in cardiology group practices and IDTFs. However, the cost profile for CVOCs is much different from these two providers. In terms of relative costs used in calculating the practice cost index, CVOC costs are also higher than the average of most physician services, reflecting the specialized labor, supplies, and equipment needed to perform sophisticated cardiac catheterization procedures. The CMS approach thus undervalues CVOC costs, which, in turn, leads to undervaluing of Medicare's payments to CVOCs.

IDTF ISSUES: Standards

IDTFs represent a diverse group of providers, including freestanding diagnostic cardiac catheterization labs. In fact, IDTFs represent 65 percent of left heart catheterization utilization (CPT code 93510 TC). We commend CMS in proposing the application of standards for IDTFs comparable to those that were developed for suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). The standards addressed in the proposed rule reflect the general standards related to operational and financial management issues. CMS needs to work with the various types of IDTFs to ensure that additional standards are developed and are consistent with the approach taken with the DMEPOS standards where there are a set of specific requirements for each type of DME supplier. For example, DMEPOS standards address the specific needs of oxygen suppliers compared to suppliers of monitors and supplies for diabetic patients.

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

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS' observation that these types of IDTFs are different, we believe that CVOCs are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center and that the payment needs to reflect this reality. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average cost profile of all IDTFs obtained from the supplemental survey used to develop the practice cost index. The cost study also showed that the

cost profile of outpatient diagnostic cardiac catheterization is comparable for centers that are part of a cardiology group practice or operate separately as an IDTF.

We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers, because the data can be used to estimate the impact that each standard has on practice expenses. As we mentioned above, we believe the cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

Recommendations

Cardiovascular outpatient centers provide high-quality, cost-effective cardiovascular catheterization services to Medicare beneficiaries. The CMS proposed rule on the 2007 physician fee schedule would rely on Medicare contractors to price these procedure codes rather than the national physician fee schedule. COCA is concerned that carrier pricing could be based on the flawed PE RVUs for these codes that were contained in the June 29th Notice. Unless CMS addresses the flaws in the PE RVUs, the precipitous drop in payments to these centers will lead the centers to exit the market, thereby depriving Medicare beneficiaries of a high-quality, lower-cost alternative to hospital-based catheterizations. To avoid this result, COCA makes the following recommendations.

1. CMS should perform a new micro-costing analysis tailored to the special characteristics of the technical services associated with cardiac catheterizations.

Such an analysis could capture direct costs more completely and estimate indirect costs more accurately, thus allowing CMS to more precisely calibrate Medicare's payments to the actual resources that CVOCs use in providing technical services. It may be that CMS will need to devise a special means for calculating values for services, like cardiac catheterizations, that fit less naturally into the physician fee schedule. In any event, the analysis will be complex, and, to ensure reliability, will require considerable time to complete.

COCA has conducted an analysis of direct costs for cardiac catheterizations and is ready to work with CMS regarding our methodology and findings and how it can be expanded to include other procedure codes.

2. For 2007, while this analysis is being conducted, CMS should use the 2006 PE RVUs to base the fee schedule payment for those procedures that are performed in an outpatient catheterization center.

While, admittedly, the 2006 PE RVUs may be imperfect, they represent more reasonable estimates than those produced by the incomplete and flawed calculations underlying the CMS proposal. The 2006 PE RVUs result in fee schedule payment for cardiac catheterization related procedures at relative parity with the hospital outpatient APC

payment for the three related procedure codes. In the absence of using the 2006 values, CVOCs will not be able to meet operating costs and will be forced to exit the market, thereby thwarting Medicare's ability to lower spending by providing beneficiaries access to high-quality, lower-cost CVOC services. The four-year transition will limit the impact to approximately 17 percent for the family of three codes comprising the catheterization APC. However, by 2010, payments will be reduced 69 percent and payments will not even approximate the cost of performing the procedure.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and at the suggestion of CMS staff, sponsored a study to assess the validity of those concerns. The study results validate the central premise of our comments that the RUC direct cost estimate is an inaccurate reflection of the direct costs, particularly those related to clinical labor. Therefore, we request that the 2006 PE RVUs be used in 2007 so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We are available to brief CMS on the results of the COCA study and will be collaborating with the American College of Cardiology and the Society for Cardiac Angiography and Interventions as they prepare for the RUC activities in 2007. We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis and respectfully request that you base 2007 payments for procedures performed in a cardiac catheterization center on the current practice expense relative value units.

We look forward to working with CMS concerning these issues. If you have any questions, please do not hesitate to contact me at (615) 250-1706.

Sincerely,

Steve Blades, President

cc: Herb B. Kuhn

Submitter : **Mr. James Archetto** **Date: 10/10/2006**

Organization : **Radi Medical Systems, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-861-Attach-1.PDF

#861

RADI
Improving Patient Care

October 9, 2006

Docket: CMS-1321-P –
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Center for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21235

Re: RADI Medical Systems Inc.;
Proposal for Non-Facility Practice Expense;
CPT 93571 and CPT 93572

The following comments are submitted in response to the proposed Medicare Part B physician fee schedule for 2007, regarding revision of the non-facility practice expense value for the above-referenced CPT codes. This change is needed to reflect equipment acquisition costs incurred by non-hospital providers that utilize RADI's PressureWire® Sensor in free-standing cardiac catheterization laboratories. (In addition this document was submitted in April, 2006 for inclusion on the agenda of the Practice Expense Advisory Committee Meeting scheduled for October, 2006.)

I. RADI Medical Systems

RADI develops and manufactures medical devices in the field of interventional cardiology, including intravascular sensors (pressure measurement) and hemostasis management products. More information regarding RADI is available at www.radi.se/index.asp?siteId=1.

II. The RADI PressureWire®

RADI's PressureWire® is an intravascular sensor mounted at the end of a 0.014"diameter high-torque interventional guidewire. The guidewire connects to an analyzer monitor via a connector cable. The tip of the PressureWire® is composed of an easy-to-shape platinum spring around a central core wire. At the proximal end of this tip is a high fidelity pressure transducer that measures intravascular pressure. In addition, the PressureWire® includes a PTFE-coated shaft that provides lubrication and enhances handling.

The PressureWire® or a comparable device is required to perform the procedures described by CPT code 93571, Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, initial vessel; and CPT 93572, each additional vessel.

Once a suspected occlusion has been identified, a PressureWire® can be used to ensure any stent is applied to the culprit lesion and to avoid unnecessary stenting, as follows:

- The PressureWire® is calibrated;

- The PressureWire® is advanced through a guiding catheter and the sensor is brought distal to the tip of the guiding catheter;
- Pressures between the guide catheter and the PressureWire® are equalized;
- The PressureWire® is then advanced distal to the suspect lesion;
- The patient is stressed pharmacologically;
- If during stress the pressure as measured by the PressureWire® drops to <75% of the aortic pressure, the suspect lesion is the culprit (with 100% specificity) and should be treated; whereas if the distal pressure is >75% of the aortic pressure, the suspect lesion is not the culprit (with 88% sensitivity) and the patient may be managed medically;
- If intervention is required, a stent can be deployed over the PressureWire®.

The PressureWire® can then be used after the intervention for assessment of the success of stent deployment.

III. Clinical use of the RADI PressureWire® has evolved

The procedures described by CPT 93571 and CPT 93572 have historically been performed in hospitals in both inpatient and outpatient settings. Over time, however, evolving standards of medical practice have made it feasible for these procedures to be performed in non-hospital facilities, such as independent cardiac catheterization laboratories or other diagnostic testing facilities.

Some private payors of health care expenses cover (and, until recently, Medicare required national coverage for) certain cardiac catheterizations in non-hospital settings. The existing physician reimbursement rates for CPT 93571 and CPT 93572, however, have not been adjusted to reflect the providers' equipment acquisition costs resulting from this evolution in site of service.

IV. Current payment rates do not include reimbursement for cost of the PressureWire® in non-facility settings

As the procedures in CPT 93571 and CPT 93572 have historically been performed in the hospital inpatient and outpatient settings, the Medicare physician fee schedule reflects a presumption that the PressureWire® will be acquired by a hospital. The cost of the device is reflected, for example, in the hospital outpatient fee for Ambulatory Payment Classification 670, which includes CPT 93571 (CPT 93572 is assigned to APC 416).

A key difference between APC 670 and APC 416 (and corresponding CPT 93571 and 93572) is that the follow-on procedure of APC 416 uses the same PressureWire® that was used for the initial procedure covered by APC 610. Accordingly, the hospital's device acquisition cost represents most of the difference in reimbursement rates between APC 670 and APC 416.

The difference in the base fee for APC 610 and APC 416 is $732.48, most of which is attributable to the approximate $690 cost of acquiring a PressureWire® or a comparable device. Current hospital fee information is summarized as follows:

Description (APC code)	Relative Weight	Payment Rate	National unadjusted copayment	Minimum unadjusted copayment
Level II Intravascular and Intracardiac Ultrasound and Flow Reserve (APC 670)	28.7546	$1,711.22	$536.10	$342.24
Level I Intravascular and Intracardiac Ultrasound and Flow Reserve (APC 416)	16.4464	$978.74	———	$195.75
Difference		**$732.48**		

Similarly, current reimbursement rates under the physician fee schedule reflect the assumption that the hospital—and not the physician—will acquire the PressureWire® used to perform CPT 93571 and CPT 93572. This is evidenced by the modest non-facility technical component practice expense of CPT 93571, as follows:

CPT	Mod	Physician Work RVUs[3]	Non-Facility PE RVUs	Facility PE RVUs
93571		1.80	5.25	NA
	26	1.80	0.68	0.68
	TC	0.00	**4.57**	NA
93572		0.00	0.00	0.00
	26	1.44	0.50	0.50
	TC	0.00	**0.00**	0.00

The non-facility practice expense technical component of 4.57 relative value units equates to approximately $165.33 at the current 2006 fee schedule conversion factor. Compared to the $690 cost of a PressureWire®, the non-facility practice expense technical component does not adequately reflect the device acquisition cost for non-hospital providers.

V. It is cost-effective for Medicare to promote non-hospital sites of service

By removing an obstacle that discourages clinically appropriate non-facility cardiac catheterization services, the proposed change will reduce net costs to Medicare. Specifically, the increased non-facility practice expense will enable physicians to provide a medically necessary service, while avoiding the much higher facility fees incurred when those services are provided in a hospital. The proposed change will affect only physicians' choice of *where* to provide the service and will not alter the clinical standards for determining *whether* the service is needed. Thus, the proposed change will promote a more efficient use of Medicare-funded hospital resources.

VI. Adjusting the non-facility practice expense technical component for CPT 93571 on the physician fee schedule is preferable to other changes in the reimbursement system

An adjustment to the physician fee schedule's non-facility practice expense technical component for CPT 93571 is the preferred method to properly reimburse for these services in non-hospital settings, as the resulting reimbursement rate will remain subject to the scaling and spending-growth restrictions of the physician fee schedule and will avoid the undesirable effects of "unbundling" a necessary device.

Moreover, the HCPCS Working Group is inclined against creating a separately reimbursable HCPCS code for the PressureWire® sensor. In its preliminary analysis, the Working Group concluded that adjustment of the practice expense, rather than a new HCPCS code, is the preferred method for reflecting the cost of PressureWire® when used in the non-hospital settings. *See* HCPCS Request No. 06.88, Agenda Item No. 20 (May 5, 2006).

Accordingly, RADI respectfully requests CMS to evaluate the present reimbursement of PressureWire® when used in a non-facility setting and to initiate a process for adjusting the physician fee schedule's non-facility practice expense relative value so that it provides reasonable reimbursement for use of this treatment-enhancing and cost-saving device in non-hospital settings.

Sincerely,

James M. Archetto
Chief Operating Officer
RADI Medical Systems, Inc.

CC: Wayne Powell, SCAI
Denise Garris, ACC
Pam West, CMS
Carolyn Mullen, CMS

Submitter : **Ms. Norma Border** **Date: 10/10/2006**

Organization : **AADA/ASDS - Dermatology Community**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-862-Attach-1.DOC

#862

American Academy of Dermatology Association
American Society of Dermatologic Surgery

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1321-P**

Dear Administrator McClellan:

On behalf of the dermatologic community, we appreciate the opportunity to submit written comments regarding the 2007 Medicare Physician Fee Schedule. As advocates for dermatologists and their patients, our organizations believe that an adequate physician fee schedule ensures fairness and continued beneficiary access to quality, dermatologic health care services.

Sustainable Growth Rate (SGR)
A sharp -5.1 percent cut in Medicare physician payments will take effect on January 1, 2007 unless Congress takes action this year to avert this reduction, and keep the program strong for seniors and disabled patients and the physicians who care for them. At the heart of the problem is the Sustainable Growth Rate (SGR) formula which calculates annual updates in Medicare payments for Part B physician services. Under this formula, physicians are penalized for increases in the volume of services they provide that are beyond their control – such as new benefits authorized by legislation, regulations, coverage decisions, new technology, growing patient demand for services, and the growing number of beneficiaries.

Further, according to the 2006 Medicare Trustees Report, if the SGR formula is not fixed, physicians will receive negative updates of approximately five percent each year from 2007 until 2015. These reductions may prompt a number of physicians to reconsider their participation in the Medicare program, to limit services to Medicare beneficiaries, or to restrict the number of new Medicare patients they are able to accommodate in their practice.

Budget Neutrality
Adding to the pending -5.1 percent cut, the proposed notice requires budget neutrality adjustments to physician work relative value units only as a result of changes from the five-year review process and other payment policy revisions. Application of the budget neutrality adjustment to the conversion factor would impact all physician services, whereas the application of the budget neutrality adjustment to the work RVUs would impact only those services that have physician work RVUs. Thus, we strongly urge CMS to implement any budget neutrality adjustments to the conversion factor.

Practice Expense
We appreciate CMS's proposal to incorporate dermatology's practice expense supplemental survey data to the 2007 fee schedule. Considerable staff and physician volunteer time and significant financial resources were dedicated to submitting supplemental survey data, as provided by the Balanced Budget Refinement Act of 1999 (BBRA) and requested by CMS. Incorporating this data into the CY2007 fee schedule will increase the accuracy in determining the PE RVUs for the services our members provide, as well as improving the overall accuracy of the practice expense component of the fee schedule. Again, we appreciate CMS at last including the supplemental survey data into the proposed rule and request that the data be implemented in the final rule.

As you know, the AMA is sponsoring a multi-specialty supplemental study of practice expense costs. We have already agreed to participate in and contribute to this additional practice expense survey. However, we are deeply concerned that the design and structure of the new survey in fact focus on practice expense costs – as originally communicated to the physician community – and also be in compliance with all of the criteria established for the specialty specific practice expense supplemental surveys accepted by CMS. Additionally, the new multi-specialty practice expense survey results must be held to the same standard relating to the level of precision as the supplemental surveys already accepted by CMS.

Thank you for the opportunity to comment on this proposed notice. For further information, please contact Norma Border at nborder@aad.org or 847-330-0230 or Ted Thurn at tthurn@asds.net at 847-956-9126.

Sincerely,

American Academy of Dermatology Association
American Society of Dermatologic Surgery

growth in the gross domestic product instead of the health care needs of Medicare beneficiaries and the true cost of maintaining a medical practice.

We believe the looming 5.1% cut in payment slated for 2007 will have a negative impact on Medicare beneficiaries' access to breast health services. For example, results of a recent American Medical Association survey [1] indicate that Medicare payment cuts to physicians will hurt access to care for America's seniors. The results show that 45 percent of physicians will either stop accepting or decrease the number of new Medicare patients they accept if Medicare payments are cut in 2007. In that breast cancer is largely a disease of the aging this could have devastating effects on hundreds of thousands of breast cancer patients across the country.

Moreover, according to the survey report, in rural areas more than 1/3 of physicians say they will be forced to eliminate outreach services. This is extremely troublesome and could have dire consequences on access to care for low-income patients who are already disproportionately impacted by breast cancer.

The Komen Foundation urges you to reconsider the cuts slated for 2007 and the disastrous impact such cuts will have on breast cancer patients and their families. We further believe that the entire payment system must be reformed in the long-term. We realize that the necessary changes require congressional action, but we respectfully encourage you to direct your legislative staff to work with congressional staff to develop a viable solution.

As you know, the 5.1 percent reduction in overall physician payment is slated to take affect concurrently with the significant changes CMS proposed in June regarding the five-year review of work relative value units and with the phasing in of the practice expense methodology as well. For many breast health services, the combined impact on physician payment is substantial. We have attached our comment letter to the June rule, and we respectfully request that CMS consider such comments, in addition to the comments set forth herein, when formulating the final Physician Fee Schedule rule.

We are particularly concerned about the rate reductions for the following procedures:

HCPCS/CPT	Descriptor
76092	Mammogram screening
G0240	Diagnostic mammography
76095	Stereotactic breast biopsy
19350	Nipple areola reconstruction
12162	Partial mastectomy w/ lymph node removal
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction, with latissimus dorsi flap, with or without prosthetic

[1] AMA press release on the 2006 AMA Medicare Physician Payment Survey accessed at http://www.ama-assn.org/ama/pub/category/16117.html.

	implant
19364	Breast reconstruction with free flap
19366	Breast reconstruction with other technique
19367	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle
19368	Breast reconstruction with TRAM, single pedicle, with supercharging
19369	Breast reconstruction with TRAM, double pedicle

B. Imaging Provisions in the Deficit Reduction Act

Komen is also concerned about the effect of scheduled cuts in Medicare imaging reimbursement under Section 5102 of the Deficit Reduction Act (DRA)[2] and the negative impact that they will very likely have upon the care that Medicare beneficiaries receive. Specifically, we want to draw your attention to the provision of the law that stipulates that if the technical component of specified imaging services under the physician fee schedule exceeds the outpatient department (OPD) fee schedule amount for such service, payment will be capped at the OPD amount. The provisions would reduce Medicare reimbursement for imaging services by as much as 50 percent in some cases. These services are critical to life-saving early detection for breast cancer patients.

Several imaging codes integral to the practice of breast health services are included in Addendum F of the proposed rule despite the explicit language in the DRA excluding them from the provision. Section 5102(b)(1) of the DRA could not be more clear. It defines imaging services as "...imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, **but excluding diagnostic and screening mammography**." We are extremely troubled by the fact that the following codes are slated to be capped at the OPD rate:

HCPCS/CPT	Short Descriptor
76086	X-ray of mammary duct
76088	X-ray of mammary ducts
76093	Magnetic image, breast
76094	Magnetic image, both breasts
76095	Magnetic image, both breasts
76096	X-ray of needle wire, breast
76098	X-ray exam, breast specimen
76645	Ultrasound exam, breast(s)

[2] Section 5102 of Deficit Reduction Act of 2005 (Pub.L. 109-171).

The Susan G. Komen
Breast Cancer Foundation

We urge the agency to correct this oversight in the final rule.

The Komen Foundation appreciates the opportunity to comment on the proposed regulations and urges the agency to work with Congress to preserve beneficiary access to care by providing appropriate payment to physicians in 2007. We also believe CMS plays a critical role in advising Congress on the design of a sustainable payment system for the future. We hope that our letter highlights our sincere interest in continuing to work with CMS to make breast health services cost effective, properly reimbursed and readily accessible. Please feel free to contact me at 972-855-4315 if you have any questions regarding these comments

Sincerely,

Diane L. Balma

Diane Balma
Public Policy Director

The Power of a Promise
20 YEARS

#864-2

The Susan G. Komen Breast Cancer Foundation

5005 LBJ Freeway
Suite 250
Dallas, Texas 75244
Tel: 972.855.1600
Fax: 972.855.1605
Helpline: 1.800 I'M AWARE®
www.komen.org

Headquarters

August 31, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512 -PN
PO Box 8017
Baltimore, MD 21244-8017

Dear Mr. McClellan,

I am writing on behalf of the Susan G. Komen Breast Cancer Foundation regarding the proposed changes in RVU codes CPT 19160 and 19180 for physician reimbursement of mastectomy and lumpectomy surgical procedures.

The Susan G. Komen Breast Cancer Foundation is a global leader in the war against breast cancer. Founded in 1982, the Komen Foundation is now comprised of 121 Affiliates nationwide, three international Affiliates and 75,000 volunteers. Komen has invested more than $630 million dollars for breast cancer research, education, screening and treatment programs, and actively addresses the gaps and disparities in the needs of the medically underserved. The Komen Foundation is dedicated to our mission to eradicate breast cancer as a life-threatening disease.

The Komen Foundation commends the Centers for Medicare and Medicaid Services for understanding that total mastectomy has previously been under-reimbursed. However, our concern is that the new methodology for arranging RVU codes and the formulas for which reimbursement levels are assigned may create greater financial incentives for mastectomies over lumpectomies. The Komen Foundation is concerned that the new methodology may result in financially influencing physicians to choose one procedure over the other, and impede patient access to quality care - consequently, the patient's best surgical options.

Patients face great battles, both emotionally and physically, after being diagnosed with breast cancer, and treatment is a complex and multi-faceted process. The Komen Foundation does not endorse one procedure over the other, but we recognize that not all patients are appropriate candidates for mastectomy. Alarmingly, statistics show that mastectomies are performed at three times the rate of lumpectomies. Mastectomies are less precise surgeries than lumpectomies, and the unnecessary removal of a breast may result in the loss of the patient's sense of self and sexuality, as well as provide a constant visual reminder of cancer. Lumpectomy is a wholly appropriate procedure for saving lives afflicted by breast cancer.

The Power of a Promise
20 YEARS

The Susan G. Komen
Breast Cancer Foundation

Thank you for your consideration of the issue of reimbursements for mastectomies and lumpectomies. It is critical that women facing the battle of breast cancer have every available option opened to them. The Susan G. Komen Breast Cancer Foundation appreciates the work CMS does to make certain that breast health care and breast cancer care will not be compromised, resulting in the deterioration of quality of life and quality of care for breast cancer patients.

If the Komen Foundation may be of any assistance to you, or help answer any questions, please do not hesitate to contact us.

Sincerely,

Diane L. Balma

Diane Balma
Public Policy Director

The Power of a Promise
20 YEARS

Submitter : Dr. Robert Zwolak **Date:** 10/10/2006

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE ENCLOSED MICROSOFT WORD FILE. THIS IS A SECOND ATTEMPT TO TRANSMIT. MY APOLOGIES IF YOU GET TWO COPIES, BUT TWO IS BETTER THAN NONE.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Ann Richardson Berkey** **Date: 10/10/2006**

Organization : **McKesson Corporation**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see McKesson Corporation's comments on the ASP reporting aspects of the 2007 Medicare Physician Fee Schedule and Other Changes to Payment under Part B proposed rule.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. paul donovan **Date:** 10/10/2006

Organization : grand st medical

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

TO WHOM IT MAY CONCERN:

I AM A BOARD CERTIFIED HEMATOLOGIST/ONCOLOGIST WHO TREATS CANCER PATIENTS AND PATIENTS WITH BLOOD DISORDERS. I UTILIZE WHITE BLOOD CELL GROWTH FACTORS, IE NEULASTA AND NEUPOGEN AS WELL AS RED BLOOD CELL GROWTH FACTORS IE ARANESP AND PROCRIT. MY PRACTICE IS LOCATED IN RURAL KINGSTON NY AND I AM THE ONLY ONCOLOGIST IN THE PRACTICE. HAVING THE ABOVE DRUGS AVAILABLE TO TREAT MY PATIENTS WHO HAVE CHEMO INDUCED NEUTROPENIA AND ANEMIAS HAVE BEEN A GODSEND. BECAUSE SOME OF THE PRODUCTS CAN BE DOSED INFREQUENTLY(NEULASTA, ARANESP)I AM ABLE TO CARE FOR PATIENTS WITH RESTRICTED INCOMES THAT LIVE A GREAT DISTANCE FROM MY OFFICE BY GIVING THESE DRUGS AS INFREQUENTLY AS ONCE EVERY THREE WEEKS. THIS MINIMIZES OFFICE VISITS FOR PATIENTS AND WILL AVOID PATIENT HOSPITALIZATION FOR THIS FRAGILE GROUP. THE MORE TIME THESE PATIENTS SPEND LIVING THEIR LIVES AND NOT BEING IN DOCTORS OFFICES THE BETTER WILL BE THE OUTCOME OF THEIR ILLNESS. CURRENTLY I AM ABLE TO FREELY UTILIZE SHORT ACTING PRODUCTS SUCH AS NEUPOGEN AND PROCRIT FOR THOSE PATIENTS WHO NEED TO BE SEEN MORE FRQUENTLY BY ME AS WELL AS THE LONG ACTING AGENTS(NEULASTA AND ARANESP)FOR THOSE PATIENTS WHO WANT TO LIVE THEIR LIVES AND ONLY NEED TO SEE ME ONCE EVERY 3 WEEKS. I AM VERY MUCH AGAINST ANY CHANGE IN THE CALCULATION OF ASP FOR THESE PRODUCTS THAT IS NOT BASED ON THE ACTUAL COST OF THESE MEDICATIONS SET BY THE DRUG COMPANY. DRUG COMPANIES OFFER CONTRACTING WITH SOME PRODUCTS. THIS CONTRACTING HAS HELPED ME PROVIDE OPTIMAL CARE FOR MY PATIENTS BECAUSE MY PATIENTS HAVE ACCESS TO OTHERWISE VERY EXPENSIVE PRODUCTS THAT THEY REALLY NEED. AGAIN,I STRONGLY URGE CMS NOT TO DEVIATE FROM THEIR CALCULATION OF ASP THAT THEY HAVE BEEN USING IN 2006. CMS SHOULD ALLOW PHARACEUTICAL COMPANIES TO CONTINUE THEIR CONTRACTING STRATGEDIES WITHOUT INTERRUPTION OF ASP CALCULATED REIMBURESEMENT AS THIS BENEFITS THE PATIENTS RECIEVING THESE PRODUCTS AS I HAVE STATED ABOVE. THANK YOU FOR GIVING ME THE OPPORTUNITY TO COMMENT ON THIS PROPOSED RULE CMS-1321-P. PLEASE CONTACT ME IF YOU HAVE ANY QUESTIONS. THANK YOU.

SINCERELY,

PAUL B DONOVAN, MD

Submitter : Jacob S. Philip **Date:** 10/10/2006

Organization : IMPAC Medical Systems, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-868-Attach-1.PDF

#868

IMPAC

IMPAC Medical Systems, Inc.
www.impac.com

Corporate Headquarters:
100 West Evelyn Avenue
Mountain View, CA 94041-1464
T 650.623.8800
F 650.428.0721

October 4, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State

	Indiana – Current	Florida – Proposed 9/11/06	Texas – 9/1/06
77520	—	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

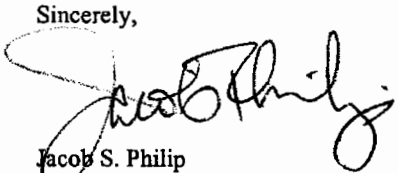
In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Sincerely,



Jacob S. Philip
Director, Radiation Oncology Business Unit
IMPAC Medical Systems, Inc.
An Elekta Company

Submitter : Mr. Louie Gohmert **Date:** 10/10/2006

Organization : Office of U.S. Rep. Louie Gohmert

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : JONATHAN LINKOUS **Date:** 10/10/2006

Organization : AMERICAN TELEMEDICINE ASSOCIATION

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-870-Attach-1.DOC

#870

American Telemedicine Association
RESPONSE TO COMMENTS
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

CMS-1321-P, TELEHEALTH SERVICES

The following comments, in accordance with guidelines published in the **Federal Register** (71 FR 48982), are submitted by the American Telemedicine Association (ATA) in response to several provisions of the proposed rule as related to Medicare Telehealth Services, Section II, C.

CMS Review

In the August 22, 2006 **Federal Register** (71 FR 48982), the Center for Medicare and Medicaid Services published Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. Included in this proposed rule were responses to the American Telemedicine Association's (ATA) requested additions for telehealth services Current Procedural Terminology (CPT) codes. In accordance with the requirements for submitting requests for additions of telehealth CPT codes, as published in the December 31, 2002 **Federal Register** (67 FR 79988), ATA requested the addition of Skilled Nursing Facility, Speech and Language, Audiology, and Physical Therapy codes, providing substantive background and studies to support the request. In addition, ATA followed the precedent set by CMS in 2004 and 2005 with respect to expansion of eligible practitioners and originating sites. ATA submits the following comments in response to CMS' proposed decisions regarding the request for telehealth CPT code additions.

Background

The process for submitting and justifying requests for additional CPT codes, as set forth by CMS, specifically outlines a method for quantifying whether a request for additional CPT codes meets the definition of telehealth services (Section 1834(m)(4)(F) of the Act) as professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000 by CPT codes 99241-99275, 99201-99215, 90804-90809, and 90862) and any additional service specified by the Secretary (71 FR 48994). The requests are assigned to either Category 1 or Category 2 services. Category 1 services are those that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing requests, CMS looks for similarities between the proposed and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, as well as similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment (71 FR 48994). Category 2 Services are considered "not similar to the current list of telehealth services". CMS' review of Category 2 requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face "hands on" delivery of the

same service. Category 2 requests require a substantive scientific justification for approval.

Since establishing the process, the following CPT codes have been added to the list of Medicare telehealth services: psychiatric diagnostic interview examination (90801); ESRD services with two to three visits per month and four or more visits per month (although CMS requires at least one visit a month by a physician, CNS, NP, or PA to examine the vascular access site); and individual medical nutritional therapy. CPT codes for dialysis were added to the approved list of telehealth services by CMS without a request to do so from the public through the process outlined in the **Federal Register** (69 FR 66276), and without dialysis centers being an approved originating site. Psychiatric diagnostic interview examination also was not formally requested through the established process. In 2005, CMS added medical nutrition therapists and other nutrition professionals to the list of eligible practitioners permitted to furnish Medicare telehealth services without legislative mandate, and without any report from the Secretary considering or recommending that these health professionals be permitted to provide and receive payment for Medicare telehealth services at the distant site.

Speech Therapy, Audiology and Physical Therapy Services Requested Codes

ATA submitted a request to add various speech therapy, audiology and physical therapy services to the list of Medicare telehealth services and requested the CMS add physical therapists, speech language pathologists and audiologists to the list of approved telehealth practitioners, following the action taken by CMS in 2005 to add medical nutrition therapists. ATA understands that the request for the addition of the codes for speech therapy, audiology and physical therapy services was denied based on the premise that physical therapists, speech language pathologists and audiologists are not permitted under current law to provide and receive payment for Medicare telehealth services at the distant site.

ATA respectfully disagrees with the position taken by CMS. As previously delineated, the addition of CPT codes to the list of approved telehealth services is contingent upon the regulatory process, outlined in the **Federal Register**, as an assessment of whether or not additional services are those services similar to office and other outpatient visits, consultation, and office psychiatry services. This regulatory process does not provide the discretion to not consider a CPT code addition based on whether or not the providers connecting to a distant site are eligible practitioners under the law. The process simply allows CMS to look for similarities between the proposed and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, as well as similarities in the telecommunications system used to deliver the proposed service.

In 2005, CMS approved medical nutrition therapy codes without pre-existing eligibility for medical nutrition therapists for the provision or receipt of payment for Medicare telehealth services. The contradiction is quite apparent in the process for approving codes in 2005 and that specified in the proposed rule published in August 2006. ATA,

therefore, proposes that CMS either reverse its decision to disallow the skilled nursing facility codes or explain the contradiction in process used between 2005 and 2006.

In addition, CMS stated in response to ATA's request for additional Medicare telehealth services that although speech language pathologists, audiologists and physical therapists are not permitted under current law to provide and receive payment for Medicare telehealth services at the distant site, CMS is exploring this issue as part of a Report to Congress (required by section 223(d) of the Benefits Improvement and Protection Act (BIPA) of 2000) on additional sites and settings, geographic areas, and types of non-physician practitioners that could be reimbursed for the provision of telehealth services in addition to those permitted under section 1834(m) of the Social Security Act. The Report to Congress, as specified in section 223(d) of BIPA, as part of Public Law 106-554, was due "not later than 2 years after the date of the enactment of this Act . . .", and called for the Secretary to submit the Report together with "such recommendations for legislation that the Secretary determines are appropriate." The legislation became public law on December 21, 2000. In lieu of the yet-to-be-released Report to Congress, now several years overdue, ATA asks for CMS' clarification on the expected date of release of the Report and legislative recommendations.

Nursing Facility Care

ATA requested the codes for skilled nursing care (now called nursing facility care) and the request for addition of these codes was denied. ATA would again reiterate that the regulatory process does not require an originating site to be approved prior to the approval of the requested CPT code addition. The process for approving a code used in a health care facility that is not an approved originating site has been demonstrated by CMS in 2004 with the approval of dialysis codes for telehealth. We are confused by the apparent contradiction in process from 2004 to 2006 and would request that CMS either add the requested nursing facility codes, based on the required assessment for Category 1 services, or explain this contradiction in process.

Section 418 of the Medicare Modernization Act (Public Law 108-173, Title IV, Subtitle B) required the Health Resources Services Administration (HRSA), a component of HHS, in consultation with CMS, to conduct an evaluation of demonstration projects under which SNFs, as defined in section 1819(a) of the Act, are treated as originating sites for Medicare telehealth services. The MMA also required the Secretary to submit a Report to Congress that includes recommendations on "mechanisms to ensure that permitting a SNF to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS), as is otherwise required by the Secretary", and provided the authority to include SNFs as a Medicare telehealth originating site "If the Secretary concludes that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services, and the Secretary can establish the mechanisms to ensure that such permission does not serve as a substitute for in-person visits, the Secretary may deem a skilled nursing facility to be an originating

site beginning on January 1, 2006." (P.L. 108-173, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ173.108.pdf).

The findings of the Report are not required to add CPT codes, as requested formally by the public, to the list of approved telehealth CPT codes. The Report to Congress with recommendations on adding SNFs to the list of approved originating sites is mutually exclusive of the process for approving CPT codes. Further, as stated in Public Law 108-173, the Secretary's Report to Congress was required to be submitted no later than January 1, 2005. Although this Report is currently under review in DHHS, as stated in the CMS Review of the nursing facility care request, we request that CMS move forward with approval of the SNF code requests, as not to delay implementation of the recommendations that will be forthcoming from DHHS.

Additionally, CMS has indicated in its response that CMS will review and consider the recommendations of the Report to Congress once it is issued, and, if it is determined that SNFs should be added as an originating site, the change will be considered in future rulemaking (71 FR 48995). ATA requests clarification of what process is referred to in CMS' use of the phrase "future rulemaking". Will the public be required to formally resubmit the SNF codes or will CMS take the lead and approve the codes at the same time that SNFs are added as originating sites? ATA respectfully requests clarification on this issue.

Submitter : Dr. Myron Gerson **Date:** 10/10/2006

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-871-Attach-1.DOC

#871

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

4550 Montgomery Avenue
Suite 780 North
Bethesda, Maryland 20814
Telephone: 301-215-7575

Website: www.asnc.org
Email: admin@asnc.org
Fax: 301-215-7113

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

October 10, 2006

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

ATTN: FILE CODE

Re: Medicare Program; Proposed Changes to the Physician Fee Schedule Calendar Year 2007 Payment Rates; Proposed Rule II - CMS-1321-P

Dear Administrator Norwalk:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the Medicare Physician Fee Schedule. We look forward to working with the agency collaboratively as you respond to our concerns and recommendations.

As you know, ASNC is a nearly 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

ASNC is aware that many of the major policy and data issues underlying the CY 2007 proposed PFS rates were actually subject to notice and comment earlier this year, in conjunction with a Proposed Notice published in the Federal Register on June 29, 2006 ("June 29 Notice"). At this time, ASNC would like to strongly reaffirm our comments related to the results of the five year review and to certain changes in the methodology for determining practice expense (PE) relative value units (RVUs), which the Society submitted to CMS on August 21, 2006.

One issue that ASNC addressed in these August comments may deserve special attention in light of events that occurred after the June 29 Notice comment deadline. Since that time, it has come to our attention that the AMA and some other groups have objected to the budget neutrality adjustment methodology proposed in the June 29 Notice, under which the five year review changes are to be absorbed exclusively through a 10% reduction in work RVUs and the PE methodology and related changes are to be absorbed exclusively through a reduction in the PE-RVUs.

The AMA's position appears to be that the budget neutrality adjustment for the five year review should be made by reducing the conversion factor, while the budget neutrality adjustment attributable to the PE methodology changes should be absorbed exclusively by the PE-RVUs. ASNC understands that the position of these groups is motivated in large part by the fact that, under the proposed budget neutrality methodology, some physicians will not see the full increases that they had anticipated as the result of the five year review changes, and especially the increases in evaluation and management (E&M) work RVUs.

However, ASNC remains concerned about the solution outlined by the AMA in its comment on this issue: This letter proposes shifting the budget neutrality adjustment resulting from the five year review to the conversion factor, while leaving the budget neutrality adjustment for PE methodology changes to be absorbed exclusively by PE-RVUs. This change clearly would unfairly disadvantage technical component services, including those within nuclear cardiology. Since the proposed five year review and PE changes will already result in steep reductions for a number of nuclear cardiology services, we strenuously oppose the change in the budget neutrality adjustment methodology urged by the AMA and other groups.

In the event that CMS shifts the budget neutrality adjustment attributable to the five year review to the conversion factor, the budget neutrality adjustments necessitated by the new PE-RVU methodology (and most certainly the 32% reduction in direct cost allowances) clearly should be shifted to the conversion factor as well. The AMA and other organizations argue that the budget neutrality adjustment attributable to PE-RVU methodology changes should be absorbed exclusively by PE-RVUs until certain modifications are made in the equipment utilization and related assumptions and until a multi-specialty survey of indirect costs is completed by the AMA.

However, neither changing the equipment-related assumptions nor substituting new indirect cost survey data would affect the 32% direct cost budget neutrality adjustment. There simply is no rational policy reason to treat budget neutrality adjustments made as the result of PE methodology changes differently from those necessitated by the five year review. And while there may be some technical difficulty in determining the amount of the budget neutrality adjustment

for indirect PE RVUs, there certainly is no such difficulty in determining the budget neutrality adjustment for direct costs.

As CMS has noted, the Practice Expense Advisory Committee has essentially verified all of the direct cost inputs and CMS considers the refined values sufficiently reliable to make substantial methodology changes based on these values. These data represent real costs, and any adjustment made to ensure that these costs "fit" into the direct cost pool represent a real reduction in payment necessitated by budgetary constraints. There simply is no convincing rationale for requiring such reductions to be born exclusively by technical component and other services that are PE-heavy while shifting the additional expenditures necessitated by the five year review to the conversion factor.

Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

ASNC has strongly and consistently supported efforts to eliminate or severely reduce opportunities for fraud and abuse in the Medicare program. However, as the apparent abuses targeted by the proposed revisions to the physician self-referral rules appear to be aimed at pathology services, ASNC recommends that CMS strictly limit the application of these changes—if adopted—to the field of pathology at the present time.

We believe this is the most appropriate course of action for CMS to pursue at this time, as it is our understanding that the medical societies representing pathologists initiated the development of these proposed rule changes with the agency out of concern for the specific practices emerging in that field (i.e. "pod-labs."). Further, we also understand that these proposed revisions are the product of a collaborative effort between CMS and those pathologist groups, and that the revisions generally meet with the pathology groups' approval. ASNC commends CMS for taking this collaborative approach to rulemaking.

As noted by the preamble itself, CMS is seeking comments on whether the proposed changes should apply strictly to pathology services, or if they should also extend to diagnostic imaging and other services beyond pathology (71 Fed. Reg. 49056; August 22, 2006).At the present time, we believe that the impact of these proposed regulations on diagnostic imaging and other non-pathology services cannot be accurately studied within the relatively short timeframe afforded by the comment period for the proposed 2007 Medicare Physician Fee Schedule. Among possible ASNC concerns requiring additional study:

- The proposed conditions of permissible billing for technical and/or professional components (TC/PC, respectively) of testing services may significantly interfere with physician group practices' flexibility in

legitimately contracting with independent physicians, thereby potentially increasing costs to the Medicare program; and

- The proposed changes to the reassignment rules, along with the modifications to the "centralized building" requirements may also significantly impede the incorporation of certain diagnostic imaging services into (non-radiology) physician group practice settings—potentially closing opportunities to reduce costs and inefficiencies in the delivery of these critical services to Medicare beneficiaries.

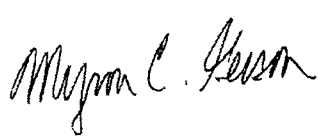
To ensure that such rules with potentially wide-ranging and disruptive effects on the quality of care are adequately studied prior to adoption, CMS should limit the application of these proposed revisions strictly to pathology services (e.g. pod-labs, etc.), and that the agency engage with ASNC and other stakeholder groups to study and develop solutions to potential fraud and abuse concerns in other areas of care

Independent Diagnostic Testing Facility (IDTF) Issues

With regard to the application of the proposed standards to IDTFs, ASNC recommends that CMS carefully evaluate whether, as currently written, they should apply uniformly to the diverse array of services provided by these entities. We also encourage CMS to consider accreditation status as an alternative mechanism for compliance with the proposed standards. Specifically, we suggest that entities that have been accredited by a nationally recognized accreditation body, such as the Intersocietal Accreditation Commission, could be deemed to be in compliance with Medicare's IDTF standards. In the alternative, ASNC urges CMS to work with IDTFs and other stakeholders to ensure that the proposed standards properly target questionable practices while not impeding the provision of legitimate and beneficial services for Medicare beneficiaries.

Again, ASNC appreciates the opportunity to comment on the proposed rule. Should you have questions or need additional information, please contact Christopher Gallagher, Director of Health Policy, at 301-215-7575 or via email at Gallagher@asnc.org.

Sincerely,



Myron Gerson, MD
President

Submitter : Dr. Robert Rothbard **Date:** 10/10/2006

Organization : Cardiology Consultants

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attatchment

CMS-1321-P-872-Attach-1.PDF

CMS-1321-P-872-Attach-2.PDF

#872

Cardiology Consultants

JAMES L. BOLEN, M.D., F.A.C.C., P.A.
ROBERT B. BOSWELL, M.D., F.A.C.C., P.A.
ROBERT L. ROTHBARD, M.D., F.A.C.C., F.A.C.P.,P.A
EGERTON K. VAN DEN BERG JR., M.D., F.A.C.C., P.A.

DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

Cardiovascular disease is the #1 killer in the United States. Given the magnitude of cardiovascular morbidity and mortality, a reasonable person would expect medicare to make it a priority to support cardiovascular specialists who lead the way in the battle against this dreaded disease. Instead, medicare plans to make crippling cuts in the reimbursement we receive for diagnostic procedures in our office practices. The current range of cuts is from 40%-62%, and involve essential diagnostic procedures including echocardiography, nuclear stress testing and outpatient diagnostic cardiac catheterization. Over the last several years, medicare reimbursements to physicians have failed to keep pace with medical inflation and cost of living increases. Nonetheless cardiologists have managed to maintain high levels of care for both medicare and non-medicare patients alike, including those patients who have no health insurance and receive care for free. Current medicare proposals that will take effect in January 2007 threaten our ability to deliver care to these patients. The net results of these cuts will be that the cost of providing cardiovascular services in the office setting will actually be greater than the reimbursement. Compounding the problem is the fact that private insurance companies use medicare as a guideline and this reduction in fees will impact our ability to deliver care to non-medicare patients as well. the magnitude and depth of these cuts will have a rippling catastrophic effect on cardiovascular care throughout Central Florida. It is unlikely that physicians will be able to afford to make new medical and information technologies available through their office practices. I anticipate many cardiologists will be forced to close their practices in the State of Florida and move to other states with a smaller medicare population. The remaining practices will have no choice but to reduce office staff substantially, and reduce or eliminate services in order to survive in this environment. Many cardiologists may find that they are unable to see new medicare patients, others will have no choice but stop seeing medicare patents at all.

In an effort to reverse these unfair cuts, the major cardiology groups in Central Florida have been meeting to discuss possible solutions. These cardiac groups include Cardiology Consultants, Florida Heart Group, Central Florida Cardiology, Mid Florida Cardiology, Orlando Heart Center, Florida Cardiology, Cardiac Care Specialists and Cardiovascular Associates. These groups together comprise 120 cardiologists who provide care for greater than 80% of the cardiac patient's in Central Florida. We have been meeting with our representatives who include Senator Bill Nelson and Congressmen Ric Keller and Thomas Feeney. In addition we have met without representatives from the Florida Medical Association and the Florida chapter of the American College of Cardiology. We are all in agreement that the proposed cuts will destroy our practices, and force many of us out of business. Therefore, we would ask that you freeze the reimbursement rates for the current office diagnostic procedures which include echocardiography, carotid ultrasound, Nuclear stress testing and diagnostic cardiac catheterization at the current levels.

We would ask that you develop a fair solution that addresses the issues of compensation for these services. Any solution that is fair should include the participation of clinical cardiologists like ourselves who have a vital stake in this process and actually take care of the patients.

Thank-you so much for considering these comments.

Sincerely,

Robert L. Rothbard, M.D., F.A.C.C., F.A.C.P

Cardiology Consultants

JAMES L. BOLEN, M.D., F.A.C.C., P.A.
ROBERT B. BOSWELL, M.D., F.A.C.C., P.A.
ROBERT L. ROTHBARD, M.D., F.A.C.C., F.A.C.P.,P.A
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DIPLOMATES OF AMERICAN BOARD
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Thank-you so much for considering these comments.

Sincerely,

Robert L. Rothbard, M.D., F.A.C.C., F.A.C.P

Submitter : **Ms. Saira Sultan** **Date: 10/10/2006**

Organization : **Sanofi Aventis**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-873-Attach-1.DOC

#873

sanofi aventis

Because health matters

Hugh M. O'NEILL
Vice President

October 10, 2006

BY ELECTRONIC MAIL

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

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

Dear Administrator McClellan:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on August 22, 2006 (the Proposed Rule). 1/ As a pharmaceutical company backed by world class research and development, we are developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real

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1/ 71 Fed. Reg. 48982 (Aug. 22, 2006).

300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel. (908) 243-6000 - www.sanofi-aventis.com

therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

As a company dedicated to bringing advanced therapies to patients, our comments focus on our concerns about protecting patients access to therapies and necessary services. First, we applaud CMS' implementation of the provision from the Deficit Reduction Act of 2005 (DRA) that eliminates the Part B deductible for colorectal cancer screening. Second, we support CMS' decision to modernize the bone mass measurement benefit by encouraging the use of state-of-the art technology to assess a patient's bone health, with cautionary considerations. Third, we urge CMS to institute policies that will protect beneficiary access to care by ensuring adequate reimbursement for the acquisition and administration of drugs 2/ under Medicare Part B. Toward that end, we offer two suggestions for CMS to refine its guidance regarding average sales price (ASP). In addition, as we have discussed with CMS, we would recommend that the HCPCS Workgroup adopt a unique code for each sodium hyaluronate product and that CMS assign a discrete payment amount for each product based upon the ASP for the individual product. Finally, we encourage CMS to revise measures in the core starter set for the Physician Voluntary Reporting Program (PVRP) to ensure quality of care for Medicare beneficiaries.

I. CMS Should Adopt the Proposal to Exempt Colorectal Cancer Screening from the Part B Deductible Requirement. ["DRA Proposals"]

Sanofi-aventis strongly supports CMS' proposal to eliminate the Part B deductible for colorectal cancer screening. Colorectal cancer is a life-threatening disease for which early screening is one of the most effective ways to reduce mortality. 3/ Congress recognized this fact by adding provisions to the DRA to exempt colorectal cancer screening services from the Part B deductible, effective January 1, 2007. 4/ The Proposed Rule implements these provisions of the DRA. 5/ Currently, many beneficiaries may refrain from accessing these important screening services because of cost concerns. Excepting these services from the Part B deductible undoubtedly will encourage many of these beneficiaries to ask their doctor for a colorectal cancer screening. Sanofi-aventis applauds CMS for implementing this life-saving policy change.

2/ We use the term "drugs" to refer to both drugs and biologicals.

3/ U.S. Preventive Services Task Force, Screening for Colorectal Cancer, http://www.ahrq.gov/clinic/uspstf/uspscolo.htm (July 2002).

4/ DRA of 2005, Pub. L. No. 109-171 § 5113 (2006).

5/ 71 Fed. Reg. at 48999.

II. CMS Should Adopt the Proposal to Modify Coverage for Bone Mass Measurement Tests. ["Bone Mass Measurement Tests"]

Sanofi-aventis appreciates CMS' efforts to incorporate scientific advances into its coverage policies and supports the proposed changes to Medicare's coverage of bone mass measurement (BMM) tests, with cautionary considerations. 6/ Medicare beneficiaries are at high risk of bone disease and fracture, and the BMM test is a critical tool to diagnose patients that may be at risk and allow for appropriate interventions. The technology for conducting a BMM has changed, however, and single-photon absorptiometry (SPA) is not considered an accurate predictor of fracture risk. 7/ Rather, the medical community generally agrees that dual energy x-ray absorptiometry (DXA) is more precise, safe, and is lower in radiation exposure than SPA. 8/ We believe CMS' proposal to revise the definition of "bone mass measurement" to remove coverage of SPA is consistent with current medical literature and support the proposed revision.

Further, sanofi-aventis supports CMS' proposal to change the conditions of coverage of BMM to encourage the use of DXA of the axial skeleton for confirmatory baseline tests and for monitoring a patient's response to therapy. 9/ DXA tests provide useful data on whether a patient is adhering to medication and responding to therapy. We caution, however, that the medical literature does not support the use of DXA or other BMMs to assess the efficacy of osteoporosis therapies. 10/ We recommend that CMS clarify that BMM is not appropriate for monitoring the efficacy of osteoporosis therapies in preventing bone fractures.

Sanofi-aventis also supports CMS' proposal to lower the threshold for BMM coverage for individuals receiving or expecting to receive glucocorticoid therapy. A threshold equivalent to 5 mg/d prednisone per day for 3 months or longer will help initiate prevention in patients at high risk for fracture. We urge CMS to implement this proposal in its final rule and to consider further lowering the threshold to 2.5 mg/d.

6/ Id. at 49059.
7/ Id.
8/ U.S. Surgeon General, Bone Health and Osteoporosis, http://www.surgeongeneral.gov/library/bonehealth/ (Oct. 14, 2004); National Osteoporosis Foundation, Physician's Guide to the Prevention and Treatment of Osteoporosis, http://www.nof.org/professionals/clinical.htm (last visited Sept. 22, 2006).
9/ 71 Fed. Reg. at 49060.
10/ Cummings et al. Am. J. Med. 2002;112:281-289; Sarkar et al. JBMR 2002; 17(1):1-10; Watts et al., JBMR, 18 (Suppl 2): SU334 (2003); Watts et al., J Clin Densitom 2004; 7:255-261.

Although we support CMS' proposal to cover DXA, we request that CMS give Medicare carriers discretion to cover new and advanced technologies that become available to screen for risk of fracture rather than requiring that such technologies go through the national coverage determination (NCD) process. The NCD process can often be long and cumbersome, and requiring that new technologies be added through this process could prevent beneficiaries from having access to these new and better technologies for some length of time.

We note for CMS that the World Health Organization (WHO) is currently in the process of developing a standardized methodology for determining fracture risk. Although DXA is one tool for measuring fracture risk, there are other clinical risk factors that also are important to the evaluation, specifically to determine which patients are likely to best respond to treatment. Employing the risk assessment methodology developed by the WHO will lead to better patient outcomes by helping providers better identify those patients who should be on therapy. Sanofi-aventis asks that upon WHO releasing this assessment, CMS recognize this fracture risk assessment, as well as DXA, for coverage under Medicare Part B.

We also are deeply concerned that CMS' proposal to encourage the use of DXA will be of little benefit to Medicare beneficiaries if CMS' proposal to change the methodology for calculating practice expense (PE) Relative Value Units (RVUs), published on June 29, 2006, goes into effect. 11/ The proposal will have a devastating impact on providers of bone densitometry, resulting in a 71 percent drop in reimbursement for central DXA (Current Procedural Terminology (CPT) 12/ code 76075) when fully implemented over the next four years. 13/ These cuts in reimbursement will significantly reduce Medicare beneficiaries' access to care in the physician office where DXA services currently are being delivered. We urge CMS to revise its proposed changes to ensure adequate reimbursement for this important tool for measuring the risk of bone disease and fracture.

III. CMS Should Ensure Appropriate Reimbursement for Drug Administration Services.

Sanofi-aventis is committed to developing new therapies that will improve patients' lives, but our efforts can be successful only when patients have access to our therapies. Patient access to drug therapies depends on providers' ability to purchase and administer the products they believe are most appropriate

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11/ 71 Fed. Reg. 37170 (Jun. 29, 2006).
12/ Current Procedural Terminology or CPT is a trademark of the American Medical Association.
13/ 71 Fed. Reg. at 37379.

for their patients. We therefore are troubled by CMS' proposed changes to the work and practice expense relative value units (RVUs) for drug administration services. We believe these changes, combined with the scheduled cut of an estimated 5.1 percent in the conversion factor, 14/ could reduce beneficiaries' access to Medicare services significantly. We therefore encourage CMS to rigorously assess the potential impact on beneficiary access to care before implementing any cuts in reimbursement for drug administration services. We appreciate CMS' commitment to protecting patients' access to critical, life-saving therapies, and believe the best way to achieve that goal is to ensure adequate reimbursement for the providers that administer these therapies.

In addition to the above, we also ask that CMS clarify which therapies should be regarded as biological response modifiers to be billed under the chemotherapy drug administration codes. The CPT describes chemotherapy administration codes as applying to "substances such as monoclonal antibody agents and other biologic response modifiers." Although the identification of monoclonal antibodies is relatively simple, there is no common definition of what products constitute biological response modifiers. Sanofi-aventis is developing a new treatment for critical limb ischemia in patients with peripheral arterial disease. This therapy uses a DNA plasmid that when placed in the patient's tissue produces an angiogenesis protein that encourages the development of new vasculature in a limb that might otherwise be amputated. This DNA plasmid therapy has all the hallmarks of a biological response modifier including stimulating the body to overcome a disease (through the regrowth of new vasculature), complex administration, and careful patient monitoring. We therefore recommend that CMS include DNA-based therapy in any definition it develops of products that would be considered biological response modifiers.

IV. CMS Should Issue Additional Guidance on ASP ["ASP Issues"]

Sanofi-aventis appreciates CMS' guidance on the ASP calculation provided in the Proposed Rule. The proper calculation and reporting of ASP is critical to ensure adequate provider reimbursement and Medicare beneficiary access to life-saving treatments. First, we ask that CMS recognize that, although ASP is an adequate measure of acquisition cost for the majority of therapies, it is inadequate for certain important medicines. As such, CMS should develop a systematic approach for determining when ASP plus six percent does not cover a provider's acquisition cost for a therapy. CMS should have discretion in that instance to increase physician payment rates so that physicians are not under-reimbursed for important medicines. Second, we ask that CMS clarify that

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14/ 71 Fed. Reg. at 49077.

programs. 16/ This distinction is of critical importance in evaluating the proposed CMS methodology, as sanofi-aventis strongly urges CMS to conclude that its proposed methodology does not require the exclusion from ASP of units reimbursed by entities that do not take possession.

As noted above, the ASP calculation is defined by statute as a measurement of average sales prices to purchasers. The removal from the ASP calculation of units attributable to non-possession-taking, reimbursing entities is inappropriate because it has the effect of removing from the ASP calculation units that the manufacturer has sold to a possession-taking ASP-eligible entity. The products for which such ASP-ineligible entities provide reimbursement are first sold by the manufacturer to an ASP-eligible possession-taking entity such as a wholesaler, specialty distributor, physician, or retail pharmacy. The removal of that unit from the ASP calculation because a Part D plan has reimbursed the ASP-eligible entity for dispensing or administering it to a patient would have the distorting effect of removing a unit from the ASP calculation that actually otherwise should have been included. Sanofi-aventis therefore asks that CMS clarify that the only sales that are to be removed from the ASP calculation, and estimated in the case where they are lagged, are sales to ASP-ineligible possession-taking entities.

If CMS determines that sales reimbursed by ASP-ineligible entities must be removed from the ASP calculation, sanofi-aventis requests that CMS provide specific guidance regarding the exclusion of qualified retiree prescription drug plans (QRPDPs).17 Manufacturers typically contract to provide rebates on QRPDP utilization through its commercial contracts with Pharmaceutical Benefit Managers, covering both QRPDPs as well as commercial health plans. The rebate claims that PBMs submit to manufacturers under these agreements typically do not itemize the utilization under each plan. As a result, manufacturers do not have available to them utilization amounts that are specific to QRPDPs so that that utilization can be excluded from the ASP calculation. Sanofi-aventis therefore asks that CMS specify that a manufacturer need only remove from the ASP calculation ASP-ineligible transactions that it is able to identify. 18/

16/ See Social Security Act (SSA) § 1847A(c)(2) (defining ASP-ineligible entities by reference to those entities identified in SSA section 1927(c)(1)(C)).

17 Id. § 1927(c)(1)(C)(i)(VI).

18/ In reviewing the best price exemption for prices negotiated by qualified retiree plans, we also observed that the exemption could be interpreted to apply only to the rebates paid on the utilization of the qualified retiree him or herself, and not to utilization from the retiree's dependents that also are covered by the qualified retiree plan. The exemption excludes "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of such title." Id. In general, it is only the retiree that is entitled to benefits under Part A or enrolled in Part B, and one could therefore interpret this provision as excluding only

V. Coding and Payment for Sodium Hyaluronate Products (Hyaluronans/Hylans)

In our submissions, we have recommended that the HCPCS Workgroup adopt unique codes for each of the sodium hyaluronate products given the unique features of each product. Consistent with this recommendation, we would also request that each product be assigned a discrete payment amount based upon the ASP for each product.

Sodium hyaluronate products (hyaluronans/hylans) are single source products administered by intra-articular injection for the treatment of pain in patients with osteoarthritis of the knee. Currently, there are 5 sodium hyaluronate products approved for commercial use in the US: (1) Hyalgan (sanofi-aventis), (2) Euflexxa (Ferring), (3) Orthovisc (Johnson & Johnson), (4) Supartz (Smith & Nephew) and (5) Synvisc (Genzyme). These products differ in terms of molecular weights, biological activity, the scope and extent of published clinical evidence, dose-per treatment, number of treatments-per course 19/ and labeling for repeated treatment courses.

Although there are 5 distinct sodium hyaluronate products, the current ASP-based payments identify only 3 codes and payment amounts across these products. The chart below demonstrates the payment disparities that result from CMS' current coding policy on hyaluronans:

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retiree utilization. Even in situations where a manufacturer is able to identify qualified retiree plan utilization, such data is unlikely to differentiate between retiree and dependent utilization. Accordingly, sanofi-aventis also requests that CMS clarify that, in a situation where a manufacturer is able to identify those sales made to qualified retiree plans for purposes of excluding them from the ASP calculation, the manufacturer need not differentiate between retiree and dependent utilization.

19/ According to package labeling, Hyalgan is given as 3 or 5 injections per course, Orthovisc as 3 or 4 injections per course, Supartz as 3 or 5 injections per course and Synvisc as 3 injections per course.

Product	Mol Wt	Code	Payment Amount Identified in 4Q2006 ASP Files 20/
Euflexxa 21/	2.4-3.6 MDa	J7317	$106.709
Hyalgan	0.50-0.73 MDa		
Supartz	0.62-1.17 MDa		
Orthovisc	1.0-2.9 MDa	NOC 22/	$201.082
Synvisc	>6 MDa	J7320	$198.739

As we have indicated in written comments to CMS, in meetings with CMS staff and at the HCPCS Workgroup public meeting in May 2006, the current coding structure for the sodium hyaluronate products is not supportable on scientific or clinical grounds and creates financial incentives that distort clinical decision making and appropriate market forces. We believe the most appropriate and scientifically defensible approach for this class of products is to adopt a unique code for each sodium hyaluronate and to assign discrete payment amounts for each product using product-specific ASP amounts. There is no scientific justification for maintaining the status quo, or any other version of the status quo, where some products are assigned to product-specific codes while others are lumped together in a shared code.

VI. CMS Should Revise Measures in the Core Starter Set for the Physician Voluntary Reporting Program (PVRP) to Ensure Quality of Care for Medicare Beneficiaries

Sanofi-aventis believes that certain quality measures developed as part of the 16-measure core starter set in the Physician Voluntary Reporting Program (PVRP) should be revised to reflect the current scientific literature on quality. Specifically, we encourage CMS to consider adding to the PVRP core starter set antiplatelet therapy (clopidogrel, aspirin) for patients with coronary

---

20/ CMS, http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/oct06asp_hcpcs.zip (J7317 and J7320); file oct06_aspnoc[1].zip at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage (Not Otherwise Classified)

21/ Euflexxa has been assigned to code J7317 under the Part B ASP drug listings: http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/oct06_asp_cross.zip.

22/ Not Otherwise Classified

artery diseases, as endorsed by the National Quality Forum (NQF) as an ambulatory care measure. 23/ CMS should also consider updating the Hemoglobin A1c control standard for patients with Type I or Type II diabetes mellitus to be consistent with clinical guidelines established by the American Diabetes Association (ADA). These guidelines, supported by a broad collection of public health experts and medical societies, provide a quality care measure of A1c less than 7 percent for people with diabetes. 24/ CMS' Core Starter Set Specifications only require documentation of A1c less than 9 percent. 25/ The ADA recommends lowering A1c to less than 7 percent to reduce the microvascular and neuropathic complications of diabetes. 26/ CMS should revise its specifications under the PVRP to ensure the quality of care standards for Medicare beneficiaries are consistent with what is recommended for all patients. Lastly, sanofi-aventis encourages CMS to revise the PVRP measure for the assessment of elderly patient falls to require an assessment of patients 65 years or older. Currently, CMS' core starter set would measure these assessments only for patients aged 75 or older. 27/ But studies endorsed by a World Health Organization (WHO) working group on osteoporosis have shown that hip fracture risk increases 4-fold between ages 50 and 80. 28/ CMS should ensure that all Medicare beneficiaries at risk for osteoporosis are assessed for falls, not just those aged 75 or older.

VII. Conclusion

We thank you for your consideration of these comments on the Proposed Rule and hope we can continue to work with you to advance Medicare beneficiaries' access to innovative and life-saving therapies. Please contact me, or Saira Sultan, Director of Federal Government Affairs, at 202-360-9985, if you have

---

23/ National Quality Forum (NQF), National Voluntary Consensus Standards for Ambulatory Care: An Initial Physician-Focused Performance Measure Set at 10, http://www.qualityforum.org/ (May 2006).

24/ American Diabetes Association (ADA), *Standards of Medical Care in Diabetes 2006*, Diabetes Care, 29:1 (Jan. 2006).

25/ CMS, PVRP 16 Measure Core Starter Set G-Code Specifications and Instructions at 2, http://www.cms.hhs.gov/pvrp/ (effective date Jul. 1, 2006).

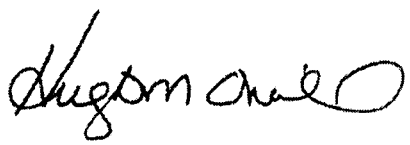
26/ ADA, Standards of Medical Care in Diabetes 2006 at S11.

27/ CMS, PVRP 16 Measure Core Starter Set G-Code Specifications and Instructions at 7.

28/ J. Kanis, et al., *Assessment of Fracture Risk*, Osteoporosis Int 16: 581-589 (2005).

any questions on these comments. Thank you for your attention to these important issues.

Sincerely,



Hugh O'Neill
Vice President, Market Access and Business Development

Submitter : **Date: 10/10/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. John Pfeifer** **Date: 10/10/2006**

Organization : **UMHS**

Category : **Physician**

Issue Areas/Comments

Background

Background

Making these revisions will negatively impact Medicare patients access to quality healthcare. The reduction in reimbursement will also reduce access to MDs currently performing these treatments

GENERAL

GENERAL

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

John R. Pfeifer MD
19900 Haggerty Rd Suite # 105
Livonia Mi 48152

Impact

Impact

See General Comment Below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Below

Submitter : **Ms. Lorraine Tarnove** **Date: 10/10/2006**

Organization : **American Medical Directors Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1321-P-876-Attach-1.DOC

#876

amda
American Medical Directors Association

A national organization of long term care physicians committed to quality care

American Medical Directors Association

10480 Little Patuxent Parkway
Suite 760
Columbia, MD 21044
410/740-9743

Washington, DC
301/596-5774

Toll Free
800/876-AMDA

FAX
410/740-4572

www.amda.com

President
Steven A. Levenson, MD, CMD
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Edward S. Warren, MD, CMD
Inman, South Carolina

Executive Director
Lorraine Tamove

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1321-P
Mail Stop C4-26-05
Baltimore, MD 21244-1850

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

October 10, 2006

Dear Dr. McClellan:

The American Medical Directors Association (AMDA) is pleased to submit these comments on the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" published in the *Federal Register* as a proposed rule on August 22, 2006. AMDA is the national professional association committed to continuous improvement of quality patient care by providing education, advocacy, information and professional development for medical directors, attending physicians, and other professionals who practice in the long-term care continuum. We represent more than 7,000 physicians who provide hands-on care in nursing homes and for community-based patients.

Our comments will address blood glucose monitoring in skilled nursing facilities (SNFs) [Clinical Diagnostic Lab Tests, Other Laboratory Issues] and the work values for the home visit codes.

Blood Glucose Monitoring in Skilled Nursing Facilities

CMS is predicating their blood glucose payment guidance based on the seriously flawed medical practice belief that each and every blood glucose measurement must be ordered by a physician and subsequently responded to by a physician. This is contrary to what is universally known to be good diabetic management, contradicts everything that the medical, nursing and even home-based consumer community currently practices and directly opposes all respected practice guidelines on diabetic management including AMDA's *Clinical Practice Guideline on Managing Diabetes in the Long Term Care Setting*. CMS should clearly indicate that SNFs do not have to phone a physician after each test to acquire an order for the next test, but must provide the test at the frequency ordered by the physician and notify the physician when test results lie outside the range indicated by the physician's order for that patient.

Rationale: In an April 5, 2001 letter to CMS on Program Memorandum AB-00-108, we stated that the agency's policy of misinterpreting sliding scale insulin dosage determination by glucose monitoring as "standing orders" undermines individualization and optimization of glucose control and may jeopardize the achievement of quality outcomes. AMDA requested further clarification of the policy to state that sliding scale insulin dosage determination by glucose monitoring does not constitute standing orders. CMS should clearly indicate that SNFs do not have to phone a physician after each test to acquire an order for the next test, but must provide the test at the frequency ordered by the physician and notify the physician when test results lie outside the range indicated by the physician's order for that patient.

AMDA's 2001 comments are supported by the AMDA clinical practice guideline *Managing Diabetes in the Long Term Care Setting* published in 2002. AMDA does not consider routine blood glucose monitoring to be a standing order. Frequency and timing is individualized depending on the severity of the disease, the degree of complications, and the stability of the patient. Blood glucose testing is *monitoring* of a disease state, just as taking blood pressures regularly is necessary to monitor hypertension. Reacting to each individual value rather than the long-term or short-term trends can be detrimental to our patients. There is indication when the physician should be called in the instance of extreme of hypo/hyperglycemia and the physician may wish to note specific individual blood glucose value or symptom parameters for immediate notification in the orders. AMDA consensus guidelines recommend the use of a short term order for both increased blood glucose monitoring and sliding scale insulin for no more than a two week period for newly admitted patients. It also should be done for patients experiencing a change of condition that is affecting, or could affect, their blood glucose levels.

The following is pertinent information from the American Medical Directors Association's Managing *Diabetes in the Long Term Care Setting*:

The American Medical Directors Association (AMDA) understands the importance of diabetic management. Diabetes care in the elderly accounts for about 25% of the Medicare budget. About 25% of patients in the long-term care setting have diabetes. The estimated annual cost of treating diabetes and its associated complications in the United States is more than $100 billion annually; 38% of this total is accounted for by hospitalization costs[i]. The cost of caring for patients with diabetes aged 65 and over in nursing facilities is estimated to be $6 billion per year[ii]. Diabetes is an independent predictor of nursing facility placement in the elderly[iii]. Nursing facility residents who have diabetes are a vulnerable group who experience increased cardiovascular complications, frequent infections (especially of the skin and urinary tract), increased rates of dehydration, hyperosmolar states, hospitalization, and increased physical and cognitive disability.

The prevalence of functional disability and multiple comorbid conditions in the long-term care population increases the complexity of diabetes management. Hyperglycemia impairs cognition and, when untreated, may contribute to further functional decline in patients with dementia. Additionally, hyperglycemia decreases pain thresholds, impairs vision, and may increase the risk for falls[iv].

Frail elderly people with diabetes are also at higher risk for hypoglycemia, which when untreated may cause falls or permanent neurological impairment. Symptoms of hypoglycemia are often atypical in the elderly. Residents of long-term care facilities are frequently unable to perceive or communicate hypoglycemic symptoms. Unrecognized hypoglycemic symptoms may be attributed to dementia, psychosis, behavior changes, cardiovascular events, seizures, or other conditions and treated inappropriately. [v,vi]

Achieving control of a patient's diabetes by watching for high and low blood sugar patterns and keeping track of them as part of the overall blood glucose monitoring routine is essential to managing the patient's diabetes.

Both hypoglycemia and hyperglycemia often present with atypical symptoms in the frail elderly. It is advisable to do a fingerstick test promptly to check the patient's blood glucose level. This protocol is not considered a standing order in the long-term care setting but is regarded as good clinical care. It is standard to then communicate the result of any *abnormal* findings to the treating physician.

Strong evidence now exists that appropriate intervention to control sustained hyperglycemia reduces or slows the development of complications of diabetes such as retinopathy, neuropathy and nephropathy in patients with type 2 diabetes. However, to mange diabetes appropriately, especially on a newly admitted patient or a patient with an acute illness, the physician needs to establish a pattern of the patient's blood glucose levels and their sensitivity to insulin.

Step three of the AMDA diabetes management guideline[vii] suggests determining whether the patient has diabetes by ordering appropriate laboratory tests. Depending on the degree of abnormality of the blood glucose, fingerstick tests may immediately need to be ordered several times a day to recognize if the patient has diabetes or another condition that is affecting the blood glucose. It may take multiple days of monitoring the blood glucose to determine if there is blood sugar fluctuation and if so, the cause. It is not helpful to the physician to be called with each separate result but rather to be called with information about the glucose trends. In the long-term care setting, a patient may not have just one single physician and calling different physicians randomly with results of blood glucose tests several (average of 4 times a day) will not be beneficial to the patient. It would encourage a reactive approach to each abnormal value rather than an analytical proactive approach to improve glycemic control. Certainly if a blood glucose result is outside of the original order's parameters, an urgent call would be made to the physician at that time.

Although "sliding-scale" insulin is widely used in long-term care facilities, its prolonged use is not recommended. It is frequently ordered for short-term use (e.g., following admission to a long-term care facility or during an episode of acute illness), but the order may remain in effect indefinitely. Widespread use of sliding-scale insulin may result in greater patient morbidity and an increase amount on nursing time because patients' blood glucose levels must be monitored more frequently and more insulin injections given than medically indicated. As a result, the patient's activities and quality of life may be compromised. In general, AMDA recommends that any patient on sliding-scale insulin be re-evaluated within 1 week and switched to fixed daily doses as soon as clinically indicated, in the judgment of the treating physician. However, the physician needs to assess the cumulative results of the daily blood glucose levels in order to determine the total daily insulin dosage for the patient. Blood glucose levels normally are known to fluctuate throughout the day and may depend on diet, activity level, and the development of acute inter-current illnesses. These conditions may require adjustment of insulin doses.

The blood glucose should be monitored and the findings recorded. Once the physician has identified a pattern of high or low blood sugars at the same time on at least three successive days, it is easier to determine the frequency and type or types of insulin the patient should be on. It is also important for the physician to note insulin sensitivity (by the use of finger stick blood glucose monitoring and sliding scale insulin) to determine total daily insulin dose.

AMDA recommends the use of standing orders that are approved by the primary care physician when the patient is admitted. For example, the physician may write an order stating that he or she is to be notified when an individual patient's blood glucose values are outside of a specified range. When patients' blood glucose levels are poorly controlled and when patients are extremely frail or cognitively impaired, the physician may wish to note specific individual blood glucose or symptom parameters in the orders.

AMDA does agree that the physician be called as soon as possible when:

- The patient has a blood glucose value <60 mg/dl ***OR*** <75 mg/dl if the patient has signs and symptoms suggestive of hypoglycemia. (Treatment of symptomatic hypoglycemia should not be delayed.)
- The patient has two or more blood glucose values >250 mg/dL ***IF*** this is a new or markedly different clinical situation that is accompanied by a change in condition or functional status.
- The patient has blood glucose values >300 mg/dL during all or part of 3 consecutive days (unless this represents an improvement from a recently measured value or existing orders specify how the patient's hyperglycemia should be managed).
- When the patient shows a consistent pattern of poorly controlled or deteriorating blood glucose levels.

AMDA suggests the following pattern of communication to physicians of blood glucose values for the following scenarios:

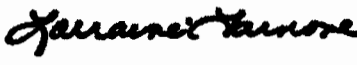
- communicate all values each 24 hours when the patient is unstable in addition to the stat communications under the orders (re: substantial instability in glucose control);
- communicate all values every 72 to 96 hours if the patient is moderately stable, but with a potential for more rapid changes; and,
- communicate all the values weekly if the patient is more stable, while the sliding scale is still being used.

Home Visit Codes (99341-99350)

AMDA supports the efforts of the American Academy of Home Care Physicians (AAHCP) to gain appropriate recognition for home care services. We are concerned that this family of codes is undervalued.

We appreciate this opportunity to comment on the proposed rule. We look forward to continued interactions with CMS officials on this issue. If you have any questions, or if we can be of any assistance to you or your staff, please feel free to contact me at the AMDA office at 410-740-9743.

Sincerely,



Lorraine Tarnove
Executive Director
American Medical Directors Association

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[i] Chronic Diseases and Conditions. 2000. U.S. Centers for Disease Control and Prevention. Available online at www.cdc.gov.

[ii] National Center for Health Statistics, U.S. Centers for Disease Control and Prevention. Available online at www.cdc.gov/nchs

[iii] Tsuji I, Whalen S, Finucane TE. Predictors of nursing home placement in community-based long-term care. J Am Geriatr Soc 1995;43:761-766.

[iv] Reed RL, Mooradian AD. Management of diabetes mellitus in the nursing home. Ann Long-Term Care 1998;6(2):102-108

[v] Kuhle CL, Ferguson K. Diabetes in the nursing facility resident. Nurs Home Med 1997;5(4):124-127.

[vi] Lawhorne LW, Lebedovych V. Nocturnal fingerstick blood glucose levels in nursing home residents with diabetes: A medical care evaluation study. Nurs Home Med 1995;3:35-38.

[vii] American Medical Directors Association. Managing Diabetes in the Long-Term Care Setting Clinical Practice Guideline. Columbia, MD. AMDA:2002

Submitter : Dr. John Rossi **Date:** 10/10/2006

Organization : Kunkel Surgical Group

Category : Physician

Issue Areas/Comments

Background

Background

The revisions as proposed will have an adverse impact on the Medicare patients' access to quality health care. The reduction in the reimbursement rates could drastically limit the access to physicians who perform these procedures.

GENERAL

GENERAL

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous laser ablation. I have reviewed the proposed 2007 fully implemented, non-facility practice expense PE)RVUs for CPT codes 36478 and 36479 and find several issues of great concern:
1)RVUs have consistently been reduced from 2005 levels. While practices expenses rise it has become increasingly difficult to provide these necessary services. CMS guideline compliance requires that the physician employ a Registered vascular technologist to provide imaging services. This skilled technologists are in drastic shortage & high demand, and command high salaries, benefits, and continuing educational expenses. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop. The 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. There are also proposed cuts for non-invasive vascular imaging. All these cuts will cripple the ability of the physician to provide a thorough diagnostic work-up and perform these important procedures and it will ultimately limit access to care for these Medicare beneficiaries.
2) The proposed coversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.
3) I would request that the fully implemented , non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

Thank you for your consideration in this matter.

Sincerely,

John A. Rossi, M.D.
Camp Hill, PA 17011
jar2455@comcast.net

Impact

Impact

See general comment.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

CMS-1321-P
Medicare Program;Revisions to payment policies under the Physician Fee Schedule for Calendar year 2007 and other changes to Payment under Part B. Proposal dated August 8, 2006.

Submitter : Dr. John Coster **Date:** 10/10/2006

Organization : National Assocation of Chain Drug Stores

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-878-Attach-1.DOC

#878

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 30, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-1850

Subject: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) is writing to provide comments on the proposed regulation that would change for 2006 the supplying fees and dispensing fees paid to pharmacies by Medicare Part B drugs. NACDS represents more than 200 chain pharmacy companies operating almost 35,000 community retail pharmacies. Our industry is the primary provider of outpatient pharmacy services in the United States, providing about 70 percent of all retail prescriptions. We are also providers of Medicare Part B drugs to Medicare beneficiaries.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

In summary, the supplying fees proposed for 2006 for supplier-provided Part B drugs, as well as the intention to reduce the dispensing fees for inhalation drugs, may underpay pharmacies for their total cost of purchasing the drug and supplying or dispensing the drug. As a result, Medicare beneficiaries may see a reduction in their ability to obtain Part B drugs from community retail pharmacy based suppliers.

Supplying Fee

MMA Changed Reimbursement Model for Part B Covered Drug

The Medicare Modernization Act (MMA) changed the basis of Medicare Part B drug reimbursement from an AWP-based system to an Average Sales Price (ASP)-based system. The ASP-based system significantly reduced pharmacy payment amounts for many Part B drugs, including those provided by community retail pharmacies. Some of these Part B drugs are very expensive, such as drugs to prevent organ rejection.

The use of ASP as a reimbursement method for retail pharmacies is problematic because ASP reflects manufacturer's revenues from sales to all pharmaceutical "classes of trade", including the rebates, discounts, and price concessions made available to those purchasers. However, retail pharmacies do not have access to the same discounts and other price concessions of these other purchasers, such as hospitals, nursing homes and HMOs.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

This places retail pharmacies at a disadvantage compared to other purchasers, since the ASP for a product, inclusive of the 6 percent add on, may reimburse pharmacies at an amount lower than their costs of acquisition. ASP is retrospectively determined and therefore based on pricing information that is out of date by several months. As a result, pharmacies may have to absorb any manufacturer price increases for covered Part B drugs that occur before the ASP is updated.

Some of our members may find that ASP reimbursement for some Part B drugs is significantly below their costs. This is true with expensive brand name drugs where retail pharmacies have no negotiating leverage with drug manufacturers. Many brand name manufacturers typically increase their prices at the start of the new calendar year. Therefore, the ASP-based amounts that pharmacy suppliers will be paid in the first quarter of 2006 (January-March 2006) will be based on sales data from the time period July-September 2005. Moreover, the pharmacy will continue to be underpaid for any drugs that had price increases on January 1st for the second quarter as well (April-June 2006) because that quarter's ASPs are calculated based on sales from the time period October-December 2005. Thus, it will take two whole calendar quarters until the pharmacy's payment under Medicare Part B will reflect the price increases taken by manufacturers on January 1st. If the prices increase significantly on many expensive Part B drugs, especially if the pharmacy's purchase price is above the ASP plus 6 percent amount calculated, the pharmacy may have to dispense the drug at a loss.

Moreover, it generally costs retail pharmacies significantly more to bill Medicare claims than other third party prescription claims because of cumbersome Medicare billing requirements. This leads to many Part B drug claims being rejected due to administrative errors. Also, several claims are never paid because the pharmacies cannot obtain the full or proper information. The bottom line is that pharmacies have significant bad debt write offs in Medicare as compared to other third party plans whose claims are adjudicated online, in real-time. Thus, the amount of the supplying fee established by CMS is critical to assuring that pharmacies are compensated for ASP-based product reimbursement that may be below their costs, and to compensate for Medicare Part B's unusually burdensome billing requirements.

As it moved to the ASP-based payment system in 2005, CMS established the current supplying fee for covered Part B drugs in its final Physician Fee Schedule Rule, dated November 15, 2004. This rule requires that "a supplying fee of $24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals... and a supplying fee of $50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals ...provided to a patient during the first month following a transplant." CMS does not currently pay a fee for a different strength of the same Part B covered drug that is supplied in the same day.

Because the ASP-based reimbursement system was first introduced this year for Part B drugs, many pharmacies didn't know what their total reimbursement would be, and whether they would be able to financially supply Part B drugs to Medicare beneficiaries.

The uncertainty for providers regarding the ASP-based payment rates for the drugs was somewhat mitigated by the amount of the supplying fees being paid by Medicare in 2005. The higher fees paid by CMS in 2005 (the agency had initially proposed a $10 per prescription supplying fee) helped to mitigate the impact of the move to an ASP-based system. In theory, the supplying fees set by CMS in 2005 were to pay pharmacies for the supplying costs and the additional administrative costs of participating in Medicare Part B. However in reality, these higher fees may have been necessary to compensate retail pharmacies in many cases for the underpayments for drugs under the ASP-based system.

This is because retail pharmacies generally do not have access to the rebates, discounts and price concessions of other Part B purchasers, and therefore may buy at higher than the ASP plus 6 percent amount.

Thus, the proposal to reduce the supplying fee from $24 for each Part B prescription to $24 for the first prescription dispensed in a month and $8 for each subsequent Part B prescription would represent a serious and significant reduction in total reimbursement. This reduction, when combined with the underpayment for the drug products on the ASP side, as well as the continuing additional costs to pharmacies of participating in Part B, could result in many pharmacies not being able to further provide Part B drugs.

There are other consequences to this policy. Many Medicare beneficiaries come into the pharmacy at the end of the month to obtain their full prescription for next month. Under the proposed supply fee scheme, a pharmacy could be paid only one full supplying fee for two full months worth of prescriptions. For example, if the beneficiary is only taking one Part B medication, the pharmacy would be paid $24 for the first prescription the first of the month. If the beneficiary seeks a refill on the 31st of the same month, the pharmacy would only be paid $8 for the next month's full prescription because the pharmacy dispensed it in the same month as the original prescription. If the physician added another drug to the beneficiary's regimen, the pharmacy would only be paid one $8 to refill a previous prescription and fill a new prescription with all its accompanying paperwork. Some pharmacies might ask the beneficiary to come back a few days later to obtain the prescription since the pharmacy would obtain their full supplying fee for the refill prescription by actually dispensing it in the next month.

This system also encourages pharmacies within the same chain to send beneficiaries to other pharmacies in the chain to obtain their prescriptions. That is because the preamble to the proposed rule indicates that "If a beneficiary obtains prescriptions at two separate pharmacies during a one-month period, each pharmacy would be paid a $24 fee for the first drug it supplied." The current and proposed supplying fees could be creating unintended consequences in the delivery of Part B medications to Medicare beneficiaries.

Cost of Dispensing Medicare Part B Prescriptions

In the proposed rule, CMS indicates that in the November 2004 final regulation, it "established a supplying fee that was higher than that of other payers due to the lack of online claims adjudication for Medicare Part B oral drugs." But, in its proposed 2006 payment rule, CMS justifies the proposed reduction in supplying fees by indicating that "we believe that there are likely to be substantial economies of scale and that the burden associated with the lack of online claims adjudication would be relatively similar whether one prescription or multiple prescriptions were supplied during the same month."

This conclusion, and the proposed subsequent reduction in Part B supplying fees for 2006, incorrectly assumes the following: 1) that $8 is the actual current average cost of filling any prescription; 2) that the cost of filling the average or incremental Medicare Part B prescription is the same as filling the average or incremental non-Medicare Part B prescription; and, 3) the additional costs of participating in Medicare are solely relating to the lack of an online claims adjudication system in Medicare. CMS has offered no evidence in its proposed regulation that it has performed any of its own cost of dispensing studies for Medicare Part B prescriptions to justify this significant reduction.

First, we appreciate that CMS has proposed to pay a fee for each prescription dispensed by the pharmacy or supplier, even if for a different strength of the same drug dispensed on the same day. Fees for such prescriptions should have been paid in 2005, but were not. In fact, CMS' own regulations required that a fee be paid for each supplied prescription drug or biological.[1]

Second, a recent assessment by the University of Texas Center for Pharmacoeconomic Studies found in July 2005 that the average cost to fill a prescription was $9.62. Therefore, the proposal to use $8 as the new supplying fee for Part B prescriptions is below even a recent assessment of a retail pharmacy' costs to fill an average prescription, not a more-costly non-adjudicated Medicare Part B prescription. Moreover, because of the many additional administrative tasks that have to be performed by the pharmacy in order to appropriately bill and receive payment for a Medicare Part B prescription, a fee of $8 does not adequately cover these additional costs.

For example, depending on the extent of their Part B business, many of our members have to hire additional personnel just to handle the extra burden of preparing Part B claims for submission to the DMERCs. A traditional third party prescription claim will have significantly less administrative tasks regarding its submission for payment. In addition, the pharmacy will know instantly whether or not the claim is adjudicated, and the amount that the pharmacy will be paid. That is not the case with Medicare Part B claims, which, even though electronically submitted in batch form through the NCPDP 1.1 standard, are not adjudicated real-time.

Each group of Part B drugs has different coverage and billing issues that must be resolved before the pharmacy can submit a "clean" claim to the DMERC. The extent of the additional time involved depends on the category of drug and the willingness of the physician to work with the pharmacy to obtain the information necessary for billing. Transplant drugs tend to have the highest administrative costs, but the pharmacist must also check that the other oral drugs covered under Part B (i.e., anticancer drugs and antiemetic drugs) are being used for an indication that is covered under Part B. This requires that the pharmacist spend additional time working with the physician's office to obtain the appropriate information necessary to appropriately bill Medicare Part B.

Even after "clean claims" are submitted to the DMERC, Medicare Part B has a higher rejection rate than traditional third party prescription plans because of the lack on an online claims adjudication system. As a result, pharmacies incur a significant amount of "bad debt" in Medicare Part B as compared to other third parties, which must be reflected in the supplying fee amount paid. If just a single pharmacy or supplier claim for an expensive Part B drug is rejected by the DMERCs or eventually unpaid, it could eliminate or sharply reduce any margin that the pharmacy might earn on Part B prescriptions. This requires additional administrative tasks by the pharmacy to resubmit the claim to Medicare, even though they thought they were submitting a clean claim. Some of the rejections for these clean claims are due to the fact that DMERCs still have issues with converting NDC codes for drugs to HCPCS codes.

Medicare Part B takes more time to pay pharmacies than traditional third party payers, tying up the pharmacies' cash flow for a longer period of time. This is especially true in regards to very expensive immunosuppressive drugs.

[1] See 42 CFR 414.1001, Basis of Payment, which says that "(a) A supplying fee of $24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q) and 1861(s)(2)(T).

Because of the higher number of rejects in Medicare Part B and the longer time it takes to pay Medicare claims on average, a pharmacy may have dispensed several expensive Part B drugs to a Medicare beneficiary before the pharmacy would even know if they were going to be paid for the initial Part B claim submitted.

At the pharmacy counter, the lack of a real-time claims adjudication system means that the pharmacy does not know whether the beneficiary is eligible for Part B, or has met their annual Part B deductible. While this is primarily an issue at the beginning of each calendar year, the pharmacist should check the deductible status for each new beneficiary that seeks to have a prescription filled. The pharmacy must contact the DMERC by phone and wait to get a response before the pharmacist can proceed to fill the prescription.

Pharmacies have the additional costs of needing to contract with a separate billing entity – other than the standard third party billing contractor - to convert Medicare Part B claims from an NCPDP format to an ANSI X837 format so they can batch bill the DMERCs. This factor, in and of itself, requires that Medicare Part B pay pharmacies a significantly higher supplying fee to maintain beneficiary access to these Part B products. The cost of installing and maintaining these systems are expensive.

Based on these additional costs, some of our chain pharmacy members have indicated that the average cost of dispensing a Medicare Part B prescription is about $19-21 per prescription. However, given that CMS is not currently paying a supplying fee for a prescription of the same drug for a different strength dispensed on the same day, it would appear that the $24 fee remains a reasonable reflection of the minimum cost of supplying an average Part B Medicare prescription. However, the agency should consider an increase in this fee to keep pace with inflation and escalating pharmacy salaries. Please note that these data represent only a few chains' costs to dispense, and may not be representative of the costs to dispense across the industry. Smaller chains and independents may have somewhat higher costs to dispense.

We also urge CMS to increase the fee paid for filling the initial-supplied prescription in the first month after a transplant, which is currently $50. In addition to all the paperwork involved in appropriately filling and billing this first prescription, there is also a higher level of intensity of monitoring services provided by pharmacies in the first several months after a transplant. This is critical to the successful transplantation of the organ, for which Medicare has invested tens of thousands of dollars. These added payments to pharmacies for the critical services provided can help ensure the success of a transplant.

Administrative Issues Relating to Medicare Part B Participation

CMS proposed in the 2005 physician fee rule to make several administrative reforms to covered Part B drug billing that would have reduced the cost and administration of participation. The preamble to the final 2005 physician fee schedule rule describes the steps that CMS was to take to "clarify or eliminate" some of these billing requirements, which would reduce pharmacy's cost of supplying these drugs. However, the 2006 rule is silent on the progress made by CMS in making these administrative changes.

In fact, it appears to be taking an exceptionally long time to make some of these changes. These paperwork and other administrative requirements, which generally do not exist in other third party plans, simply make it more time consuming and costly for pharmacies to participate as suppliers in Medicare. We describe these below.

Assignment of Benefits Forms Not Yet Eliminated: We continue to be concerned that the Assignment of Benefits (AOB) form has not yet been eliminated for Medicare covered Part B drugs.

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

[redacted]

McKESSON
Empowering Healthcare

October 10, 2006

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

Re: CMS-1321-P

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), I am submitting comments on the ASP reporting provisions included in the CMS Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B".

For over 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. McKesson also supplies pharmaceuticals to the entire Department of Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities.

As the largest pharmaceutical supply management and health information technology company in the world, we are also building on our years of experience in the distribution business to provide specialty pharmaceutical services for providers and patients with chronic conditions. These high-cost, often injectable bio-pharmaceutical drugs call for special handling and storage and complex shipping requirements. The services associated with such complex distribution processes expand access to necessary medication treatments, increase cost-effectiveness, and improve the convenience and quality of patient care by enabling the administration of these drugs in a lower cost, outpatient setting.

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

Because of our extensive experience in the pharmaceutical distribution business, we are pleased to provide comments to CMS on the Average Sales Price (ASP) reporting issues in the proposed rule.

ASP REPORTING ISSUES

As a member of the Healthcare Distribution Management Association (HDMA), McKesson supports the association's comments and recommendations on this proposed rule.

Prompt Pay/Cash Discounts

McKesson strongly encourages CMS to reconsider its position and clearly state that prompt pay discounts should be excluded when manufacturers calculate their ASP. In particular, we concur with HDMA that CMS has the legal authority to exclude prompt pay discounts to wholesalers for the ASP calculation.

As we noted in the comment letter we submitted to CMS on the proposed Interim Final Rule on June 7, 2004, prompt pay/cash discounts, which are terms used interchangeably in our business, are provided by manufacturers to wholesalers as a function of the time-value of money. These discounts are standard financing incentives used to encourage customers to process and pay their invoices faster. In order to earn the discount, the wholesaler must pay the vendor within a specified time period, which is generally 30 days. The speed of the payment determines whether the wholesaler earns or forfeits the discount. These discounts are completely unrelated to the cost or pricing of the drug and should not be included in the calculation of the average sales price.

Since prompt pay or cash discounts must be earned and are dependent on the ability of the wholesaler to pay the invoice within a specific time period, we do not believe it is relevant or appropriate to include them in the calculation of the average sales price of the drug. This revision would be consistent with the language contained in the 2006 Deficit Reduction Act which excluded prompt pay discounts from the Average Manufacturer's Price (AMP) calculation.

Bona Fide Service Fees

Pharmaceutical distributors play a vital role in ensuring the safe, secure, and timely delivery of pharmaceutical products to tens of thousands of retail pharmacies and hospitals. We enable a "just in time" pharmacy distribution model that helps hospitals and pharmacies control costs and ensure safety, while guaranteeing that patients and customers have access to a multitude of over-the-counter and prescription drugs when and where they need them.

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

McKesson endorses the CMS proposal to exclude *bona fide* services from ASP calculations. Currently, bona fide services performed by third party logistic providers are excluded from the calculation of ASP; wholesale distributors provide the same services, as well as a significant number of additional bona *fide* services, which should likewise be excluded from this calculation.

McKesson applauds the CMS proposal to clarify the definition of *bona fide* services. We do, however, recommend that the term "itemized" be deleted from the definition in the proposed rule. It could be construed as requiring individualized pricing terms for each particular service covered by a distribution agreement, which would further complicate the negotiation of these agreements.

To provide clarity for manufacturers and all other stakeholders, McKesson further recommends that CMS include in the final rule a non-exclusive list of bona fide services that should be excluded from the ASP calculation. Because we anticipate that wholesalers will continue to develop additional, innovative future services in response to the needs of manufacturers, any such list should be clearly identified as non-exclusive. By incorporating such a non-exclusive list in the final regulation, CMS would provide much needed guidance to manufacturers, who may otherwise continue to adopt inconsistent interpretations of the types of services for which fees should be excluded. Such a list will help ensure that fees paid by manufacturers to wholesale distributors are treated uniformly in the ASP calculations and that ASP will be a reliable reflection of actual market prices. We specifically recommend that the distribution industry list of bona fide wholesaler services included in the HDMA comments on this rule be considered as the reference list for these services.

Fair Market Value

McKesson recommends that the final regulation should include explicit guidance that, for purposes of the ASP calculation, a bona fide service fee will be presumed to reflect Fair Market Value if it has been determined through a process of arms' length negotiations between the parties.

The final rule should also make clear that bona fide service fees should be excluded irrespective of how the fees are calculated. A commonly used industry formula calculates these fees on a percentage of revenue basis. This method takes into account the many cost drivers of the industry that vary in proportion to the value of the product sold, such as building insurance, transportation insurance, security, damage risk and cost of capital, in addition to the many others that vary in proportion to units sold, such as pick, pack and ship and special handling requirements.

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

Conclusion

McKesson recognizes the need to achieve consistency in price reporting and metrics for drug reimbursement in healthcare. To promote clarity and ensure consistency, we support the CMS decision to codify the definition of bona fide services and to exclude those fees in the calculation of ASP.

In summary, we recommend that the following changes be incorporated in the final rule:

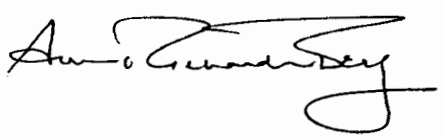
1. Exclude prompt pay discounts provided to wholesalers by manufacturers from ASP calculations;

2. Exclude bona fide services provided by wholesalers from ASP calculations; and

3. Include a non-exclusive list of bona fide services that would be excluded from the ASP calculation.

Thank you for the opportunity to provide our comments on Proposed Rule CMS-1321-P, and to endorse those submitted by the HDMA. We hope these comments provide constructive insights for the development of an Average Sales Price calculation that represents an equitable and reasonable approach to reimbursement for the products we distribute. Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

cc: Leslie Norwalk, Deputy Administrator, CMS