

**CMS-1512-PN-2215 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Dr. Gregory Shove

**Date & Time:** 08/21/2006

**Organization :** Dr. Gregory Shove

**Category :** Physician

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

CMS,I am attaching my full comment(hopefully.)If I don't succeed the short version is please remove IN-office infusion therapy from Practice expense methodology and recalculate the DEXA reimbursement as per recommendations from the ISCD.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
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. Robert J. Hardesty  
**Organization :** the North Baltimore Center, Inc.  
**Category :** Social Worker

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

Sec Attachment

CMS-1512-PN-2216-Attach-1.DOC

#2216

August 21, 2006

Department of Health and Human Services  
CMS-1512-PN  
PO Box 8014  
Baltimore, MD 21244-8014

To Whom It May Concern:

Please do not cut any reimbursement rates for Social Workers. Our agency already has difficulties with reimbursements and the number of clients that they can serve due to restrictive measures and lower reimbursement rates. Do not reduce work values for clinical social workers. Please withdrawal the proposed increase in evaluation and management codes until they have the funds to increase reimbursement rates for all Medicare providers. I do not support the bottom up formula to calculate practice expense. Please choose a formula that does not create a negative impact for clinical social workers.

Sincerely,

Robert J. Hardesty, LCSW-C

**Submitter :**

**Date: 08/21/2006**

**Organization :**

**Category : Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

CMS-1512-PN-2217-Attach-1.DOC

#2217



Centocor, Inc.  
800 Ridgeview Drive  
Horsham, PA 19044  
phone: 610.651.6000  
fax: 610.651.6100

August 21, 2006

**By Electronic Delivery**

Mark McClellan, M.D., Ph.D  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Ave. S.W.  
Washington, DC 20201

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

Dear Dr. McClellan:

On behalf of Centocor, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule published in the June 29, 2006 Federal Register at pages 37170-37430. Centocor appreciates this opportunity to comment on important aspects of the practice expense methodology, and looks forward to working with CMS to make appropriate adjustments in the CY 2007 physician fee schedule proposed rule to reflect its concerns.

As a leading biopharmaceutical company that discovers, acquires and markets innovative medicines and treatments that improve the quality of life of people around the world, Centocor believes in ensuring equitable and fair access to all necessary medicines for all patients. Among other life-improving medicines,<sup>1</sup> Centocor manufactures Remicade<sup>®</sup>, a product used by patients who suffer from the debilitating effects of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis, enabling these individuals to enjoy longer, more productive lives. Rheumatoid arthritis is a chronic disease that attacks the body's joints, causing inflammation, tissue destruction, and joint erosion. It affects over two million Americans, many of whom are Medicare beneficiaries. Each year, an additional 50,000 Americans are diagnosed with rheumatoid arthritis. Crohn's disease and ulcerative colitis are relatively rare conditions, causing inflammatory disease of the intestine with symptoms that include diarrhea, severe abdominal pain, fever, chills, nausea and, specifically in the case of Chron's disease, fistulae.<sup>2</sup> Without proper treatment, the pain associated with rheumatoid arthritis and Crohn's disease can severely impact the quality of life of afflicted individuals.

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<sup>1</sup> Centocor also manufactures ReoPro<sup>®</sup> for acute coronary care.

<sup>2</sup> Fistulae are painful, draining abnormal passages between the bowel and surrounding skin.

Although rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis are chronic and debilitating conditions, Remicade® is a highly effective treatment that can slow the progression of these diseases and significantly enhance the quality of patients' lives by reducing their pain and other incapacitating conditions. Because Remicade® cannot be self-administered by patients, the Medicare Program provides Part B coverage for this infused therapy both in the hospital outpatient department and physician office settings. Thousands of Medicare beneficiaries afflicted with these conditions rely on Remicade® and other medications to manage their conditions and improve the quality of their lives.

### **Proposed Change to Drug Administration Practice Expense Relative Value Units (RVUs)**

Remicade® is a monoclonal antibody that is administered by intravenous (IV) infusion and generally takes about two hours to infuse. Thus, its administration is billed using Current Procedural Terminology (CPT) code 96413 (Chemotherapy Administration, IV Infusion, 1<sup>st</sup> Hour) and CPT code 96415 (Chemotherapy Administration, IV Infusion, Each Additional Hour). In the proposed rule, the practice expense RVUs would decline from 2006 to 2007 by 3.1 percent and 3.9 percent, respectively, for codes 96413 and 96415. If the reductions were to go forward and be fully phased-in as proposed, they would be 11.8 percent and 10.7 percent, respectively, by 2010.

In the proposed rule, CMS indicated it was proposing the "bottom-up" methodology to calculate the direct practice expenses included in the RVUs because it believes the proposed methodology would be more intuitive and result in fewer situations than the current methodology where changes affecting one code have unanticipated effects on other codes. Centocor shares the goal of a more understandable and predictable physician payment system. However, these drug administration codes have already undergone extensive review and revisions over the past several years. We are concerned that these proposed reductions, particularly combined with the proposed payment reductions due to the sustainable growth rate (SGR) formula, will lead to underpayment for these services, potentially resulting in more limited access to important therapies like Remicade®.

### **Drug Administration Codes Should Not be Revised Under the New Methodology**

The Medicare Modernization Act of 2003 (MMA) required CMS to make a number of changes to its policies surrounding payments for drug administration. First, it required the inclusion of practice expense per hour survey data that was collected by the American Society of Clinical Oncologists (ASCO). Second, the MMA required CMS to ensure the drug administration CPT codes take into account, among other things, the complexity of the administration and the resource consumption of these codes. As a result, CMS implemented new codes that allowed the administration of Remicade® to be billed under the codes associated with administration of chemotherapy. The new codes also reflected updated direct practice expense input data approved by the American Medical Association's (AMA) Relative Value Update Committee (RUC).

Contrary to the MMA requirement, CMS' proposed methodology would no longer use the ASCO survey data for direct practice expenses. In addition, by proposing to reduce

payments for these services below the current amount that reflects the changes mandated by the MMA, CMS is violating Congressional intent to ensure continued full access. **Therefore, we urge CMS to exclude these drug administration codes from the proposed changes to the practice expense methodology until CMS makes the changes noted below.**

Last year CMS proposed to exclude these codes from the methodology changes when it proposed to move to a bottom-up methodology. Although the reason given at the time was that CMS did not have accurate utilization data corresponding to the new codes (which it now has), we believe a more compelling reason to exclude these data is that the current RVUs reflect Congressional intent and the concerted efforts of the AMA, CMS, and many other stakeholders to comply with that intent.

In addition, the MMA required the Medicare Payment Advisory Commission (MedPAC) to conduct two studies on the effect of the MMA's drug administration payment changes on the quality of care furnished to beneficiaries and the adequacy of reimbursement. In January 2006, MedPAC issued the first of these reports, which focused on services provided by oncologists. MedPAC concluded that it was difficult to assess the impact of the payment changes on physicians' practices because the MMA provided for additional transitional payments for two years and CMS made additional payments available to oncologists through its quality-of-life demonstration project. MedPAC's second report, due in January 2007, will focus on drug administration services provided by other specialties. Because the impacts on beneficiary access to care have not been fully analyzed at this point, we urge 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.

### **Pharmacy Management Costs Should be Fully Recognized**

The current payments fail to adequately recognize all of the costs associated with handling pharmaceuticals. These costs are related to storage space, preparation, inventory management, quality assurance, and environmental and safety measures related to disposal of unused medications. In its June 2005 Report to Congress, MedPAC found that 26 to 28 percent of costs related to hospital pharmacy management are attributable to factors other than acquisition costs.<sup>3</sup> This suggests that physicians may have substantial uncompensated expenses associated with pharmacy management for complex biologics as well.

Although the RUC did include some pharmacy preparation and physician supervision in the direct practice expense inputs for the new drug administration codes, it is not sufficient to cover all of physicians' pharmacy management costs. The proposed reduction of the practice expense RVUs for these codes would result in further underpayment. **Therefore, CMS should exclude the drug administration codes from the bottom-up calculation of practice expense RVUs until it establishes new codes to recognize pharmacy management costs.**

### **Prolonged Physician Services Should be Compensated**

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<sup>3</sup> Medicare Payment Advisory Commission, "Report to the Congress: Issues in a Modernized Medicare Program", June 2005, 141.



Physicians caring for medically-complex patients often spend extended time managing the disease apart from direct patient encounters for which they are not compensated. For example, developing treatment plans for patients receiving chemotherapy (including complex biologics such as monoclonal antibodies) requires additional attention and consumes additional resources that are not captured in the current chemotherapy infusion codes or the evaluation and management (E&M) codes recognized by Medicare. Other activities include consulting with other professionals involved in treating these patients and answering questions from the patients and their families.

Currently, Medicare does not pay separately for prolonged physician services without direct patient contact, despite the existence of CPT codes 99358 and 99359, Prolonged Physician Service Without Direct (Face-to-Face) Patient Contact for chemotherapy patients. Medicare considers these services to be bundled into other E&M codes (70 FR 70459)

The work and practice expense inputs associated with codes 99358 and 99359 were approved by the RUC and represent costs that are not associated with other E&M codes. In fact, many other payers currently use these codes to compensate physicians for prolonged services in addition to direct, face-to-face, patient services. **We believe all physicians should be fully compensated by Medicare for providing these services, particularly in the management of chronic diseases. This would be entirely consistent with the movement to align Medicare's payments with improved quality of care.<sup>4</sup> However, as a first step, CMS should activate these codes for patients receiving complex therapies, the administration of which is described by CPT codes 96401 through 96417.**

This step should be taken regardless of whether CMS includes the drug administration codes in its proposal to revise the calculation of practice expense RVUs. But it is critically important to take this step should CMS elect to revise the drug administration practice expense RVUs as proposed. Otherwise the agency will be taking the risk of impeding patient access to these services, as described above.

### **Indirect Practice Expenses**

As described in the proposed rule, the source data for indirect practice expenses are either the AMA's Socioeconomic Monitoring Survey (SMS) data from 1999, or more recent data for specialties that voluntarily undertook a survey in order to update the 1999 SMS data. These data would continue to be the source data for indirect practice expenses under the proposed bottom-up methodology. CMS describes several options for updating these data, including continuing to accept supplemental survey data or an SMS-type survey of only indirect costs for all specialties.

To achieve CMS' goal to make the practice expense RVU calculation fair and predictable, it is critical to update the indirect expenses for all specialties in a consistent manner.

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<sup>4</sup> In the June 21, 2006 press release accompanying the proposed rule, 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."

This should be a top priority, given the high percentage of overall practice expenses attributable to indirect costs. **We recommend that CMS delay the implementation of the bottom-up methodology until it has received updated and consistent indirect practice expense data for all specialties. If implementation cannot be delayed entirely, we recommend that, until the indirect practice expense data are updated, the implementation of the proposed methodology should go no further than the second year of the scheduled phase-in, with 50 percent of practice expense RVUs calculated using the current methodology and 50 percent of practice expense RVUs calculated using the bottom-up methodology.**

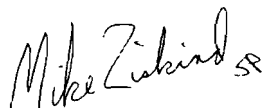
For example, the proposed rule states the practice expense RVUs calculated using the bottom-up methodology would be phased in over four years as follows: 25 percent during CY 2007; 50 percent during CY 2008; 75 percent during CY 2009; and 100 percent during 2010 and thereafter. Under this recommendation, the blend of the current methodology and the bottom-up methodology would remain at 50 percent each until the indirect practice expense survey data were updated for all specialties.

### **Summary and Recommendations**

We applaud CMS's efforts to develop a new methodology that better recognizes actual practice expense consumption. However, due to the special consideration Congress gave to drug administration services in the MMA, we believe these codes should be excluded from this proposed change. This is particularly important given the potential for a 5.1 percent payment reduction resulting from the SGR formula. At a minimum, CMS should exclude these drug administration codes from the bottom-up methodology until it has enacted changes to fully compensate physicians for their pharmacy handling and overhead costs, as well as their prolonged services costs for managing their patients' illnesses. Furthermore, CMS should not move to full implementation of the bottom-up methodology until it has received updated indirect practice expense data for all specialties.

I appreciate the opportunity to comment upon the important issues raised by this proposed rule, and look forward to working with the agency to ensure that the methodology appearing in the final rule is implemented in an equitable manner that preserves beneficiaries' access to quality health care under the Medicare Program. Please contact us if you have any questions about this matter.

Sincerely,

A handwritten signature in cursive script that reads "Mike Ziskind" followed by a small "SR" to the right.

Michael Ziskind  
Senior Director  
Public Payer Policy, Strategy and Marketing  
Centocor, Inc.

**Submitter :** Jill Rathbun

**Date:** 08/21/2006

**Organization :** Society of Gynecologic Oncologists

**Category :** Physician

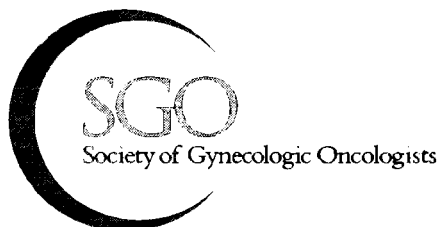
**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment for comments on Discussion of Comments - Evaluation and Management Visits, Other Issues, and Practice Expense

CMS-1512-PN-2218-Attach-1.DOC



August 21, 2006

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

Delivered via [http://www.cms.hhs.gov/eRulemaking/01\\_Overview.asp](http://www.cms.hhs.gov/eRulemaking/01_Overview.asp)

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

Dear Dr. McClellan:

The Society of Gynecologic Oncologists wishes to provide comments on the "Proposed Notice Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology"

The Society of Gynecologic Oncologists (SGO) is a national surgical specialty society of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract. Its purpose is to improve the care of women with gynecologic cancer by encouraging research, disseminating knowledge which will raise the standards of practice in the prevention and treatment of gynecologic malignancies, and cooperating with other organizations interested in women's health care, oncology and related fields.

SGO's members make it the leading organization of gynecologic oncologists in the United States. As gynecologic oncologists, our members are women's cancer specialists who have received an additional 3-4 years of intensive medical training in the study and treatment of malignancies arising in the female reproductive tract

Our comments will address CMS' proposals regarding the third five-year review and the proposed practice expense methodology change.

**I. Summary**

- Five-Year Review of Work Relative Value Units:

- We believe CMS was right with regard to including the increases in evaluation and management services to 10 and 90 day global CPT codes. However given the number of CPT codes with either a 10 or 90 day global period, we encourage CMS to double check all of these codes to ensure that their proposed work RVUs include the increases proposed for the established office visit codes.
- Applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward with 90 day global services such as radical hysterectomy with complete debulking for an indication of ovarian cancer offsetting much of the dollars needed to satisfy Congressional mandated requirements. SGO urges CMS to instead apply any necessary adjustments to the conversion factor.
- Proposed Changes to Practice Expense Methodology:
  - In general, SGO is concerned that compared to last year's "bottom-up" method for calculating PE RVUs, this year's method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. SGO urges CMS to investigate these steps.
  - SGO urges CMS as it calculates the service level allocators for the indirect PEs, the direct PE RVUs and the work RVUs, to not use direct PE RVUs or work RVUs that are been adjusted for budget neutrality. Indirect costs for a service need to allocated using all of the inputs for a service.

## **II. Detailed Discussion**

### **A. Five-Year Review of Work Relative Value Units**

#### **1. Discussion of Comments – Evaluation and Management Services**

- Extending Evaluation and Management Service Increasing to CPT codes with 10 and 90 day global periods

We believe CMS was right with regard to including the increases in evaluation and management services to CPT codes with 10 or 90 day global periods. Time that a physician spends in post-operative follow-up visits during the days and weeks following a surgical procedure are no less with regard to time and intensity than if the patient was coming in for a cold or flu appointment, and in many instances these visits last longer due to counseling with the patient and/or family members regarding post-surgical wound care or changes in lifestyle or activities. However given the number of CPT codes with either a 10 or 90 day global period, we encourage CMS to double check all of these codes to

ensure that their proposed work RVUs do actually include the increases proposed for the established office visit codes.

- Other Issues – Budget Neutrality

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. SGO 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.

## B. Practice Expense (PE)

### 1. Budget Neutrality

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

### 2. Indirect Allocation Formula

#### A. Allocation Formula

We urge CMS as it calculates the service level allocators, direct PE RVUs and the work RVUs for the indirect PEs, to not use direct PE RVUs or work RVUs that are been adjusted for budget neutrality. Indirect costs for a service need to allocated using all of the inputs for a service. If work

RVUs are reduced by 10% prior to being used in the formula that essentially reduces the number of minutes of indirect costs that a service receives. This actually disadvantages procedures with higher numbers of minutes, and subsequently higher work RVUs, in the indirect allocation process, while these are the procedures that actual use more indirect costs, such as rent, utilities, administrative staff.

By using the CPEP direct cost inputs and then calculating the direct PE RVUs and using the nonadjusted work RVUs, codes with high costs are able to gain an appropriate share of indirect costs, versus being penalized twice, once through budget neutrality and then by the indirect allocation method. Also, since CMS is continuing to use an indirect scaling factor as the final step in the indirect allocation process, the indirect RVUs are still going to be “scaled” to fit the amount of money available in each specialties indirect allocation pool.

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The SGO appreciates the opportunity to provide comments on this proposed notice. If the Society can provide CMS with additional information regarding this matter, please do not hesitate to contact Jill Rathbun, SGO Director of Government Relations at 703-486-4200.

Sincerely,

*Gary S. Leiserowitz, MD*  
Gary S. Leiserowitz, MD  
Chair, Coding and Reimbursement Ctme.

*Carol L. Brown, MD*  
Carol L. Brown, MD  
Chair, Government Relations Ctme.

**Submitter :** Mr. THOMAS CRAFT  
**Organization :** MEDICAL CENTER LLP  
**Category :** Physician

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACMENT

CMS-1512-PN-2220-Attach-1.RTF



# 2220

**MEDICAL CENTER L.L.P.  
908 HILLCREST PKWY.  
DUBLIN, GA 31021  
(478) 272-7411 OR FAX (478) 274-9809**

08/18/2006

**Centers for Medicare and Medicaid Services,  
Department of Health and Human Services,  
Attention CMS-1512-PN,**

**This letter is to address the proposed changes to the Medicare Physician Fee Schedule (CMS-1512-PN), in which the current reimbursement from 140.00 for a DXA will be reduced to 38.00.**

**I strongly disagree with this ruling. If these changes do come in to effect, our facility may no longer be able to offer this service to our patients. This ruling will negatively impact women's access to this important test at our and other facilities. Women's bone health is an important issue and should not be trivialized by inadequate reimbursement.**

**Thank you in advance for your reconsideration in this matter.**

Sincerely,

*Thomas Craft, M.D.*

**Thomas E. Craft M.D.**

**Submitter :** Dr. Lawrence Rosenblum  
**Organization :** Central Diagnostic Imaging  
**Category :** Radiologist

**Date:** 08/21/2006

**Issue Areas/Comments**

**Discussion of Comments-  
Radiology, Pathology, and Other  
Misc. Services**

Discussion of Comments- Radiology, Pathology, and Other Misc. Services  
see attachment

CMS-1512-PN-2221-Attach-1.DOC

CMS-1512-PN-2221-Attach-2.DOC

ATTACHMENT 1 TO # 2221

Monday, August 21, 2006

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

RE: CMS- 1512-PN

CPT Codes 76082 and 76083

We strongly recommend that CMS withdraw its proposed reduction for the technical component for CAD until such time that providers can differentiate between the utilization of CAD with either analog or digital mammography. The CPT codes for CAD with mammography (76082, 76083) contain the phrase "with or without digitization of film radiographic images".

According to CMS, "These revisions reflect changes in medical practice, coding changes, new data on relative value components, and the addition of new procedures that affect the relative amount of physician work required to perform each service as required by statute." This statement is incorrect with reference to analog mammography. There have been no changes to substantiate this proposed rule for the use of CAD with analog mammography.

Sincerely,

Lawrence J. Rosenblum, M.D.  
Radiologist  
Central Diagnostic Imaging  
6 Newton Avenue  
Norwich NY 13815  
(V) 607-334-7144  
(F) 607-334-7054  
e-mail: cdinorwich@frontiernet.net

Monday, August 21, 2006

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

RE: CMS- 1512-PN

CPT Codes 76082 and 76083

We strongly recommend that CMS withdraw its proposed reduction for the technical component for CAD until such time that providers can differentiate between the utilization of CAD with either analog or digital mammography. The CPT codes for CAD with mammography (76082, 76083) contain the phrase "with or without digitization of film radiographic images".

According to CMS, "These revisions reflect changes in medical practice, coding changes, new data on relative value components, and the addition of new procedures that affect the relative amount of physician work required to perform each service as required by statute." This statement is incorrect with reference to analog mammography. There have been no changes to substantiate this proposed rule for the use of CAD with analog mammography.

Sincerely,

Lawrence J. Rosenblum, M.D.  
Radiologist  
Central Diagnostic Imaging  
6 Newton Avenue  
Norwich NY 13815  
(V) 607-334-7144  
(F) 607-334-7054  
e-mail: cdinorwich@frontiernet.net

**Submitter :** Mr. Christian Downs  
**Organization :** Association of Community Cancer Centers  
**Category :** Association

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

Attached document to replace previous submission.

CMS-1512-PN-2222-Attach-1.DOC

#2222

The premier education and advocacy organization for the oncology team



Association of Community Cancer Centers

August 21, 2006

**CCRS:**

Dr. C. Chingos, MD, CPE  
(Tomball, Texas)

Dr. B. Reiling, MD, FACS  
(Charlotte, North Carolina)

Dr. R. Anderson, Jr., MS, RPh  
(Boston, Massachusetts)

Dr. K. Gordon, RN, MS, OCN  
(Tampa, Florida)

Dr. D. Weaver, FACHE, MHSA, MBA  
(Denver, Colorado)

**CCRS:**

Dr. B. Benson III, MD, FACP  
(Chicago, Illinois)

Dr. T. Bollin, MBA, RN  
(Cincinnati, Ohio)

Dr. M. Collins, RN, MS, OCN  
(Albany, New York)

Dr. J. Curtis, MD  
(Las Vegas, Nevada)

Dr. M. Hensley, MBA, RT(T)  
(Columbus, Ohio)

Dr. R. Lamkin, RN, MPH  
(Boise, Idaho)

Dr. M. J. Petrelli, MD  
(Wilmington, Delaware)

Dr. R. Romig, RPh, MBA  
(Raleigh, North Carolina)

Dr. L. Whittaker, MD, FACP  
(Indianapolis, Indiana)

Dr. J. E. Wolfe III, MBA  
(Des Moines, Iowa)

**EXECUTIVE DIRECTOR:**

Dr. G. Downs, JD, MHA

*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).<sup>1</sup> ACCC is a membership organization whose members include hospitals, physicians, nurses,

<sup>1</sup> 71 Fed. Reg. 37170 (June 29, 2006).

social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

Medicare beneficiaries depend upon advanced drugs<sup>2</sup> 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

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<sup>2</sup> Throughout our comments, we use "drugs" to refer to both drugs and biologicals.

- 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.

**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<sup>3</sup> 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.<sup>4</sup> 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 with varying levels of complexity and resource use, and to set RVUs for any new codes.<sup>5</sup> 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.<sup>6</sup>

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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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

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<sup>3</sup> Social Security Act (SSA) § 1848(c)(2)(H) and (I).

<sup>4</sup> SSA § 1848(c)(2)(H)(iv).

<sup>5</sup> SSA § 1848(c)(2)(J).

<sup>6</sup> MMA § 303(a)(3).

<sup>7</sup> MMA § 303(a)(5).

<sup>8</sup> Id.

<sup>9</sup> MedPAC, Effects of Medicare Payment Changes on Oncology Services, Jan. 2006, at vii, 23.

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.<sup>10</sup>

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.

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<sup>10</sup> Id. at 12.

**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

Administrator Mark McClellan

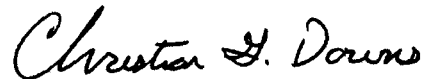
August 21, 2006

Page 7 of 7

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,

A handwritten signature in cursive script that reads "Christian G. Downs".

Christian G. Downs  
Executive Director

**Submitter :** Jill Rathbun  
**Organization :** CoalitionfortheAdvancementofProsthetic Urology  
**Category :** Physician

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment for Discussion of Comments on Urology, E&M Services, Other Issues, and Practice Expense.

CMS-1512-PN-2223-Attach-1.DOC

August 21, 2006

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

Delivered via [http://www.cms.hhs.gov/eRulemaking/01\\_Overview.asp](http://www.cms.hhs.gov/eRulemaking/01_Overview.asp)

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

Dear Dr. McClellan:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology for CY 2007. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

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

**I. Summary**

- Five-Year Review of Work Relative Value Units:
  - Many of the prosthetic urology procedures are undervalued and this is causing issues regarding access due to a lack of urologists now specializing in prosthetic urology procedures. The increase in work RVUs for CPT code 52601 is an important first step to addressing all of these codes in the near future.
  - We are concerned that within the family of established office visit codes the relative steps between the work RVUs between each code are now too great to maintain integrity within the system given that CPT code 99212 – Level II Est. Office Visit – was not increased, while CPT code 99213 – Level III Est. Office Visit was increased by 37 percent. We urge CMS to re-establish the relative

steps, prior to the five-year review, between the established office visit codes by increasing CPT codes 99211 – 99215 per the chart below.

- We believe CMS was right with regard to including the increases in evaluation and management services to 10 and 90 day global CPT codes. However given the number of CPT codes with either a 10 or 90 day global period, we encourage CMS to double check all of these codes to ensure that their proposed work RVUs include the increases proposed for the established office visit codes.
- Applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward with 90 day global services such as prosthetic urology procedures offsetting much of the dollars needed to satisfy Congressional mandated requirements. CAPU urges CMS to instead apply any necessary adjustments to the conversion factor.
- Proposed Changes to Practice Expense Methodology:
  - CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS’s stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments.
  - In general, CAPU is concerned that compared to last year’s “bottom-up” methodology for calculating PE RVUs, this year’s method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. CAPU urges CMS to investigate these steps.
  - CAPU urges CMS as it calculates the service level allocators for the indirect PEs, the direct PE RVUs and the work RVUs, to not use direct PE RVUs or work RVUs that are been adjusted for budget neutrality. Indirect costs for a service need to allocated using all of the inputs for a service.
  - CAPU appreciates CMS using the American Urological Association’s supplemental survey data as part of the process of creating a more accurate, intuitive and stable Practice Expense (PE) methodology.

## **II. Detailed Discussion**

### **A. Five-Year Review of Work Relative Value Units**

1. Discussion of Comments – Gynecology, Urology, Pain Medicine, and Neurosurgery
  - Urology

With more people over 80 years old in the Medicare program than ever before, it is imperative that surgical procedures that treat conditions of an aging population, such as stress incontinence and Benign Prostate Hypermobility (BPH), are appropriately reimbursed. We appreciate CMS identifying CPT code 52601 – Transurethral electrosurgical resection of the prostate – and CPT code 57288 – Sling operation for stress incontinence for review. In the instance of CPT code 52601, the fact of it having never been reviewed was contributing to greater phenomena with regard to the future of prosthetic urology. Many of the prosthetic urology procedures are undervalued and this is causing issues regarding access due to a lack of urologists now specializing in prosthetic urology procedures. The increase in work RVUs for CPT code 52601 is an important first step to addressing all of these codes in the near future.

## 2. Discussion of Comments – Evaluation and Management Services

- Need to Re-Establish Relativity of Established Office Visit Codes

We commend the Resource Update Committee (RUC) and CMS for undertaking the review of all evaluation and management service CPT codes as part of this third five-year review. However, we are concerned that within the family of established office visit codes the relative steps between the work RVUs for each code are now too great to maintain integrity within the system given that CPT code 99212 – Level II Est. Office Visit – was not increased, while CPT code 99213 – Level III Est. Office Visit was increased by 37 percent.

The proposed relative difference between CPT codes 99212 and 99213 has the unintended consequence of creating an incentive for “up-coding” because the relative difference will serve as a catalyst to prompt those who perform the majority of office visits to find ways to reach the number of body systems examined or level of medical decision making needing to code a 99213. Basically, all office visits will become a “99213” and CPT code 99212 will become an irrelevant code. The Medicare system will then be at fault for causing more unintentional “up-code,” not individual physicians.

We propose that to maintain the integrity of the families of evaluation and management services, CMS must seek to re-establish the relative steps, prior to the five-year review, between the established office visit codes by increasing CPT codes 99211 – 99215 per the chart below:



CPT Code	Descriptor	2006 Work RVUs	2006 Relativity Value to Reference Code (99213)	2007 Proposed Work RVUs	Relativity Value to Reference Code (99213)	Proposed 2007 Est. Office Visit RVUs to Re-establish 2006 Relativity Value Scale
99211	Office/outpatient visit, est.	0.17	-75%	0.17	-82%	<b>0.31</b>
99212	Office/outpatient visit, est.	0.45	-33%	0.45	-51%	<b>0.61</b>
99213	Office/outpatient visit, est.	0.67	0%	0.92	0	<b>0.92</b>
99214	Office/outpatient visit, est.	1.10	64%	1.42	54%	<b>1.51</b>
99215	Office/outpatient visit, est.	1.77	164%	2.00	117%	<b>2.43</b>

- Extending Evaluation and Management Service Increasing to CPT codes with 10 and 90 day global periods

We believe CMS was right with regard to including the increases in evaluation and management services to CPT codes with 10 or 90 day global periods. Time that a physician spends in post-operative follow-up visits during the days and weeks following a surgical procedure are no less with regard to time and intensity than if the patient was coming in for a cold or flu appointment, and in many instances these visits last longer due to counseling with the patient and/or family members regarding post-surgical wound care or changes in lifestyle or activities. However given the number of CPT codes with either a 10 or 90 day global period, we encourage CMS to double check all of these codes to ensure that their proposed work RVUs do actually include the increases proposed for the established office visit codes.

Furthermore, our concerns regarding the relativity between the proposed work values for 99212 and 99213 continue as we move to major surgeries with 90 day global periods. Many of the major surgical codes were not included in this third five year review and thus the only increase they are proposed to receive comes from the increase in the established office visit codes. Yet, it is the major surgical codes that contribute the majority of the per service savings need to address budget neutrality with regard to absolute reduction in work RVUs. For some of the 90 day global period codes the advent of “packages” of

evaluation and management services attributed to them by the PEAC during its previous reviews of practice expense leave them at an even greater disadvantage because these packages contain Level II established office visits, versus Level III established office visits. Again, we ask CMS to address the relative step between CPT codes 99212 and 99213 and then add any such increases, as we have proposed, to the CPT codes with 10 or 90 day global periods.

- Other Issues – Budget Neutrality

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. CAPU 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.

## B. Practice Expense (PE)

### 1. Bottom-Up Methodology

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

and CAPU strongly supports the change in methodology that does away with the need for scaling factors.

## 2. Budget Neutrality

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

## 3. Indirect Allocation Formula

### A. Allocation Formula

We urge CMS as it calculates the service level allocators, direct PE RVUs and the work RVUs for the indirect PEs, to not use direct PE RVUs or work RVUs that are been adjusted for budget neutrality. Indirect costs for a service need to allocated using all of the inputs for a service. If work RVUs are reduced by 10% prior to being used in the formula that essentially reduces the number of minutes of indirect costs that a service receives. This actually disadvantages procedures with higher numbers of minutes, and subsequently higher work RVUs, in the indirect allocation process, while these are the procedures that actual use more indirect costs, such as rent, utilities, administrative staff.

By using the CPEP direct cost inputs and then calculating the direct PE RVUs and using the nonadjusted work RVUs, codes with high costs are able to gain an appropriate share of indirect costs, versus being penalized twice, once through budget neutrality and then by the indirect allocation method. Also, since CMS is continuing to use an indirect scaling factor as the final step in the indirect allocation process, the indirect RVUs are still going to be “scaled” to fit the amount of money available in each specialties indirect allocation pool.

### B. Use of Supplemental Survey Data

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

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

Sincerely,

*John J. Mulcahy, MD*

John J. Mulcahy, MD  
Chair

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

**Submitter :** Mr. W. Maxwell Duke  
**Organization :** Medical Center LLP  
**Category :** Physician

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2225-Attach-1.RTF

#2225

**MEDICAL CENTER L.L.P.  
908 HILLCREST PKWY.  
DUBLIN, GA 31021  
(478) 272-7411 OR FAX (478) 274-9809**

08/18/2006

**Centers for Medicare and Medicaid Services,  
Department of Health and Human Services,  
Attention CMS-1512-PN,**

**This letter is to address the proposed changes to the Medicare Physician Fee Schedule (CMS-1512-PN),  
in which the current reimbursement from 140.00 for a DXA will be reduced to 38.00.**

**I strongly disagree with this ruling. If these changes do come in to effect, our facility may no longer  
be able to offer this service to our patients. This ruling will negatively impact women's access  
to this important test at our and other facilities. Women's bone health is an important issue and should not be  
trivialized by inadequate reimbursement.**

**Thank you in advance for your reconsideration in this matter.**

**Sincerely,**



**William M. Duke MD.**

**Submitter :** Jill Rathbun

**Date:** 08/21/2006

**Organization :** American Medical Systems, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment for Discussion of Comments on Gynecology, Urology and E&M Services, Other Issucs, and Practice Expense.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
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. Steven Garner  
**Organization :** Medical Center LLP  
**Category :** Physician

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2228-Attach-1.DOC

**MEDICAL CENTER L.L.P.  
908 HILLCREST PKWY.  
DUBLIN, GA 31021  
(478) 272-7411 OR FAX (478) 274-9809**

08/18/2006

**Centers for Medicare and Medicaid Services,  
Department of Health and Human Services,  
Attention CMS-1512-PN,**

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**I strongly disagree with this ruling. If these changes do come in to effect, our facility may no longer be able to offer this service to our patients. This ruling will negatively impact women's access to this important test at our and other facilities. Women's bone health is an important issue and should not be trivialized by inadequate reimbursement.**

**Thank you in advance for your reconsideration in this matter.**

**Sincerely,**



**Steven R. Garner MD**

**Submitter :**

**Date: 08/21/2006**

**Organization :** Alliance for Children & Families and Provident Inc

**Category :** Other Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-1512-PN-2229-Attach-1.DOC

H 2229

Alliance for Children and Families  
1701 K Street NW, Suite 200  
Washington, DC 20006  
[policy@alliance1.org](mailto:policy@alliance1.org)

Provident, Inc.  
2650 Olive Street  
St. Louis, MO 63103  
[keb@providentstl.org](mailto:keb@providentstl.org)

August 21, 2006

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

RE: Medicare Physician Fee Schedule, 71 Fed.Reg.  
37170 (June 29, 2006)

The Alliance for Children and Families and Provident, Inc. are writing to comment on the Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, published in the Federal Register on June 29.

The mission of the Alliance is to strengthen the capacities of North America's nonprofit child and family serving organizations to serve and to advocate for children, families and communities, so that together we may pursue our vision of a healthy society and strong communities for all children and families. The mission of Provident is to strengthen families; to provide youth the opportunity and resources to succeed; and to assist communities to be stable and productive. This is accomplished by providing prevention and treatment services that have the greatest potential for positive impact.

We are writing to oppose the changes to the Relative Value Units (RVUs) and Practice Expense (PE) Methodology that would cause a 14% fee reduction for clinical social workers. The proposed RVU changes would reduce work values for clinical social workers by 7%, and the PE changes would reduce expense values by another 2%. Contemplated adjustments for Calendar Year 2007 would further reduce fees for clinical social workers by another 5%, for a total reduction of 14% by January 1, 2007.

As advocates for vulnerable children, families and seniors across the United States and as a service provider to more than 47,000 individuals in the St. Louis region per year, we are deeply concerned by this proposed action that would adversely affect the ability of clinical social workers to continue to serve Medicare patients. If they cannot be sufficiently reimbursed for the time and services provided to patients, social workers will face a difficult choice between fiscal survival and continuing to serve the Medicare population. This population is particularly in need of quality social workers due to the increased incidence as people age of behavioral health problems, mental illness, and suicide; the potential for abuse or neglect of the elderly, disabled, and vulnerable persons; and the difficult issues that surround long-term care decisions.

The proposed Fee Schedule changes impose greater fee reductions on clinical social workers than on almost any other practice area, with the exception of radiology and anesthesiology. We believe

that this reduction is unwarranted and will cause significant harm by effectively reducing the amount of quality social services that will be available to Medicare beneficiaries. We believe that RVUs and PEs should not be increased for only certain practice areas, but that increases should be delayed until all practice areas can receive an appropriate fee increase. In the meantime, some types of providers should not experience a fee reduction in order to allow for a fee increase for other providers.

We recommend that the Centers for Medicare and Medicaid Services:

- Withdraw the proposed RVU and PE changes that would cause a 14% fee reduction for clinical social workers by January 1, 2007;
- Withdraw the proposed increases to evaluation and management RVUs and PEs until such time as all practice areas can be granted an appropriate fee increase;
- Select a formula for calculating practice expenses that does not have a negative impact on clinical social workers. The proposed “bottom up” methodology has a disproportionate negative impact on clinical social workers due to their low practice expense as providers.

Thank you for inviting our comments.

Carmen Delgado Votaw  
Senior Vice President, Public Policy  
Alliance for Children and Families

Kathleen E. Buescher  
President and CEO  
Provident, Inc.

CMS-1512-PN-2230

**Submitter :** Mrs. Teresa Hatten  
**Organization :** Medical Center LLP  
**Category :** Physician

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2230-Attach-1.DOC

#2230

**MEDICAL CENTER L.L.P.  
908 HILLCREST PKWY.  
DUBLIN, GA 31021  
(478) 272-7411 OR FAX (478) 274-9809**

08/18/2006

**Centers for Medicare and Medicaid Services,  
Department of Health and Human Services,  
Attention CMS-1512-PN,**

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**I strongly disagree with this ruling. If these changes do come in to effect, our facility may no longer be able to offer this service to our patients. This ruling will negatively impact women's access to this important test at our and other facilities. Women's bone health is an important issue and should not be trivialized by inadequate reimbursement.**

**Thank you in advance for your reconsideration in this matter.**

**Sincerely,**

A handwritten signature in black ink, appearing to read "Teresa L. Hatten". The signature is fluid and cursive, with a large initial "T" and "H".

**Teresa L. Hatten, MD**

**Submitter :** Dr. JAMES SCULLY, JR., M.D.  
**Organization :** THE AMERICAN PSYCHIATRIC ASSOCIATION  
**Category :** Health Care Professional or Association

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

PLEASE SEE ATTACHED DOCUMENT FOR APA COMMENTS.

**Other Issues**

Other Issues

BUDGET NEUTRALITY & PRACTICE EXPENSE METHODOLOGY

CMS-1512-PN-2232-Attach-1.DOC



## American Psychiatric Association

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August 31, 2006

Mark B. McClellan, M.D., Ph.D., Administrator  
Centers for Medicare & Medicaid Services, Room C5-25-25  
Department of Health and Human Services  
CMS-1512-PN  
P.O. Box 8014  
Baltimore, MD 21244-8014

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

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 36,000 psychiatric physicians, appreciates the opportunity to submit these comments concerning the proposed notice, above. This was published in the Federal Register on June 29, 2006, with the title, "Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology."<sup>1</sup>

### **Other Issues- Budget Neutrality**

APA is concerned primarily with CMS' proposal in this notice to create a new "work adjuster" to the Medicare Physician Payment Schedule, effective for services performed on or after January 1, 2007, to ensure budget neutrality under the Omnibus Budget Reconciliation Act of 1989. CMS previously used the method of applying a "work adjuster" to physician work relative value units (RVUs) in order to gain budget neutrality but found that it did not work well. In fact, this caused problems sufficient to prompt CMS to reject this methodology entirely, take a different tack and apply this adjustment to the conversion factor, as of 1999. APA agrees with this revised approach. As CMS admitted:

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<sup>1</sup> CMS Rule: "Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology.," CMS-1512-PN [Federal Register, June 29, 2006 (Volume 71, No. 125)].

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).

APA urges CMS to apply any necessary adjustments to the conversion factor, rather than to physician work relative value units (RVUs). The American Medical Association (AMA) Specialty Society Relative Value Update Committee (RUC) argues that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward and strongly urges CMS to instead apply any necessary adjustments to the conversion factor.

Physicians need to be fairly compensated for time spent and equipment required to deal with the requirements of new federal programs, such as Part D drug plans; electronic prescribing;<sup>2</sup> the “Pay for Performance” demonstration project<sup>3</sup> and the Part B Competitive Acquisition Program (CAP).<sup>4</sup> None of these aspects of physician reimbursement were covered by prior data for physician work RVUs or office expenses because they could not have been anticipated. Elements of compensation must cover physician time with patients; physician time spent handling administrative issues with external parties, such as pharmacies in Part D; staff time spent with patients and third parties; and office equipment, such as computer systems.

As CMS notes in the proposed notice, “(t)he main purpose of the 5-Year Review is to identify those services that need to be revalued because the work involved in performing the service has changed.” Since the federal government mandates that physicians allot time in their practices to facilitate these federal programs, it is fair to compensate them for that time allotment. Otherwise, physicians will further feel that there are disincentives to their continued participation in Medicare.

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<sup>2</sup> CMS Proposed Rule: “Medicare Program; E-Prescribing and the Prescription Drug Program;” CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23)].

<sup>3</sup> “CMS Demonstrations Projects under the Medicare Modernization Act (MMA) as of January 25, 2005 Section 649 -- Medicare Care Management Performance Demonstration: The Secretary is required to conduct a three-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance, however total payments must be budget neutral.” Retrieved September 26, 2005: <http://www.cms.hhs.gov/researchers/demos/MMAdemolist.asp>

<sup>4</sup> CMS Proposed Rule: “Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;” CMS-1325-IFC [Federal Register: July 6, 2005 (Volume 70, No. 42)].

As APA pointed out in its prior comments to CMS' proposed rule for revisions to the 2006 physician fee schedule.<sup>5</sup>

APA is highly concerned about the restrictive economic context in which physicians, including psychiatrists, find themselves at present. Effective January 1, 2006, multiple, administratively burdensome Medicare programs will require physician compliance: Part D drug plans; electronic prescribing;<sup>6</sup> "Pay for Performance" with an upcoming three-year, budget-neutral demonstration project<sup>7</sup> and the Part B Competitive Acquisition Program (CAP).<sup>8</sup>

All of these administrative burdens upon physicians' practices must be fairly considered and compensated within any proposed physician fee schedules. To the contrary, CMS projects that physicians will have to endure negative updates, instead of increases, under the Sustainable Growth Rate (SGR) system for future years, starting in 2006.<sup>9</sup>

The inescapable result of starkly diminishing Medicare payments to physicians, especially as their other administrative tasks become more burdensome, is to financially discourage them from taking new Medicare patients or keeping existing ones. APA is highly concerned that the Medicare system cannot continue with its complexity of disincentives for physician participation and still ensure that beneficiary-patients receive access to health care.

While APA commends CMS's efforts to update RVUs to provide more accurate, data-driven physician payments, several aspects of this process would benefit from further attention. One is to more comprehensively compensate physicians for their practice expenses by including the cost of typical, major office equipment in practice expense (PE) RVUs. CMS should create RVUs that more accurately reflect current

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<sup>5</sup> APA's comments filed September 30, 2005, to CMS' Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)].

<sup>6</sup> CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23)].

<sup>7</sup> "CMS Demonstrations Projects under the Medicare Modernization Act (MMA) as of January 25, 2005 Section 649 -- Medicare Care Management Performance Demonstration: The Secretary is required to conduct a three-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance, however total payments must be budget neutral." Retrieved September 26, 2005: <http://www.cms.hhs.gov/researchers/demos/MMAdemolist.asp>

<sup>8</sup> CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-IFC [Federal Register: July 6, 2005 (Volume 70, No. 42)].

<sup>9</sup> CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45856.

resource usage through timely data. Another is to update underlying data for malpractice RVUs and to revise the attendant risk factor for non-physician psychological practitioners. . .

### **Practice Expense Methodology**

In regard to the proposed revision to the practice expense methodology, APA commends CMS' interest in ensuring that the practice expense portion of the physician fee schedule reflects the relative resources required for the services provided. APA encourages CMS to work with the AMA and medical specialty societies to help fund and support the proposed multi-specialty practice expense survey. This coordinated effort would provide a mechanism to collect contemporary data that is reliable and consistent in scope across all specialties. Data from this survey can then be used for practice expense RVUs for all services.

### **CONCLUSION**

APA commends CMS for continuing to facilitate collection of contemporary data on physician work relative value units (RVUs), including through medical specialty society surveys geared toward specialty-specific data. This will prove very helpful for RUC to determine appropriate physician compensation parameters for the purpose of this 5-year review and those performed in the future. APA urges CMS to continue to update its databanks relevant to physician compensation, through specialty society surveys and other reliable data-collection instruments. This activity should include gathering new data applicable to time and equipment expenditures necessary for physicians and their staff to deal with the current demands of federal governmental programs, along with appropriate extrapolations for the anticipated ongoing demands of these programs.<sup>10</sup>

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<sup>10</sup> APA's comments filed September 30, 2005, to CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], pgs. 3-4:

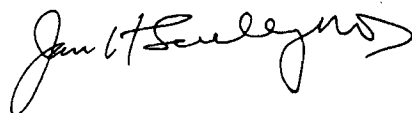
#### **"Practice Expense RVUs (PE RVUs)**

Practice expense (PE) RVUs were developed to take into account office rent and personnel wages (but not malpractice insurance). These were phased in from 1999-2002.<sup>10</sup> During the phase-in of PE RVUs, malpractice RVUs to cover the cost of professional liability insurance premiums were developed to apply to physician services provided in 2000 and thereafter.<sup>10</sup>

Of the six direct and indirect cost categories for calculating practice expense (PE) RVUs, none comprises commonly used office equipment, apart from the telephone, which is included within the indirect cost category of "office expenses."<sup>10</sup> Since most psychiatrists do not use medical equipment in their practices, as other physicians do, the type of office equipment they require for their practices may be only non-medical equipment.

For psychiatrists, especially those in solo or small group practices, common office equipment, such as computers, printers, scanners, shredders, answering machines, copy machines and fax machines, constitutes a substantial financial outlay which is not reimbursed through the

Thank you for your consideration of these comments.



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current definitions for PE RVU categories. It is neither fair, nor reasonable, to continue to exclude typical office equipment expenses from PE RVU calculations. This is especially so, since CMS is encouraging physicians to become computerized for the first time or to expand existing computer and electronic communication infrastructures. Without implementing physician incentives to invest in electronic office equipment required for federal programs such as electronic prescribing and Pay for Performance data gathering, CMS' goals are less likely to be reached.

***Recommendation- Update PE RVUs and Include Typical Office Equipment:*** APA encourages CMS to continue with its process of updating PE RVUs based on current supporting data, including that from the Practice Expense Advisory Committee (PEAC). As part of this updating process, APA strongly urges CMS to include typical office equipment used by physicians within the category of office expenses. This would include not just phones but computers, printers, scanners, shredders, answering machines, copy machines and fax machines. All of these require a substantial financial outlay which is not taken into account and remains unreimbursed, under current PE RVU categories.

Making this change will more fairly reimburse physicians, especially psychiatrists, whose primary office equipment does not fall into the category of medical equipment. This will also confer the added incentive for physicians to purchase the electronic computer and communications equipment necessary for full participation in various federal programs. In addition, it would prove useful for CMS to provide the underlying data for the PE RVUs to be revised under the proposed rule.