Submitter : Dr. Michael Picard **Date:** 08/21/2006

Organization : American Society of Echocardiography

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1512-PN-2175-Attach-1.PDF

Attach # 2175

American Society of Echocardiography

Heart and Circulation Ultrasound Specialists

August 21, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:

On behalf of the American Society of Echocardiography (ASE), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on June 29, 2006 in the Federal Register (the "Proposed Notice"). The ASE is a professional society consisting of over 11,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care.

While ASE very much appreciates the time and effort that CMS has devoted to proposed revisions to the practice expense methodology, we note that these changes will result in extraordinary reductions in Medicare payment for echocardiography services performed in non-hospital settings--reductions averaging 23% by 2010. We are concerned about the impact of so large a reduction on the ability of cardiology practices to maintain high quality echocardiography services in the non-hospital setting, in light of the substantial equipment, non-physician personnel and other costs involved.

Recognizing that there are few if any clear rules for determining and allocating practice expenses among individual services on a system-wide basis, we are organizing our comments and analysis based on CMS's own objectives for the practice expense revisions, as set forth in the Proposed Notice. As stated by CMS, the objectives of the new system are:

- To ensure that the PE portion of the PFS payments reflect, to the greatest extent possible, the relative resources required for each of the services on the PFS.

- To develop a payment system for PE that is understandable and at least somewhat intuitive, so that specialties can better predict the impacts of changes in the PE data.

- To stabilize the PE portion of the PFS payments so that changes in PE-RVUs do not produce large fluctuations in the payment for given procedures from year to year.

Our assessment of whether and to what extent the methodology described in the Proposed Notice achieves these objectives with respect to echocardiography services follows.

I. Ensuring that Payments Reflect Relative Resources

A. Use of ACC Survey Data

As discussed below, we respectfully disagree with CMS's decision to eliminate the Non-Physician Work Pool (NPWP) without first determining a methodology for more equitably allocating indirect costs. However, having made the decision to eliminate the NPWP, CMS appropriately decided to use the ACC supplemental data in its revised methodology. We strongly urge CMS to continue to use the ACC supplemental data to determine cardiology allowances. CMS should use any data resulting from the new AMA multi-specialty survey process only if it meets the same rigorous statistical tests applied to the ACC's supplemental data.

In addition, we urge CMS to make special efforts to ensure that the new AMA survey includes a representative number of cardiology practices that provide technical component services. Even more fundamentally, we advise that the new AMA multi-specialty survey--unlike the SMS survey--include the questions necessary to determine whether or not cardiology respondents provided TC services. Otherwise, neither CMS nor affected groups will have the basis to determine whether or not the results are appropriately representative. Since the ASE is not a constituent society of the AMA, we urge CMS to monitor this issue directly and to keep this consideration in mind before approving the AMA survey instrument or protocol.

B. Indirect Cost Allocation

Without doubt, the single most salient feature of the proposed PE methodology that precludes the final allowances from accurately reflecting relative costs is the use of work relative value units (W-RVUs) to allocate an estimated 40% of all practice expense dollars.[1] Technical component echocardiography services have no W-RVUs and are thus ineligible to receive any of this Medicare payment.

We understand that CMS considers all allocation methodologies for indirect practice expenses to be arbitrary, by definition. However, some allocation methodologies are clearly more arbitrary than others. We understand that physicians who perform services outside of the office setting

[1] Since indirect costs constitute approximately 60% of all practice expenses and approximately two-thirds of indirect costs appear to be allocate on the basis of W-RVUs, approximately 40% of all dollars available to pay providers for their practice expenses are allocated based on W-RVUs.

still incur overhead and other indirect costs to keep their offices open and operational, and that allocating indirect practice expenses on the basis of W-RVUs is intended to account for this. However, it may be more logical to use physician time rather than physician work to allocate indirect practice expenses to these services, since there is no basis for concluding that work intensity (which is reflected in W-RVUs) is related to indirect practice expenses (primarily overhead). Even more fundamentally, to the extent that physician time or work is used as an allocator, its use should be limited to that portion of indirect practice expenses that is reasonably attributable to out-of-office services. Yet, we estimate that approximately two-thirds of all indirect PEs are allocated based on W-RVUs under the current methodology.

In the past, CMS has indicated that because technical component services have very high direct costs, the allocation of some portion of indirect costs on the basis of W-RVUs does not unduly disadvantage technical component services. However, under the proposed methodology, it is our understanding that a budget neutrality/scaling adjustment that reduces direct practice expenses by about 33% is applied before direct costs are used as an allocator. In addition, whatever amount of indirect costs are allocated to a service on the basis of direct costs is again reduced by the (approximate) 65% "indirect adjustment"--an adjustment necessitated in large measure by the use of W-RVUs to allocate indirect costs. Thus, by the end of the process, it is unclear to us whether and to what extent direct costs actually determine indirect cost allocations.

Even more importantly, it is our understanding that CMS is considering modifying direct cost inputs in a way that may substantially reduce direct costs allocated to echocardiography and other technical component services in the future. For example, both CMS and Congress appear to be considering modifying the utilization and interest rate assumptions used to determine equipment costs, which appear to be a major component of the proposed echocardiography rate for in-office services. If CMS does modify the methodology for determining direct costs in a manner that substantially reduces allowances for echocardiography and other technical component payment, the agency cannot continue to rely on the same rationale for failing to correct the indirect cost allocation formula.

For these reasons, we urge CMS to keep the indirect cost allocation methodology open for future changes. We would hope that, during the transition period, CMS will model alternatives to the present system, including alternatives that limit the impact of W-RVUs as an indirect cost allocator. At the very least, we request CMS to commit to re-examine its allocation methodology for indirect costs when and if it changes any of the major assumptions or data used to determine technical component services.

In the interim, we support CMS's proposal to use non-physician staff time as an allocator for services with no physician work. We also suggest that CMS consider modifying the direct and indirect budget neutrality/scaling adjustments in a manner that increases the proportion of indirect practice expenses that are allocated on the basis of direct practice expenses.

II. Developing an Understandable and Intuitive Payment System

We understand that one of CMS's primary priorities in the Proposed Notice is to ensure an understandable and intuitive payment system. Unfortunately, while the "bottom up" treatment of direct costs is more understandable than the "top down" methodology that CMS currently uses, the methodology for determining indirect practice expense allowances remains obtuse. Moreover, as we understand the proposed new PE methodology, the results may vary each year based on annual utilization changes and changes in specialty mix. These elements of the methodology may not only affect the system's transparency but may also affect its overall stability.

We believe that transparency of the system would be improved considerably if CMS simply released the underlying programming to the medical community, along with the Notice of Proposed Rulemaking for each year's PFS update. As it is, those specialties with significant resources are in a position to hire consultants to replicate the CMS methodology, while less affluent specialty and subspecialty groups are not. And because of the time it takes to work out "glitches" in programming, even those specialty societies that are in a position to hire consultants are left with minimal time to put together useful comments. To the extent that CMS truly wants to assure that its system is transparent, we urge the agency to make its programming more fully available to the entire medical community when future proposed rules are published. At a minimum, we hope that CMS will continue to work with the medical community and other affected parties to further improve the transparency of the methodology and the underlying data.

III. Ensuring Stability

We cannot overestimate the importance of stability and predictability of Medicare payment under the PFS, especially for technical component services, which are by definition capital intensive. We applaud CMS for including payment stability among the primary goals of the new system.

For this reason, we strongly support CMS's proposal to provide a four-year transition for practice expense changes, and urge CMS to provide a similar transition period for the five-year review changes described in the Proposed Notice. While five-year review changes are generally incorporated into the PFS without a transition period, the magnitude of the changes proposed for CY 2008 are unprecedented. While these changes will benefit many physicians who provide evaluation and management services and post operative services, the burden will be borne disproportionately by echocardiography and other professional component services that will be adversely affected by the 10% budget neutrality adjustment in W-RVUs. To further assure stability, CMS should phase these changes in over a four-year period, like the PE changes.

In order to further enhance the stability of the methodology, we encourage CMS to model the extent to which the new methodology is sensitive to annual changes in utilization and specialty mix. We are not in a position to assist CMS in this regard since we do not have access to the

underlying programming, but we note that, several years ago, when NPWP allowances were based on one year's utilization, there was an unanticipated drop in allowances. We urge CMS to modify the methodology to the extent necessary to assure that utilization and other year-to-year variations do not result in significant year-to-year fluctuations.

In fact, we urge CMS to consider adopting a review cycle that does not necessitate significant changes on an annual basis, similar to the five-year review cycle for W-RVUs. For example, once the transition to the new system is completed, we would hope that there will be no further modifications of PE allowances until new PE survey data are available. When such new PE survey data do become available, they should be incorporated into the PFS through a multi-year transition.

IV. Other issues--Budget Neutrality

While we recognize that the budget neutrality adjustment methodology set forth in the Proposed Notice is not ideal, we believe that it is the best of the available alternatives under the circumstances. Under the proposed option, W-RVUs will be reduced by 10% to absorb the cost of the five-year review changes, and PE-RVUs will be scaled and adjusted (by an estimated 58%, according to one consultant's report) to maintain budget neutrality on the PE side.

We understand that a number of specialties may object to the 10% reduction in W-RVUs, urging CMS to spread the cost of these changes across the entire fee schedule. This alternative potentially would result in an additional across-the-board reduction of about 5% in either the conversion factor or all RVUs. However, it is our understanding that, under the proposed new PE methodology, direct practice expenses are already reduced by approximately 33% and indirect practice expenses are already reduced by approximately 65% to assure budget neutrality. It clearly would be inequitable to spread the work budget neutrality adjustment across all physician services while requiring the practice expense budget neutrality adjustment to be absorbed exclusively by the PE-RVUs. And making all budget neutrality/scaling adjustments on a fee-schedule-wide basis apparently would result in unacceptable fee-schedule-wide reductions.

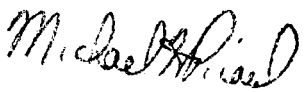
We note, however, that if the five-year review changes are incorporated into the PFS over a four-year transition period, as we suggest, the impact of the budget neutrality adjustment on W-RVUs likewise will be moderated, and we urge CMS to consider this alternative.

Finally, to the extent that CMS decides (contrary to our position) that the budget neutrality adjustment resulting from the five-year review should be spread across the entire fee schedule, we urge CMS to eliminate the direct adjustment (step 9) and modify the indirect adjustment (step 22) in a manner that shifts a comparable budget neutrality burden from PE-RVUs to the fee schedule as a whole.

We appreciate the opportunity to comment on this important notice, and look forward to working with CMS over the coming years to refine whatever methodology is adopted.

Sincerely yours,

AMERICAN SOCIETY OF ECHOCARDIOGRAPHY



Michael H. Picard, M.D.
President

Submitter : Dr. Gregory J. Dehmer **Date:** 08/21/2006

Organization : Society for Cardio. Angio. & Interventions

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2176-Attach-1.DOC

Attach #
2176

The Society for Cardiovascular Angiography and Interventions

9111 Old Georgetown Road, Bethesda MD USA 20814-1699
(800) 992-7224 Fax (301) 581-3408 e-mail: info@scai.org www.scai.org

August 21, 2006

VIA Electronic Submission

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

Dear Administrator McClellan:

The Society for Cardiovascular Angiography and Interventions (SCAI) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule on the *Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*, 71 *Fed. Reg.* 37,170 (June 29, 2006). SCAI has several concerns raised by the provisions of the five-year review proposed rule, as discussed further below.

The Society for Cardiovascular Angiography and Interventions (SCAI) is a professional association representing 3,400 invasive and interventional cardiologists nationwide. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, clinical guidelines and quality assurance to enhance patient care. Our comments concur with the AMA's on all issues they address and the American College of Cardiology's except perhaps on the budget neutrality issue. We also make some comments on the proposed payments for in-office diagnostic catheterization procedures.

BUDGET NEUTRALITY ("OTHER ISSUES")

Under the proposed rule, CMS is revising physician work relative value units (RVUs) that will increase Medicare expenditures for physicians' services by $4 billion. By law, however, CMS must implement these work RVU adjustments on a budget neutral basis. To meet the budget-neutrality requirement, CMS is proposing to reduce all work RVUs by an estimated 10 percent. **The SCAI urges CMS to re-consider this proposal and instead**

apply the budget neutrality adjuster to the physician fee schedule conversion factor.

Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy, and CMS does not provide an adequate rationale for shifting to this new approach, which CMS has previously stated is neither appropriate nor effective. In the past, when CMS applied a budget neutrality adjuster to the work RVUs, it caused considerable confusion among many non-Medicare payers, as well as physician practices, that adopt the resourced-based relative value scale (RBRVS). CMS later acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs. In fact, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services. In recognition of these difficulties, CMS has been applying budget neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

Adjusting the conversion factor is preferable because it does not affect the relativity of services reflected in the recommended RVUs. In contrast, adjusting the work RVUs has the potential to inappropriately affect relativity. In addition, if the work RVUs are adjusted downward for budget neutrality, it will diminish the improvements to valuation of the evaluation and management (E&M) services and the full benefit of these improvements would not be achieved.

Further, adjusting the conversion factor is a more favorable approach because it would: (i) have less impact on other payers who use the Medicare RBRVS, along with their own conversion factor; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

With regard to transparency, we note that CMS is moving rapidly to make pricing information for physicians, hospitals and other providers more public. We urge that CMS apply this same principle of transparency to the Medicare policies that govern these prices. We believe that applying the budget neutrality adjustment to the conversion factor will be far more transparent than if applied to the work RVUs. For many physicians, the various changes in the proposed rule will exacerbate overall physician pay cuts due to the SGR. Transparency of the financial impact of these changes will allow the physicians and policymakers, including Members of Congress, to more easily understand the impact of the cuts. Thus, the budget neutrality adjustments should be made to the conversion factor to achieve transparency.

Finally, applying budget neutrality to the conversion factor rather than work adjuster is critical in light of the imaging cuts mandated by the Deficit Reduction Act of 2005 (DRA). Under this provision, effective January 1, 2007, payment rates for the technical component of imaging services furnished in physicians' offices cannot exceed the payment rate for the same service furnished in a hospital outpatient department. If the budget neutrality adjuster is applied to the work RVUs, payments for all physician services with work RVUs would be reduced, but payments for the technical component of imaging services that are slated to be cut under the

DRA will not be affected because these services have practice expense RVUs only, not work RVUs. Because the differential in payment between imaging services furnished in physicians' offices versus a hospital outpatient department would not be narrowed, the DRA cuts will ultimately remove more dollars (about $200 million in 2007, as estimated by the AMA) from the physician payment pool.

If, however, CMS applies the budget neutrality adjuster to the conversion factor, this would reduce payments for all physicians' services equally, including the technical component services, and would narrow the payment differential between imaging services furnished in physicians' offices versus a hospital outpatient department before the DRA provision is applied. Thus, when the DRA cuts are implemented, fewer dollars would be removed from the total Medicare funding for physician services. **Specifically, the AMA estimates that about $200 million dollars in 2007 would be permanently removed from physician services funding if the budget neutrality adjuster is applied to work RVUs instead of the conversion factor.**

Some would argue that budget neutrality for changes in practice expense RVUs should be applied to the conversion factor as well. The SCAI does not believe that this should occur until all of the RUC's recommendations related to the PE methodology have been addressed by CMS and PE relativity is stable. Ultimately, however, practice expenses for individual services should be evaluated under a five-year review, at which point a similar application for budget neutrality to the conversion factor could be appropriate.

Conclusion

We appreciate the opportunity to provide our views on the critical foregoing matters and stand ready to work with CMS to help achieve appropriate valuation and payment to physicians for their services furnished to Medicare patients.

If your or any members of your staff would like to communicate further about these issues, please contact SCAI's Senior Director for Advocacy and Guidelines. He may be reached at (301) 493-2341 or by email at wpowell@scai.org

Sincerely,

Gregory J. Dehmer, M.D., FSCAI
President

Q:\SCAI\Documents\Correspondence misc\2006 misc letters\CMS Proposed Phys Rule.doc

Submitter : **Mr. David Thomas** **Date: 08/21/2006**

Organization : **Michigan Heart, P.C.**

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 : **Mr. arthur flax** **Date: 08/21/2006**

Organization : **Mr. arthur flax**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1512-PN-2179-Attach-1.TXT

Attachment 2179

August 21, 2006

To: Health and Human Services Regulations Dept.

From: Arthur Flax, LCSW-C

RE: Proposed Reduction in Reimbursement Rates for Clinical Social Workers:

To Whom It May Concern:

As an in network approved provider of Medicare services to patients I am appalled by the prospect of a reduction in the fee schedule for Clinical Social Workers. Frankly, expenses to operate my health care practice, excluding the difference in my malpractice premiums, is the same a any psychiatrist or other physician. Office costs are the same, such as rent, phones, business insurance, workers compensation, continuing education, purchase and maintenance of equipment, computers, software, furnishings, automotive expenses, unemployment insurance premiums, etc.

Further, if I choose to see persons who are beneficiaries of Medicare, I must be an in network provider, unlike physicians' I have no opt out option to charge market rates. Reductions in the fee schedule will cause Clinical Social Workers, despite their values and concern for the elderly and disabled to not provide services to this population, just as many physicians have reluctantly done. Charity begins at home and clinical social workers may be altruistic, but they have to pay their expenses as noted, and earn a living consistent with their education and training and the cost of obtaining that education and training.

Thank You,

Arthur Flax, LCSW-C
1401 Reisterstown Road, Suite L-2
Baltimore, Maryland 21208
410-653-6300
Medicare Provider # 982M801F

Submitter : Mr. Jayson Slotnik **Date:** 08/21/2006

Organization : Biotechnology Industry Organization (BIO)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2183-Attach-1.PDF

Attachment
2183

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

August 21, 2006

BY ELECTRONIC DELIVERY

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-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)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed notice regarding the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology under the physician fee schedule, published in the Federal Register on June 29, 2006 (the "Proposed Notice").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state

[1] 71 Fed. Reg. 37170 (June 29, 2006).

biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO urges CMS to protect beneficiary access to important drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. Patients' access to biological therapies is dependent not only on adequate reimbursement for the therapies themselves but also for the unique costs of handling, administering, and preparing them. We recommend that CMS take the following steps to establish appropriate payments for drug administration services in 2007:

- CMS must not change the RVUs for drug administration services until it can ensure that beneficiary access to care will be protected;
- CMS must not implement the proposed changes to RVUs for administration of radioimmunutherapies;
- CMS should establish RVUs for the codes for prolonged physician services; and
- CMS should not implement the proposed changes to the practice expense RVUs for diabetes self-management training.

I. CMS Must Not Change the RVUs for Drug Administration Services until It Can Ensure that Beneficiary Access to Care Will be Protected

BIO is concerned that the proposed changes to the work and practice expense RVUs for drug administration services will harm beneficiary access to care, contrary to Congress's intent when it passed section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). When Congress created reimbursement based on average sales price (ASP) for physician-administered drugs and biological products, it also recognized that Medicare payments for drug administration services would need to be adjusted at the same time to ensure that physicians could continue to provide critical therapies. Section 303 required the Secretary to take several steps to establish more appropriate payments for drug administration services. First, the Act required the Secretary to set work RVUs for certain drug administration services equal to the work RVUs for a level 1 office visit for an established patient.[2] Second, the Act required the Secretary to use survey data submitted by medical specialty societies to set practice

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[2] Social Security Act (SSA) § 1848(c)(2)(H)(iv).

expense RVUs.3 Third, the Act required the Secretary to evaluate existing drug administration codes to "ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption" and to establish RVUs for any new codes.4 Finally, the Act created a two-year transition adjustment that increased payments for drug administration services by 32 percent in 2004 and by 3 percent in 2005.5 Congress intended that all of these requirements would improve the appropriateness of Medicare's payments to physicians for drug administration services.

BIO has been pleased by CMS' efforts to implement the MMA's requirements in a manner that recognized the need to protect beneficiary access to drug and biological therapies. We are greatly concerned, however, that the proposed RVUs for drug administration services will produce significant payment cuts that undermine the protections CMS has implemented in the past two years. Although CMS estimates that the impact of the work and practice expense RVU changes on hematologists and oncologists will be a 3 percent increase in allowed charges in 2007 and a 2 percent increase in 2010,6 we believe this projection is overly optimistic. CMS' proposed practice expense RVUs for many of these services will fall by approximately 2 to 8 percent in 2007 and 4 to 33 percent when the new practice expense RVUs are fully implemented in 2010. If the budget neutrality adjuster is implemented as proposed, the work RVUs will fall by approximately 10 percent.7 When the effect of the expected cuts in the conversion factor and the end of the oncology demonstration project are factored in, many physicians will experience a real and substantial cut in Medicare payments for drug administration services.

BIO urges CMS not to implement any cuts to reimbursement for drug administration services until it has confirmed that beneficiary access to quality health care will not be harmed by the changes. In particular, CMS should postpone any cuts at least until it has received both of the Medicare Payment Advisory Commission's (MedPAC) reports on the MMA's payment changes. The MMA requires the Medicare Payment Advisory Commission (MedPAC) to conduct two studies on the effect of the MMA's payment changes on the quality of care furnished to beneficiaries and the adequacy of reimbursement.8 MedPAC issued

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3 SSA § 1848(c)(2)(H) and (I).
4 SSA § 1848(c)(2)(J).
5 MMA § 303(a)(3).
6 71 Fed. Reg. at 37255.
7 Id. at 37241.
8 MMA § 303(a)(5).

the first of these reports, focused on oncology drugs and services, in January 2006. Based on the limited data available for analysis, MedPAC found that the "payment changes did not affect beneficiary access to chemotherapy services,"9 but also reported that some practices were sending beneficiaries without supplemental insurance to hospital outpatient departments for care.10

The effects of the MMA's payment changes on beneficiary access to care are not yet fully understood. In its January 2006 report, MedPAC noted that its ability to analyze the impact of the MMA's changes was limited because the changes had not been fully implemented yet and because claims data were available for only part of 2005.11 For example, during the time under review, physicians received transitional adjustment payments as required by the MMA, as well as payment for participation in the demonstration to evaluate the effect of chemotherapy on patients' levels of fatigue, nausea, and pain. In 2006, CMS made no transition payments, and the agency began a new demonstration project. MedPAC's second report, due in January 2007, should describe the effect of current payments on access to care, but the full effect will not be known until later, when complete claims data for 2006 are available. Because physician payments for drug administration services are critical to protecting beneficiary access to care, BIO urges CMS to postpone any cuts in payment until it can confirm that the new rates will allow physicians to continue to provide vital drug and biological therapies to Medicare beneficiaries.

II. CMS Must Not Implement The Proposed Changes To RVUs For Administration Of Radioimmunutherapies

BIO also is concerned about the proposed changes to the RVUs for administration of therapeutic doses of radioimmunotherapies. For 2007, CMS proposes to reduce the practice expense RVUs for code 79403 (Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion) from 5.17 to 4.61, a reduction of 10 percent. If the new practice expense RVUs are fully implemented in 2010, the RVUs for this service would drop by 43 percent to 2.92. We believe this change would harm beneficiary access to radioimmunotherapies such as Zevalin and Bexxar in freestanding centers, and we urge CMS to reconsider this change.

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9 Medicare Payment Advisory Commission, Effects of Medicare Payment Changes on Oncology Services, Jan. 2006, at vii, 23.
10 Id. at 12.
11 Id. at 4.

III. CMS Should Establish RVUs for the Codes For Prolonged Physician Services

In the press release on the Proposed Notice, Administrator Mark McClellan states, "We expect that improved payments for evaluation and management services will result in better outcomes, because physicians will get financial support for giving patients the help they need to manage illnesses more effectively."[12] BIO agrees that physicians should receive financial support for providing quality care. To this end, we recommend that Medicare make separate payment for codes 99258 (Prolonged evaluation and management service) and 99359 (Prolonged evaluation and management service, each additional 30 minutes). These codes are used to describe prolonged service not involving face-to-face care that is beyond the usual service.[13] They describe activities central to providing advanced drug and biological therapies, such as developing treatment plans for patients receiving chemotherapy, reviewing extensive patient records and tests, and communicating with other professionals or the patient and his or her family. Medicare currently considers these services to be bundled into evaluation and management codes, but the work and practice expense inputs associated with these services are not represented by other codes. We recommend that CMS make separate payment for these codes to support physicians' ability to provide quality care to Medicare beneficiaries.

IV. CMS Should Not Implement the Proposed Changes to the Practice Expense RVUs for Diabetes Self-Management Training

Finally, we recommend that CMS not implement the proposed changes to the practice expense RVUs for diabetes self-management training (DSMT). DSMT services help the millions of Medicare beneficiares with diabetes manage their condition to prevent or reduce the severity of diabetes-related complications.[14] Under the proposed new practice expense methodology, the RVUs for these services will decrease significantly over the next few years. In 2007, the RVUs for G0108 (DSMT per individual) will fall by 7 percent, and the RVUs for G0109 (DSMT group session) will drop by 8 percent. If the new RVUs are fully implemented in 2010, G0108 will decrease 28 percent and G0109 will fall

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12 CMS Press Release, CMS Announces Proposed Changes To Physician Fee Schedule Methodology, June 21, 2006, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1887.

13 Current Procedural Terminology 2006, at 29.

14 Diabetes Self-Management Training, http://www.cms.hhs.gov/DiabetesSelfManagement/.

by 34 percent. These codes have no work RVUs to offset the effect of the practice expense methodology changes, leading to steep declines in payment. We are concerned that these rates will not allow physicians to continue to provide these important services, denying Medicare beneficiaries the opportunity to learn how to improve their health. We urge CMS to reconsider the proposed changes to the practice expense RVUs for DSMT.

* * *

BIO appreciates the opportunity to comment on the important issues raised in the Proposed Notice. We look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact me at 202-312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement &
Economic Policy
Biotechnology Industry Organization

Submitter : Dr. Michael Maves **Date:** 08/21/2006

Organization : American Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2184-Attach-1.PDF

Attachment
2184

Michael D. Maves, MD, MBA, Executive Vice President, CEO

August 21, 2006

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

Dear Administrator McClellan:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule on the *Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*, 71 *Fed. Reg.* 37,170 (June 29, 2006).

The AMA appreciates that CMS agreed with the RUC's recommended work RVUs for numerous services, including evaluation and management (E&M) services. We are also pleased that the full increase for the E&M codes will be incorporated into the surgical global periods for each CPT code with a global period of 10 and 90 days.

The AMA, however, has several concerns raised by the provisions of the five-year review proposed rule. These are discussed further below.

BUDGET NEUTRALITY ("OTHER ISSUES")

Under the proposed rule, CMS is revising physician work relative value units (RVUs) that will increase Medicare expenditures for physicians' services by $4 billion. By law, however, CMS must implement these work RVU adjustments on a budget neutral basis. To meet the budget-neutrality requirement, CMS is proposing to reduce all work RVUs by an estimated 10 percent. **The AMA urges CMS to re-consider this proposal and instead apply the budget neutrality adjuster to the physician fee schedule conversion factor.**

Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy, and CMS does not provide an adequate rationale for shifting to this new approach, which CMS has previously stated is neither appropriate nor effective. In the past, when CMS applied a budget neutrality adjuster to the work RVUs, it caused considerable confusion among many non-Medicare payers, as well as physician practices, that adopt the resourced-based relative value scale (RBRVS). CMS later acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs. In fact, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services. In recognition of these difficulties, CMS has been applying budget neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

Adjusting the conversion factor is preferable because it does not affect the relativity of services reflected in the recommended RVUs. In contrast, adjusting the work RVUs has the potential to inappropriately affect relativity. In addition, if the work RVUs are adjusted downward for budget neutrality, it will diminish the improvements to valuation of the E&M services and the full benefit of these improvements would not be achieved.

Further, adjusting the conversion factor is a more favorable approach because it would: (i) have less impact on other payers who use the Medicare RBRVS, along with their own conversion factor; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

With regard to transparency, we note that CMS is moving rapidly to make pricing information for physicians, hospitals and other providers more public. We urge that CMS apply this same principle of transparency to the Medicare policies that govern these prices. We believe that applying the budget neutrality adjustment to the conversion factor will be far more transparent than if applied to the work RVUs. For many physicians, the various changes in the proposed rule will exacerbate overall physician pay cuts due to the SGR. Transparency of the financial impact of these changes will allow the physicians and policymakers, including Members of Congress, to more easily understand the impact of the cuts. Thus, the budget neutrality adjustments should be made to the conversion factor to achieve transparency.

Finally, applying budget neutrality to the conversion factor rather than work adjuster is critical in light of the imaging cuts mandated by the Deficit Reduction Act of 2005 (DRA). Under this provision, effective January 1, 2007, payment rates for the technical component of imaging services furnished in physicians' offices cannot exceed the payment rate for the same service furnished in a hospital outpatient department. If the budget neutrality adjuster is applied to the work RVUs, payments for all physician services with work RVUs would be reduced, but payments for the technical component of imaging services that are slated to be

cut under the DRA will not be affected because these services have practice expense RVUs only, not work RVUs. Because the differential in payment between imaging services

furnished in physicians' offices versus a hospital outpatient department would not be narrowed, the DRA cuts will ultimately remove more dollars (about $200 million in 2007, as estimated by the AMA) from the physician payment pool.

If, however, CMS applies the budget neutrality adjuster to the conversion factor, this would reduce payments for all physicians' services equally, including the technical component services, and would narrow the payment differential between imaging services furnished in physicians' offices versus a hospital outpatient department before the DRA provision is applied. Thus, when the DRA cuts are implemented, fewer dollars would be removed from the total Medicare funding for physician services. **Specifically, the AMA estimates that about $200 million dollars in 2007 would be permanently removed from physician services funding if the budget neutrality adjuster is applied to work RVUs instead of the conversion factor.**

Some would argue that budget neutrality for changes in practice expense RVUs should be applied to the conversion factor as well. The AMA does not believe that this should occur until all of the RUC's recommendations related to the PE methodology have been addressed by CMS and PE relativity is stable. Ultimately, however, practice expenses for individual services should be evaluated under a five-year review, at which point a similar application for budget neutrality to the conversion factor could be appropriate.

DISCUSSION OF COMMENTS: PROPOSED VALUATIONS FOR CERTAIN SERVICES BASED ON ERRONEOUS ASSUMPTIONS

The AMA supports the RUC in urging that CMS accept all of the RUC's work RVU recommendations. We are especially concerned about services for which CMS rejected the RUC recommendation based on an erroneous assumption. For example, CMS has proposed a decrease in the valuation of three orthopedic surgery codes for joint and hip fractures (CPT Codes 27130, 21236, and 27447), despite the RUC recommendation to maintain the current valuation for these services. CMS based its decision on the faulty premise that the specialty society did not submit appropriate survey data for the RUC review of these codes. **In fact, the appropriate survey data was submitted at the September 2005 RUC meeting at the RUC's request, and thus the AMA urges CMS to reconsider its proposal to reduce these codes and instead maintain their current valuation.**

Further, although CMS accepted all of the RUC's recommendations related to nine congenital cardiac surgery codes, the agency has proposed to either maintain the current work relative value or adjust the RUC recommendations for all 72 of the adult cardiac and general thoracic surgery codes. **The AMA supports the RUC in its request that CMS reconsider its proposals for the cardiothoracic surgery codes and instead implement the RUC recommendations for these codes.** CMS' rationale to reject the RUC

recommendation is primarily based on the agency's concern that the RUC process was circumvented. Yet, the RUC engaged in a very thorough and deliberative review process in order to achieve a reliable result for recommendations on these codes. In contrast, the CMS

method for valuing the codes has led to a number of rank order anomalies. Thus, we urge CMS to accept the RUC recommendations as they provide the correct valuation.

The AMA also supports the RUC's request that CMS accept the RUC recommendations for general, colorectal and vascular surgery; radiology and pathology services; otolaryngology and ophthalmology; spine surgery; and other services, as set forth in the RUC comment letter on the proposed rule.

DIALYSIS

The AMA supports the Renal Physicians Association (RPA) in their request that CMS review the work RVUs for the series of monthly dialysis services, G-0308 through G-0324. (We understand that the RPA is in the process of developing a proposal for CPT codes for these services.) **Since CMS will apply the E&M valuation increases to the 10- and 90-day global surgical packages, these increases should also be applied to the dialysis G-codes since these situations are fairly analogous.** The dialysis G-codes include references to the number of E&M visits in the code description and the work RVUs for the original monthly dialysis codes (CPT codes 90918-90921) were developed using E&M building block. Thus, increases for the freestanding E&M codes should be applied to the dialysis code building blocks, as well.

OTHER ISSUES: PRACTICE EXPENSE METHODOLOGY

The AMA appreciates that CMS is proposing to transition over four years the new methodology for calculating practice expense RVUs for physicians' services. This transition time will allow the RVUs to be refined and stabilized over time so that they adequately reflect the relative resources required for each physician service.

To ensure that the PE RVUS are appropriately refined during this transition process, the AMA is coordinating a new practice expense survey effort. Currently, in developing PE RVUs, CMS uses practice expense data and physician hours from the 1995-1999 AMA Socioeconomic Monitoring System (SMS) surveys. A number of other specialties have since conducted their own supplemental surveys, and CMS is proposing to use these new data sources in 2007. The new multi-specialty survey will provide an opportunity for participation by all medical specialty societies and will assist in collecting recent, reliable, consistent practice expense data that can be used in the PE RVUs for all services so that they all have a similar foundation. **Accordingly, we urge CMS to work with the AMA and the physician community in funding this multi-specialty survey effort and ensure that the resulting data may be utilized on a timely basis.**

We note that CMS has acknowledged in the proposed rule that only two-thirds of the direct expenses are recognized due to budget constraints. Physicians cannot continue to absorb these under-valuations, especially as they face Medicare cuts of 37% 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. Since we have repeatedly offered examples of such actions in the past, we will not reiterate them again in these comments. We simply note that physicians cannot engage in the quality improvement initiatives that the Administration and CMS have been advocating when Medicare physician payments are not keeping up with medical practice costs.

We note that the application of budget neutrality from the five-year review has been applied to the work RVUs utilized in the indirect practice expense allocation. It is inappropriate to apply the budget neutrality adjustment to the indirect practice expense allocation. **We urge CMS to correct this and use the work RVUs, as approved by the RUC, as the appropriate allocator in the methodology.**

We appreciate the opportunity to provide our views on the critical foregoing matters and stand ready to work with CMS to help achieve appropriate valuation and payment to physicians for their services furnished to Medicare patients.

Sincerely,

Michael D. Maves, MD, MBA

Submitter : **Date: 08/21/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1512-PN-2185-Attach-1.PDF

Attach 17
2185

August 21, 2006

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

Dear Administrator McClellan:

The undersigned organizations appreciate the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule on the *Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*, 71 *Fed. Reg.* 37,170 (June 29, 2006). We are writing to express concern regarding the agency's proposal to apply a budget neutrality adjustment to physician work, rather than to the Medicare conversion factor.

Budget Neutrality (p. 37241)

The Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in relative value units (RVUs) for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. To limit the increases in Medicare expenditures as mandated by the statute, CMS has applied various adjustments to the Medicare Physician Payment Schedule, including re-scaling the RVUs, creating a separate "work adjuster," or applying a budget neutrality adjustment to the Medicare conversion factor. CMS has proposed to create a new "work adjuster" to ensure budget neutrality following the implementation of the improved work RVUs from this Five-Year Review of the RBRVS. **Applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward and we strongly urge CMS to instead apply any necessary adjustments to the conversion factor.**

In 1993 - 1995, CMS achieved budget neutrality by uniformly reducing all work relative values across all services. We strongly objected to using work relative values as a mechanism to preserve budget neutrality. These adjustments to the work relative values caused confusion among the many non-Medicare payers, as well as physician practices,

that adopt the RBRVS payment system. The constant re-scaling also impeded the process of establishing work RVUs for new and revised services. We have consistently argued that any budget neutrality adjustments deemed necessary should be made to the conversion factor, rather than the work relative values.

In 1997, following the first Five-Year Review of the RBRVS, CMS modified the approach to apply budget neutrality and implemented a separate work adjuster. This approach was short-lived as CMS converted this adjustment to the conversion factor in 1999. CMS later articulated that the creation of the work adjuster was not effective.

> "We did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare." (*Federal Register*, Vol. 68, No. 216, Pg. 63246).

From 1998 to present, CMS has implemented all work neutrality adjustments by adjusting the Medicare conversion factor. CMS does not explain why it proposes to alter this long utilized method and move backward to an approach that the agency itself remarked was inappropriate. In fact, CMS recognizes the current policy on page 37171 of this Proposed Rule, stating that "we must make adjustments to the conversion factors (CFs) to preserve budget neutrality." We request that CMS consider the history and these additional arguments in its consideration of this issue:

1.) Adjusting the conversion factor does not affect the relativity of services reflected in the recommended RVUs. Adjusting the RVUs has the potential to inappropriately affect relativity. If the work RVUs are adjusted as proposed, it will dampen the improvements to the E/M services valuation. CMS has publicly lauded the RUC for recommending these increases to E/M and we would surmise that the agency would want to achieve the full benefit of these improvements.

2.) An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVUs. That is, an adjustment in the Medicare conversion factor will not necessarily affect the payment rates of other payers who use the Medicare RVUs and their own conversion factors. However, any adjustment in the RVUs will impact the payment rates of such payers. The payment rates of payers who peg their rates to a percentage of Medicare will be affected regardless. CMS must consider such "ripple effects" as it decides how to adjust for work neutrality.

3.) An adjustment to the conversion factor is preferable because it recognizes that budget neutrality is mandated for monetary reasons. Thus, the conversion factor, as the monetary multiplier in the Medicare payment formula, is the most appropriate place to adjust for budget neutrality

4.) Applying the work neutrality adjustment to the conversion factor would coincide with CMS' current mission of making the Medicare payment transparent.

As one rationale for applying budget neutrality to work rather than the conversion factor, CMS has pointed out that adjustments for practice expense changes are made within that component rather than applied to the conversion factor. Ultimately, it may be reasonable to apply both work and practice expense budget neutrality adjustments to the conversion factor rather than within the individual components. Before this approach is adopted, however, CMS should make further refinements in its practice expense methodology, including implementation of practice expense data from a recent, consistent, reliable multi-specialty physician practice survey to determine indirect practice expenses.

There is a key difference between the work relative values and the practice expense relative values at this point in the RBRVS. The work relativity is based on a long established methodology of magnitude estimation. Changes in the work relative values from year to year, or in the Five-Year Review, are based on changes in the services performed by physicians (e.g., a patient population that has become more complex; a procedure that requires less time). These changes do not imply that other physician services have become easier, just that CMS cannot afford to pay for the deserved recognition of work. The practice expense portion of the RBRVS payment, however, is still based on a methodology that is in flux. CMS has moved from "bottom-up" to "top-down" to a proposed blended approach. Until the actual method of practice expense relativity is firmly in place, one may not make assumptions regarding specific services. We envision a point in time in which practice expense for individual services are evaluated in a Five-Year Review and at that point, a similar application for budget neutrality would be appropriate.

Finally, applying budget neutrality to the conversion factor rather than work adjuster is critical in light of the imaging cuts mandated by the Deficit Reduction Act of 2005 (DRA). Under this provision, effective January 1, 2007, payment rates for the technical component of imaging services furnished in physicians' offices cannot exceed the payment rate for the same service furnished in a hospital outpatient department. If the budget neutrality adjuster is applied to the work RVUs, payments for all physician services with work RVUs would be reduced, but payments for the technical component of imaging services that are slated to be cut under the DRA will not be affected because these services have practice expense RVUs only, not work RVUs. Because the

American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiology Association
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Institute of Ultrasound in Medicine
American Medical Association
American Medical Directors Association
American Medical Group Association
American Orthopaedic Foot and Ankle Society
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Rhinologic Society
American Society for Aesthetic Plastic Surgery
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society for Surgery of the Hand
American Society of Anesthesiologists
American Society of Breast Disease
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of General Surgeons
American Society of Pediatric Nephrology
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Association of American Medical Colleges
Child Neurology Society
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
International Spine Intervention Society
Medical Group Management Association
National Association of Spine Specialists

National Hispanic Medical Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Critical Care Medicine
Society of Gynecologic Oncologists
Society of Hospital Medicine
Society of Interventional Radiology
Society of Thoracic Surgeons
The Endocrine Society

Submitter : Dwight Reynolds, MD **Date:** 08/21/2006

Organization : Heart Rhythm Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2187-Attach-1.DOC

Attach #
2187

Heart Rhythm Society℠

August 21, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Dr. McClellan:

The Heart Rhythm Society (HRS) welcomes the opportunity to comment on proposed rule CMS 1512-PN entitled Medicare Program: Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology published in the June 29, 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 4,600 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. While HRS applauds CMS' efforts to maintain rational and equitable payment policies for Medicare services, HRS has some concerns as addressed in the following comments.

Practice Expense

HRS appreciates that CMS has addressed the concerns regarding changes to the practice expense methodology resulting from the Town Hall meeting on February 15th. We are pleased that CMS has proposed a methodology that will result in less drastic payment reductions than those discussed at the Town Hall meeting. However, HRS continues to have

concerns about the reductions that some codes will experience in addition to the pending cuts in the conversion factor over the next several years.

However, HRS is pleased that CMS has proposed a four-year transition period for phasing in the new methodology as this will provide physicians with an adjustment period. Furthermore, the transition period allows for time to address concerns with the existing data and make revisions as necessary so that PE RVUs will be based upon accurate and appropriate data once the methodology is fully implemented.

Supplemental Surveys

HRS strongly supports the decision to accept supplemental survey data submitted by seven specialty societies as we believe these data most accurately reflect current practice expenses and allow for development of accurate PE RVUs.

Cardiac Monitoring Services

Based on the revised methodology, payment for 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 little or no practice expense inputs. HRS is very concerned about the potential negative impact on patient access to medically necessary and appropriate care if these reductions are implemented.

HRS is encouraged that CMS has requested data on PE inputs in the second Notice of Proposed Rulemaking released on August 8th and we look forward to working with the AMA and CMS to develop accurate inputs so these codes are reimbursed appropriately. Finally, HRS requests that CMS add code 93236 for 24-hour electrocardiographic monitoring to the list of codes in need of PE input data as reimbursement for this code will fall to zero in 2010.

Other Issues

Global Period

HRS appreciates that CMS has solicited input on whether post-service work should continue to be included in the global surgical package. We urge CMS to meet with stakeholders before making changes to the global package. HRS has concerns about the impact on code values should post-service work be removed from the global period and we look forward to working with CMS on this issue.

Heart Rhythm Society

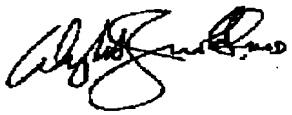
Budget Neutrality

While HRS understands that CMS must apply an adjustor to maintain the fee schedule's budget neutrality, we do not support applying the negative 10% budget neutrality adjustor to all work RVUs. CMS in conjunction with the Relative Value Update Committee (RUC) and all specialty societies has expended a great deal of time and resources to accurately value the work component. A universal reduction in work RVUs inappropriately devalues physician work.

Instead, HRS supports application of an adjustor to the conversion factor. HRS believes that this is a more equitable means of achieving budget neutrality as it would preserve accurate work RVUs and mitigate the impact of the adjustor by spreading it across all codes in the fee schedule.

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 : Mr. Christian Downs **Date:** 08/21/2006

Organization : Association of Community Cancer Centers

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2188-Attach-1.DOC

Attach F
2188

DRAFT 8/31/2006

August 21, 2006

BY ELECTRONIC FILING

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

Re: CMS-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)

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed notice regarding the five-year review of work relative value units (RVUs) under the physician fee schedule and proposed changes to the practice expense methodology (the Proposed Notice).[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

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[1] 71 Fed. Reg. 37170 (June 29, 2006).

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

For 2007, CMS proposes to make substantial changes to the work and practice expense RVUs with the goal of making payments more accurate and improving the transparency of CMS' rate-setting methodologies. With the exception of the proposed work RVUs for radiation oncology and evaluation and management services, we are greatly concerned that these changes will undercut many of Medicare's recent efforts to improve payment for cancer care. Furthermore, these changes are contrary to Congress' intent to protect beneficiary access to care by simultaneously adjusting payments for drugs and drug administration. To ensure that physicians can continue to provide Medicare beneficiaries with the critical therapies they need to fight their battles with cancer, we recommend that CMS:

- Postpone any changes to the RVUs that would reduce reimbursement for drug administration services, including administration of radioimmunotherapies, until the agency can ensure that beneficiary access to care will not be harmed;

- Not implement any reductions to the RVUs for imaging services until CMS has measured the effects of the current multiple service payment reduction policy for certain imaging services; and

- Finalize the proposed work RVUs for radiation oncology services, delay changes in the assumptions regarding equipment utilization, and review the direct practice cost inputs for medical physics services.

We discuss these recommendations below.

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[2] Throughout our comments, we use "drugs" to refer to both drugs and biologicals.

I. CMS must postpone any changes to the RVUs that would reduce reimbursement for drug administration services, including administration of radioimmunotherapies, until the agency can ensure that beneficiary access to care will not be harmed.

In the Proposed Notice, CMS describes a new methodology for calculating practice expense RVUs. This methodology would produce a two to eight percent reduction in the practice expense RVUs for many drug administration services in 2007, the first year of the proposed four-year phase-in. If the new RVUs are implemented fully, the RVUs for many drug administration services would fall by four to 33 percent. The practice expense RVUs for administration of radioimmunotherapies, such as Bexxar® and Zevalin®, also would fall by 10 percent in 2007 and by 43 percent when fully implemented. In addition to the new practice expense methodology, CMS proposes to implement an across-the-board budget neutrality adjustment of 10 percent to all work RVUs, further reducing the total RVUs for these important services.

If implemented, these changes will have a significant effect on payments for cancer care. The proposed new practice expense methodology would produce cuts in 2007 of .5 to 8.4 percent in many drug administration codes. When fully implemented, payments for these codes would be reduced by .5 to 25 percent, before factoring in any changes to the conversion factor. Combining these changes with the anticipated cut in the conversion factor and the changes in payment for imaging services mandated by the Deficit Reduction Act creates considerable uncertainty about whether Medicare's reimbursement will be adequate to protect beneficiaries' access to cancer care.

When Congress created the MMA's payment changes for drug and drug administration services, it sought to prevent instability in Medicare payment for these critical therapies. Congress included provisions in Section 303 of the MMA to ensure that beneficiary access to care remained unharmed during the transition to reimbursement based on average sales price (ASP). For example, the MMA required the Secretary to adjust the RVUs for drug administration services by using medical specialty societies' survey data to set practice expense RVUs[3] and by setting the work RVUs for certain drug administration services equal to the work RVUs for a level one office visit for an established patient.[4] The MMA also instructed the Secretary to evaluate existing drug administration codes to ensure that physicians could accurately report and bill for their services, including services

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[3] Social Security Act (SSA) § 1848(c)(2)(H) and (I).

[4] SSA § 1848(c)(2)(H)(iv).

with varying levels of complexity and resource use, and to set RVUs for any new codes.[5] The provisions demonstrate Congress' concern for establishing appropriate payment rates for drug administration services. Congress also was concerned about protecting beneficiary access to care during the period in which CMS would be collecting claims data using new codes. For this reason, it established transition adjustment payments for drug administration services in 2004 and 2005.[6]

In addition to its requirements to establish appropriate payments for drug administration services in the first two years after the passage of the MMA, the Act also required continued evaluation of the adequacy of drug administration payments. Specifically, it required the Medicare Payment Advisory Commission (MedPAC) to review the payment changes for drugs and drug administration services furnished by oncologists and other specialists.[7] In these studies, MedPAC will look at the adequacy of payment, the impact on physician practices, and whether the payment changes have affected the quality of care.[8] The first of these reports was due on January 1, 2006, and the second is due January 1, 2007. We strongly believe that it would be inappropriate to reduce payment for drug administration services until MedPAC has concluded its review and CMS can assure that beneficiary access to care will not be harmed by the changes.

The first MedPAC report, issued in January 2006, suggests that there are reasons to be concerned about beneficiaries' access to care if these payment reductions are implemented. MedPAC found that the payment changes did not affect access to chemotherapy services while physicians received transitional adjustment payments and payments for participating in the demonstration to evaluate the effects of chemotherapy on patients' levels of fatigue, nausea, and pain.[9] It is not clear whether Medicare's payment rates will be adequate to protect access to care when physicians do not receive transitional adjustments or payments under the demonstration project. Additionally, even while physicians were eligible to receive these additional payments, MedPAC found evidence that some beneficiaries faced increasingly limited access to care. Some practices reported that they sent beneficiaries who lacked supplemental insurance and thus could not afford their coinsurance obligations to receive care in hospital outpatient departments.[10]

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5 SSA § 1848(c)(2)(J).
6 MMA § 303(a)(3).
7 MMA § 303(a)(5).
8 Id.
9 MedPAC, Effects of Medicare Payment Changes on Oncology Services, Jan. 2006, at vii, 23.
10 Id. at 12.

ACCC urges CMS to continue to study the effects of the MMA's payment changes on beneficiary access to care before implementing any reductions in payment for drug administration services. We hope that the next MedPAC report, due in January 2007, will shed light on the effect Medicare's current payment policies have on access to care. This report will be focused on other specialties, however, and the effects of Medicare's policies on access to cancer care will not be known until complete claims data for 2006 are available. Until CMS has sufficient data to determine whether Medicare's current payment rates are adequate to protect access to care, it must not implement any payment cuts for drug administration services.

II. CMS should not implement any reductions to the RVUs for imaging services until CMS has measured the effects of the current multiple service payment reduction policy for certain imaging services.

ACCC also is concerned that the proposed new practice expense methodology will cause further instability in payments for imaging services. Imaging services are critical to cancer care, both for the initial diagnosis and for assessing the effectiveness of treatment. In 2006, CMS extended the multiple procedure payment reduction to selected diagnostic imaging services. Under this policy, if two or more imaging services in the same family of codes are performed on contiguous body parts of the same patient by the same physician on the same day, payment for the technical component of a second or subsequent service performed would be reduced by 25 percent. This policy had a substantial impact on payments for these services in 2006, and we expect the effect will be even larger in 2007 when CMS implements additional payment changes for these services as required by the Deficit Reduction Act (DRA). In light of these changes, we recommend that CMS postpone any changes to the RVUs for these services until the effect of the current policy and the DRA's requirements are better understood.

III. CMS should finalize the proposed work RVUs for radiation oncology services, delay changes in the assumptions regarding equipment utilization, and review the direct practice cost inputs for medical physics services.

CMS submitted nine radiation oncology codes to the AMA/Specialty Society Relative Value Scale Committee (RUC) for review. Standard RUC surveys were completed for these services, and the results indicated the codes are appropriately valued relative to other services on the fee schedule. In the Proposed Notice, CMS agrees with all the RUC-recommended work RVUs for radiology oncology and proposes to maintain the current values. ACCC supports this proposal

and recommends that the work RVUs for Current Procedural Terminology (CPT) codes 77263, 77280, 77290, 77300, 77315, 77331, 77334 and 77470 be finalized for 2007.

CMS did not make any proposals regarding the formula used to calculate the direct practice expense costs associated with equipment. Consequently, we do not anticipate any changes in the final rule. We believe this was appropriate because, as noted by Herb Kuhn, the Director of the Center for Medicare Management, in his testimony before the House Subcommittee on Health of the Committee on Energy and Commerce on July 18, 2006, "Data to substantiate alternative equipment utilization assumptions are not available." We would be pleased to assist CMS in the collection of the necessary data.

We are concerned that the proposed practice expense RVUs for medical physics services may be too low to cover the costs of these services. For example, the practice expense RVUs for CPT code 77295, *Set radiation therapy field,* are proposed to be reduced by almost 77 percent from 29.47 to 6.90 by the end of the 3-year transition in 2010. Other medical physicians services would be reduced dramatically as well. Medical physicists are essential for the safe and effective delivery of radiation therapy. As radiation therapy has become more complex, the need and demand for these highly trained individuals has increased significantly. We recommend that CMS review the direct practice expense inputs for these codes so that accurate salary and time data for medical physicists (and all other direct inputs) can be developed for the codes for CY 2008.

IV. Conclusion

In summary, ACCC is deeply concerned that the proposed changes to work and practice expense RVUs for drug administration and imaging services will harm beneficiary access to quality cancer care. Physicians will not be able to continue to provide quality care unless Medicare appropriately reimburses them for their services. We urge CMS to not implement these changes until it can assure that beneficiaries' access to quality cancer care will not be harmed. On the other hand, CMS should finalize the proposed work RVUs for radiation oncology services. Changes in the assumptions regarding equipment utilization should be delayed, and CMS should review the direct practice cost inputs for medical physics services.

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

Respectfully submitted,

Christian G. Downs
Executive Director

Submitter : **Ms. Karin Bierstein** **Date: 08/21/2006**

Organization : **American Society of Anesthesiologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1512-PN-2192-Attach-1.DOC

Attach #
2192

AMERICAN SOCIETY OF ANESTHESIOLOGISTS

August 21, 2006

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

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

Dear Doctor McClellan:

The American Society of Anesthesiologists (ASA), representing nearly 41,000 physician members, appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the Five-Year Review of the Work Relative Value Units (RVUs) under the Physician Payment Schedule, as well as the proposed update to the Practice Expense methodology, published in the Federal Register on June 29, 2006.

Before stating our concerns and questions with the proposed rule, ASA would like to commend CMS for approving the AMA/Specialty Society RVS Update Committee (RUC) recommendations on CPT codes 00797, 99291 and 99292. For 00797, this will correct a long-standing rank order anomaly and appropriately recognize the intensity and complexity of physician work associated with anesthesia for bariatric gastric restrictive procedures. In addition, CMS' approval of increased work values for the adult critical care codes, CPT 99291 and 99292, as part of the Evaluation and Management Services (E/M) review, will better recognize physician work in the challenging arena of critical care medicine. The remainder of this letter will address the relationship between the Medicare anesthesia fee schedule and the resource based relative value system (RBRVS), the application of the E/M update to the anesthesia codes, CMS' choice to utilize a work adjustor rather than the conversion factor to address budget neutrality considerations arising from the Five-Year Review, and several issues associated with the new practice expense methodology and survey data.

Other Issues: Anesthesia Services

ASA continues to pursue correction of the relationship of physician work in the Medicare anesthesia fee schedule to physician work in RBRVS services. As noted in the June 29, 2006 Federal Register discussion, ASA disagreed with the RUC's recommendations in the 2000 Five Year Review regarding the value of work during the post-induction anesthesia period and with the RUC's refusal to perform a statistical extrapolation from the 19 index codes studied to the other anesthesia codes. CMS has now referred the single question of work intensity during reportable anesthesia time after anesthesia induction back to the RUC:

520 N. Northwest Highway. Park Ridge, IL 60068-2573
Telephone: (847) 825-558. Fax: (847) 825-169. E-mail: mail@ASAhq.org

> "Thus, we are recommending the valuation of anesthesia services, namely the proposed valuation of the post-induction time period, be referred to the RUC for their review and consideration. For example, the ASA and the RUC could review the IWPUT for post-induction time, as currently proposed by the ASA and compare this to the corresponding IWPUT recognized in the last 5-Year Review of anesthesia work for the 19 surveyed codes."

We hope that the RUC will address this limited question expeditiously so that CMS will be able to apply a new methodology for updating all anesthesia work values, which can only be expressed through the anesthesia conversion factor, such as the crosswalking approach that we recently proposed. Preliminarily, we request that the Agency agree with us on a methodology to apply the results of regression analyses or other appropriate statistical techniques to the RUC's recommendations regarding the IWPUT for post-induction time in the 19 surveyed codes. **Since the exploration of post-induction anesthesia intensity would only be worth pursuing if it has the potential to lead to a work valuation correction, ASA encourages CMS to work with us to develop a method to apply the "laborious and exhaustive" review from the last Five Year Review to this problem.** If we can agree on a method to apply the other existing building block data with new and reasonable intensity inputs to achieve a fair and accurate alignment of physician work in the two payment systems, ASA stands ready to pursue the work intensity issue with the RUC.

Other Issues: E/M Global Update Application to Medicare Anesthesia Fee Schedule

In the proposed rule, CMS noted that the agency applied an E/M update to the anesthesia codes, reflecting evaluation and management work inherent in the anesthesia global payment. ASA agrees that anesthesia services warrant such an adjustment and commends CMS for doing so.

The only RUC validated proxies for E/M work equivalents known to ASA came from the 2000 Five Year Review building block model mentioned above. ASA understands that CMS applied the E/M update only to the 19 codes studied in that review. Because these 19 codes represent a broad spectrum of services from low intensity 3 base unit codes to complex 20 base units and because the RUC determined that **every** service had an E/M equivalent service in the pre-service and post-service periods, it is reasonable to conclude that **all** anesthesia services have an E/M equivalent. Furthermore, the CMS decision to apply an E/M update only to the 19 codes implies that no E/M work exists in the other approximately 250 anesthesia codes, clearly a determination that defies logic. **ASA requests CMS to apply an E/M update to all anesthesia services in the final rule.** One method to do so would be to perform a regression of E/M work by base unit value from the last work study using the new E/M work values and applying the calculated E/M update from the regression to the remaining codes in the anesthesia fee schedule.

Other Issues: Work Adjustor vs. Conversion Factor Approach for Budget Neutrality Adjustment

CMS proposes to use a work adjustor to address budget neutrality matters arising from the Five Year Review. ASA urges CMS to abandon the work adjustor approach, replacing it with an adjustment to the conversion factor. ASA believes that the work adjustor approach will increase confusion for those using RBRVS and place us further from the oft-stated agency goal of increased transparency in the payment system.

CMS previously used a work adjustor after the first Five-Year Review, but abandoned that approach by 1999. CMS described the reasons for abandoning a work adjustor in the *Federal Register*, Vol. 68, No. 216, Pg. 63246:

> "We did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare."

From 1998 until now, CMS has used a conversion factor adjustment to recognize work neutrality changes and even notes in this proposed rule that, "we make adjustments to the conversion factors (CFs) to preserve budget neutrality." **ASA encourages CMS to continue to use a conversion factor adjustment for budget neutrality corrections as: a CF adjustment does not affect the relativity of services; it has less impact on third party payers who use RBRVS; its use recognizes that the budget neutrality adjustment is applied for monetary reasons with the conversion factor being the most appropriate place for such an adjustment; and finally, a CF adjustment improves transparency of the payment system.**

While a conversion factor update could be used to address budget neutrality updates arising from the change in Practice Expense methodology, ASA supports CMS's decision to apply a budget neutrality update for Practice Expense through updates to the PE RVUs. ASA justifies this dichotomous approach because the calculation of work RVUs has a stable, well-established methodology while the PE system is in tremendous flux. Also, as will be noted below, even the new method for calculating PE RVUs has a number of significant unresolved issues, including inaccurate utilization data, faulty cost of capital assumptions and outdated overhead cost inputs for most specialties. Once CMS addresses these matters and the PE system demonstrates a similar methodological stability compared to physician work, applying future PE updates through the conversion factor would likely be appropriate.

Practice Expense: Revised Practice Expense Methodology

CMS proposed a new Practice Expense (PE) methodology in the June 29, 2006 proposed rule. ASA appreciates the agency seeking comments from the physician and provider community over the past year, leading to substantial improvements to the proposal first presented in 2005. ASA remains concerned about several items that have not been fully resolved in the latest proposal and has a technical question specific to pain medicine.

ASA supports the multi-specialty practice expense survey being developed by the American Medical Association (AMA) and has made a pledge to AMA to contribute money to fund this initiative. We strongly encourage CMS to also help support this effort through an agreement to purchase the resulting data for use in refining indirect practice expense inputs. The results of the supplemental practice expense surveys from a small number of specialty societies clearly demonstrate major changes in overhead expenses since the AMA last performed a Socio-Economic Monitoring Survey in the late 1990's. **While ASA recognizes that CMS' decision to phase-in the new PE methodology over four years will mitigate some of the distortions created by accepting the supplemental surveys, ASA still encourages CMS to delay implementing the supplemental survey results until current data from all specialties are available.**

In addition to deficiencies in the data used to calculate indirect practice expense inputs, ASA also remains concerned that CMS' failure to adjust utilization assumptions, particularly for high cost and highly utilized equipment such as CT and MRI scanners, as well as failure to adopt a more realistic method to determine cost of capital, perpetuate significant distortions in the practice expense pool. **ASA supports previous RUC recommendations to increase utilization assumptions above the current 50%, while affording specialty societies the opportunity to present data supporting lower utilization rates for specific services. We also support the RUC recommendation to adjust the cost of capital assumptions from the current 11% to a market competitive rate. These issues and the aforementioned indirect data problems require resolution and thus ASA urges a delay in implementation of the new Practice Expense methodology until these items are adequately addressed.**

In a meeting this past spring between CMS and representatives from ASA and several pain societies, CMS indicated that, for the purpose of calculating practice expenses, the specialty designator for "interventional pain medicine" (CMS Specialty Code 09) would crosswalk to "all physicians" rather than "anesthesiology." We

support that decision, as the practice expense profile for an office-based specialist practicing pain medicine is dramatically different than that of the typical facility-based anesthesiologist. **In addition, we also note that the specialty designator "Pain Management" (CMS Specialty Code 72) should also cross to "all physicians" if CMS is using anesthesiology SMS data to calculate relevant PE inputs. We request that CMS clarify whether the agency will use crosswalks for both CMS Specialty Codes 09 and 72 to the "all physicians" category in calculating practice expense RVUs for the 2007 fee schedule.**

Discussion of Comments – Cardiothoracic Surgery

ASA has long been concerned that the RUC survey process for determining physician work and time data is susceptible to inaccuracy with a potential bias toward overstating physician time. By virtue of receiving payment through the Medicare anesthesia fee schedule, anesthesiologists must report actual time data for every case performed. This time data is easily validated through operating room logs and other mechanisms. If the CMS time data for RBRVS, which is primarily based on Hsiao and RUC survey results, systematically overstates the actual time spent in the delivery of a service, then the Medicare payment system unfairly pays more both for physician work and practice expense for RBRVS services than for anesthesia care, where the work and practice expense payments are tied to actual time. The RUC's approval of the use of national data repositories, such as the Society of Thoracic Surgery (STS) and National Surgical Quality Improvement Project databases, for validating physician time and work is an excellent step toward addressing this potential survey bias. CMS expressed concerns about the methodology used in the Five Year Review by the RUC with these databases and the potential barriers, particularly for smaller specialties, to have access to such data stores. Despite these concerns, ASA encourages CMS to work with the RUC to pursue alternative means of valuing physician work and time that is data-driven and not as subject to potential bias as is the current system.

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Thank you for considering our comments. Please do not hesitate to call Norman Cohen, M.D. at (503) 299-9906 or Karin Bierstein, JD, MPH at (202) 289-2222 for any questions or clarifications.

Sincerely,

Orin F. Guidry, M.D.
President
American Society of Anesthesiologists

AMERICAN SOCIETY
OF ANESTHESIOLOGISTS

August 21, 2006

Mark McClellan, MD, PhD
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Department of Health and Human Services
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Thank you for considering our comments. Please do not hesitate to call Norman Cohen, M.D. at (503) 299-9906 or Karin Bierstein, JD, MPH at (202) 289-2222 for any questions or clarifications.

Sincerely,

Orin F. Guidry, M.D.
President
American Society of Anesthesiologists

Submitter : Dr. Steven White **Date:** 08/21/2006

Organization : American Speech-Language-Hearing Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2194-Attach-1.PDF

A-Hachment 2194

AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

August 21, 2006

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

RE: **CMS-1512-PN**
Comments on the Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule & Proposed Changes to Practice Expense Methodology

Dear Dr. McClellan:

The American Speech-Language-Hearing Association (ASHA) appreciates the opportunity to comment on this proposed rule. ASHA is the professional and scientific association representing over 123,000 speech-language pathologists, audiologists and speech, language and hearing scientists.

DISCUSSION OF COMMENTS – OTOLARYNGOLOGY AND OPHTHALMOLOGY

Our concern relates to the classification of the activities of speech-language pathologists and audiologists as clinical staff payable under the practice expense (technical) component of the fee schedule. As we have said on numerous occasions, speech-language pathologists and audiologists are independent professionals whose effort should be valued under the "work" (professional) component of the fee schedule. That is the way the work of other health professionals, including physical therapists, occupational therapists, and psychologists for both their clinical and testing services is valued. In the most recent proposed rule, the work of medical nutritionists is also included in the professional

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component under Medicare. We have been discussing this issue with the Centers for Medicare and Medicaid Services (CMS) for many years.

Most recently, ASHA requested that this issue be considered by the Relative Value Update Committee (RUC) as part of the 5-year review of physician work values and CMS referred the list of procedures to the RUC. However, on April 15, 2006, the RUC deferred the issue until CMS provided guidance on the authority to assign work values to these services. The RUC asked to have the response by May 15, 2006. Consequently, ASHA withdrew the procedures from the 5-year review process because CMS did not respond by the May 15 deadline and not because we changed our position on this issue. To the best of our knowledge, the guidance requested by the RUC has never been provided by CMS.

The current classification of the professional services of audiologists and speech-language pathologists as clinical staff activities has a twofold adverse impact on ASHA members. First, the valuation of their services under the practice expense component, which is based on time multiplied by the wage rate, results in a substantial underestimation of the value of audiology and speech-language pathology services in comparison with other health care professionals whose services are based on the work component. For example, Code 92610, Evaluation of Swallowing Function, has 72 minutes of time associated with this procedure and is assigned a wage rate of $0.55 per minute. This results in an estimated cost of about $38.00. Applying the direct cost budget neutrality factor which we understand leads to reductions in the PEAC estimates of about one-third, this would reduce the allowable direct costs to about $25 or the equivalent of about 0.67 RVUs. Compare that, for example, to the physical therapy or occupational therapy evaluation codes 97001 and 97003 which are assigned a current work value of 1.20 for substantially less time.

Second, the absence of a work value adversely affects the allocation of indirect costs. CMS is proposing to allocate indirect expenses using specialty-specific percentage factors to the direct expenses. Those procedures performed by audiologists and speech-language pathologists that are without physician work will lose the allocation value.

Modification of PE Proposals

ASHA believes that CMS should recognize the services of audiologists and speech-language pathologists as it does our colleagues in occupational therapy and physical therapy. However, because the issue of assigning a work value to these services has not been resolved certain audiology and speech-language pathology codes with no work value, including technical component codes, would experience a devastating reduction in payment.

For example, Code 92610 referenced above would experience over a 50 percent reduction in payment under the fully implemented practice expense system. We believe fairness dictates that until the issue of assigning a work value to these services has been resolved, that some means must be found to temper these losses. ASHA is confident that these reductions would be greatly minimized, if not totally eliminated, with the assignment of a work value to these procedures.

As an interim measure, we again repeat our request that CMS consider the use of proxy work values for allocating indirect costs for these services. The proxy work value could be derived by applying the Intra Work per Unit of Time (IWPUT) methodology to the time data using the IWPUT derived from services for other health professionals such as physical therapists or occupational therapists. Alternatively, we would ask for a temporary "hold harmless" protection that would impose, for example, a 5 percent limit on reductions in payment for these codes for 2007. This would assure that our members are not unfairly penalized while the work value issue is being considered.

Thank you for the opportunity to offer these comments. Please contact Steven White, ASHA's Director of Health Care Economics & Advocacy, at 301-897-0126 or swhite@asha.org should you have any questions.

Sincerely,

Alex F. Johnson

Alex F. Johnson, Ph.D.
President

Submitter : Mr. **Date:** 08/21/2006

Organization : VNUS Medical Technologies,Inc.

Category : Device Industry

Issue Areas/Comments

Practice Expense

Practice Expense

Please see attachment

CMS-1512-PN-2195-Attach-1.PDF

CMS-1512-PN-2195-Attach-2.PDF

Attach #
2195

August 21, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Attention: CMS-1512-PN
Rm. 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

Re: CMS-1512-PN, *Five-Year Review of Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*, 71 *Fed. Reg.* 37,170 (June 29, 2006)

Dear Dr. McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed changes to the Practice Expense methodology. We have several concerns in regards to the five-year review proposed rule, and how it will impact the physicians using our technology.

- **Work Budget Neutrality-** VNUS Medical Technologies urges CMS to apply as much transparency as possible to their proposed regulations. One area to achieve this would be applying the budget neutrality adjuster to the physician fee schedule conversion factor vs. reducing the overall work RVU's for selected procedures. We believe that applying the budget neutrality adjustment to the conversion factor will be far more transparent than if applied to the work RVU's as it is currently proposed. By applying it to the conversion factor it will enable the physicians to more easily understand the impact of the proposed cuts.

- **PE Methodology**-While VNUS supports CMS's proposal to implement a revised methodology for calculating practice expense (PE) RVUs so that the process is more transparent and more easily understood, VNUS strongly recommends that CMS eliminate the proposed reductions in PE RVUs for endovenous RFA procedures described by CPT codes 36475 and 36476. These recently established CPT codes were surveyed late in 2004 and therefore the current values more closely reflect accurate PE expenses.

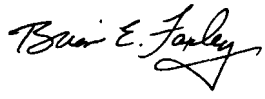
  For this reason, we encourage CMS to maintain the current 2006 PE values (listed below) for CY 2007.

CPT	Description	2006 Facility PE RVUs	2006 Non- Facility PE RVUs
36475	Endovenous RFA, 1st vein treated	**2.54**	**51.54**
36476	Endovenous RFA, vein add-on	**1.14**	**7.9**

Should you have any questions in the meantime, please contact me or Gail Daubert at 202.414.9241.

Thank you for your consideration of this important matter.

Very truly yours,



Brian Farley
President and CEO
VNUS Medical Technologies, Inc.

Submitter : **Date: 08/21/2006**

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

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2196-Attach-1.DOC

Attach #
2196

American Academy of Physical Medicine and Rehabilitation

aapmr

www.aapmr.org

August 18, 2006

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

Re: Medicare Five-year Review of Work RVUs under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; CMS-1512-PN

Dear Dr. McClellan:

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) appreciates this opportunity to submit comments on the *Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes in the Practice Expense Methodology* as set forth in the June 29, 2006 Federal Register.

AAPM&R is the national medical specialty society of almost 7,000 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, 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.

Five-Year Review

AAPM&R commends Centers for Medicare and Medicaid Services (CMS) for supporting the AMA/Specialty Societies Relative Values Update Committee's (RUC) recommended work relative value units (RVUs) for the Evaluation and Management Services. Members of AAPM&R, together with many other specialties, put considerable effort into developing recommendations that accurately reflect the relative physician work involved in providing these services. We are very pleased that CMS has accepted the RUC recommendations for these services.

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Changes to Practice Expense Methodology

Bottom-Up Approach

AAPM&R supports CMS' proposal to adopt a "bottom up" approach to the development of direct cost practice expense RVUs. We believe this approach goes a long way towards making the RBRVS practice expense methodology more understandable and logical.

AAPM&R appreciates CMS' proposed four year transition to the new methodology for calculating practice expense RVUs for physicians' services. To ensure the appropriate adjustments to the PE RVUs, the American Medical Association will be conducting a practice expense survey. Currently, CMS utilizes practice expense data and physician hours from the 1995 – 1999 AMA Socioeconomic Monitoring Systems (SMS) surveys. AAPM&R supports the efforts of the AMA to provide recent, reliable and consistent practice expense data to CMS and will be participating in the practice expense survey.

Allocation of Indirect Practice Expense RVUs

AAPM&R has serious concerns regarding the proposed methodology for allocating indirect costs across services. In particular, we question the use of physician work to allocate indirect costs and believe that physician time would be a more accurate and equitable way to allocate indirect costs at the service level. By using physician work instead of time, procedures with higher intensity are rewarded to the disadvantage of more time-consuming but less intense services. We believe physician time correlates much more directly with indirect costs than the intensity of a service. Consequently, we ask that CMS change to physician time to allocate indirect PE RVUs rather than physician work.

Effect on Specific Services

Under the CMS proposed methodology, a number of diagnostic tests and procedures used by physiatrists to diagnose and treat musculo-skeletal disorders and conditions would undergo very significant cuts. Since there are no changes in work or to the direct cost inputs for most of the codes in question, we assume the reductions are a result of the methodology used to allocate indirect PE RVUs.

For example, the RVUs for electromyography (EMG) performed on one limb (CPT Code 95860) would be reduced by 11.43% by 2010. At the same time, the

identical test when performed on two or three limbs (CPT Codes 95861 and 95863) would increase by 7.47% and 4.26%, respectively. We find these results confusing and inconsistent. There is no rational basis for decreasing the PE RVUs for the single limb test and increasing them for two and three limb tests. Further, CMS has provided no explanation for this result.

Similarly, the motor nerve conduction tests (CPT Codes 95900 – 95903) also undergo significant cuts of between 9% and 19%, by 2010 (without the reductions taken as a result of the proposed 10% budget neutrality adjustment). These reductions apparently result from the application of the proposed indirect cost methodology, since there are no changes in the direct costs or work RVUs associated with these services. However, again, there is no explanation of the reason for these cuts. At the same time, most of the automatic nerve function and somatosensory testing swing the other way with increases of over 200%. There are similar unexplained reductions in reimbursement for a number of nerve block injection procedures (CPT Codes 23350, and 64000-64484) ranging approximately 5% to 41% by 2010.

AAPM&R questions the wisdom of implementing a methodology that results in such enormous fluctuations in PE RVUs that are largely unrelated to changes in work values or actual direct costs. While we appreciate CMS' efforts to make the RBRVS methodology more transparent, as reflected in the change to the "bottom up" approach for allocation of direct costs, the methodology used to allocate indirect costs is far from transparent. The enormous modifications in codes, even within the same family, appear arbitrary and lack any apparent relationship to the actual resources used in providing the service.

Budget neutrality adjustment

CMS is proposing to implement budget neutrality adjustments resulting from the 5-year review through reductions to work RVUs rather than to the conversion factor. AAPM&R does not support this method of adjusting for budget neutrality. It is more consistent with CMS' past practice, and would better preserve the relativity in the work RVUs, if budget neutrality adjustments were made to the conversion factor. Further, a downward adjustment of work RVUs reduces the effect of the improvements to the valuation of the evaluation and management (E&M) services. We urge that CMS reconsider its proposal and that budget neutrality be implemented through a change in the conversion factor.

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We appreciate the opportunity to comment on this proposed rule. If you have any questions about this letter, please contact Rebecca Burke at (202) 872-6751 or Rebecca.Burke@ppsv.com.

Sincerely,

Steve M. Gnatz, MD, MHA
President

Submitter : Dr. Myron Bell **Date:** 08/21/2006

Organization : South Carolina Heart Center

Category : Physician

Issue Areas/Comments

Practice Expense

Practice Expense

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. Wayne Leimbach MD **Date:** 08/21/2006

Organization : Oklahoma Heart Institute

Category : Physician

Issue Areas/Comments

Practice Expense

Practice Expense

see attachment

CMS-1512-PN-2198-Attach-1.PDF

Attach #
2198

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments regarding Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (Federal Register: June 29, 2006)

August 21, 2006

Dear Dr. McClellan:

Oklahoma Heart Institute appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the June 29, 2006 Proposed Notice re: Proposed Changes to the Practice Expense (PE) Methodology and the Five-Year Review of Work RVUs under the Physician Fee Schedule.

Oklahoma Heart Institute represents 22 physicians and 160 employees who serve more than 7,000 patients in the greater Tulsa and Northeast Oklahoma area. We, along with more than 220 private practices and 3,700 cardiologists as represented by the Cardiology Advocacy Alliance (CAA), are concerned that the changes currently proposed by CMS to the practice expense portion of the Relative Value Unit (RVU) system are based on incomplete data and a flawed methodology. Oklahoma Heart Institute requests that CMS delay implementation of the rule for one year until (1) data are corrected to accurately reflect the direct and indirect costs of providing care, and (2) the methodology is updated to better reflect the ratio of direct to indirect costs. Our comments on the five-year review of the Work RVUs under the Physician Fee Schedule also are included below.

Comments regarding Proposed Changes to the Practice Expense Methodology

Oklahoma Heart Institute wants to ensure that the revisions to the practice expense component of Medicare's RBRVS are methodologically sound and are driven by accurate, representative data on physicians' practice costs. Our physicians are particularly concerned about the methodology, data sources and assumptions used to estimate the direct and indirect practice expense costs associated with cardiovascular CPT codes, including services performed in cardiac catheterization labs.

The rule as currently proposed is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component (TC) is a significant part of the overall procedure. **Oklahoma Heart Institute will use catheterization procedures as an example as outlined below of the impact of the proposed methodology on all procedures with significant TC costs. We also believe that the same solution should be applied to all procedures with significant TC costs.**

With regard to catheterizations: the proposed change in PE RVUs would decrease payments for CPT 93510 TC by more than 53 percent. Payment for two related codes—93555 TC and 93556 TC - also would decrease significantly. Under the Medicare Physician Fee Schedule (PFS), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description
93510 TC	Left Heart Catheterization
93555 TC	Imaging Cardiac Catheterization
93556 TC	Imaging Cardiac Catheterization
93526 TC	Rt & Lt Heart Catheters

The stated purpose of the proposed change to a bottom-up cost approach is consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comply with the statutory requirement to match resources to payments. After reviewing the proposed methodology, including the 19-step calculation, CAA and other organizations have identified several flaws that result in an underestimation of the resources needed to provide the technical component of cardiac catheterizations:

Direct Costs

The estimate of direct costs is critical first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee (RUC) and are to reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. However, the direct costs submitted to CMS by the RUC do not reflect estimates of additional labor, supply and equipment costs that were submitted by the Society for Cardiovascular Angiography and Interventions (SCAI). As a result, the RUC-determined cost estimate is about half of what would result if all of the data were included. Including these additional costs, consistent with the RUC protocol, would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns.

For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19-step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	*Included In RUC- Determined Estimate*	*Excluded From RUC-Determined Estimate*
Clinical Labor	• Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery)	• Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	• Supplies Used For More Than 51% of Patients	• Supplies Used For Less Than 51% of Patients
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	• Approximately 55% of the direct costs are included in the RUC estimate	• Approximately 45% of the direct costs are not included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. In addition, there are further improvements that can be made in the manner by which the indirect costs are estimated.

<u>Indirect Costs</u>

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties - Independent Diagnostic Treatment Facilities (IDTFs), which account for about two-thirds of the

utilization estimate for 93510 TC, and Cardiology. The IDTF survey includes a wide range of facilities, but does not reflect the cost profile of cardiac catheterization facilities that may have a cost profile similar to Cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both the direct costs at the procedure level and the indirect costs at the practice level.

Summary of Oklahoma Heart Institute comments on the Proposed Rule re: Practice Expense changes

Our practice believes that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization and other TC-heavy procedures, and that CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterizations. Should CMS adopt its proposed rule on practice expenses as it is currently written, the unintended consequences would be significant:

1. Insufficient reimbursement would force outpatient cath labs to close. Medicare patients would be directed back to the inpatient setting for cath services. This runs counter to CMS' long-term goal of providing care in the outpatient setting whenever clinically appropriate.
2. Hospitals are not prepared to handle a large influx of catheterization cases, and the resulting wait times may very well endanger Medicare beneficiaries who need these critical cardiac services.
3. Medicare beneficiaries' out-of-pocket costs would increase, as hospital co-pays are up to 40 percent higher than those in the outpatient setting.
4. Medicare patients also would be inconvenienced by longer drive times and increased waiting periods for test results.
5. Driving Medicare patients back into the hospital setting for imaging tests also would include increased costs to the Medicare program as a whole.
6. Physician practices are small businesses, employing hundreds of thousands of people and providing valuable services to the Medicare population. The physician sector must have stable reimbursement patterns that keep pace with the increasing cost of providing care.

The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. We are concerned that the problems with the catheterization codes as outlined above may extend to other CPT codes with significant TC costs as well, since the inadequate funding of catheterization codes illustrates that the data and formula used to calculate practice expense components is incomplete and inaccurate. As a result, **Oklahoma Heart Institute requests that CMS delay implementation of the practice expense changes for one year. During this time period, CMS, RUC, SCAI, CAA and other interested parties will be able to complete a thorough assessment of the direct and indirect cost data and the methodology currently under consideration to ensure that they are accurate and complete. CAA will be collaborating with our members and other organizations to develop improved estimates**

of direct costs and to offer additional comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007.

Comments regarding Proposed Notice re: Five-Year Review of Work Relative Value Units under the Physician Fee Schedule

Oklahoma Heart Institute understands that CMS is required by statute to offset costs in excess of $20 million that result from the Agency's mandatory five-year review of Work RVUs under the Physician Fee Schedule. Our practice believes that the $20 million offset threshold set for five-year mandatory reviews in the early 1990s should be adjusted for inflation and the rising costs of providing medical care to our nation's growing Medicare population. We and other CAA members are working with Congressional leaders to address this issue legislatively. It seems nonsensical that CMS must complete the rigorous task of realigning Work RVU weights every five years only to reduce the fee schedule as a whole to pay for the review, which was mandated to ensure that Work RVUs accurately reflect the amount of time medical professionals devote to procedures and ensure appropriate reimbursement. CAA members will see their total reimbursements slashed by up to $1.65 million in 2007 as a result of the 2006 review, depending upon the method CMS chooses to offset costs. Until such time as the arbitrary $20-million cap is changed, we acknowledge that CMS must continue its actions to offset the 2006 Work RVU review.

Sincerely,

Wayne N. Leimbach, MD
Steve M. Struttmann
sstrutt@oklahomaheart.com
On behalf of Oklahoma Heart Institute
1265 South Utica, Ste. 300
Tulsa, OK 74104
918-592-0999

CMS-1512-PN-2199 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule

Submitter : Dr. Angela McCain **Date & Time:** 08/21/2006

Organization : Dr. Angela McCain

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1512-PN

I write regarding the drastic change in RVU for the Technical and Professional Components of DXA scanning.

I understand that, if allowed to go into effect, the technical component would fall by 80% and the professional component by 50%.

The assumptions regarding the equipment are wrong. They are based on single beam, when most of us are using (and paying for) DEXA (double beam) machines.

Most importantly, if the reimbursement falls this drastically and the machines become unavailable (as they will if they are not fiscally possible to own) then access for women will be severely restricted to DEXA scans.

Please consider a more equitable scheme for reimbursement based on more realistic numbers.

Sincerely,

Angela McCain, MD