Submitter : **Dr. Donald Quest** **Date: 08/21/2006**

Organization : **American Association of Neurological Surgeons**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Also note, the comment letter previously submitted regrettably was an unfinished draft that had several typos. The Temporary Comment Number for the first draft submitted was 90476. This is the correeted and final version.

CMS-1512-PN-2233-Attach-1.DOC

#2233

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President
RICHARD G. ELLENBOGEN, MD
University of Washington
Seattle, Washington

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, Maryland 21244-8014

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

Dear Dr. McClellan:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing over 4,000 neurosurgeons in the United States, appreciate the opportunity to comment on the above referenced Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on June 29, 2006.

The subjects on which we are commenting include:

- **Spine and Aneurysm Code Values**. The AANS and the CNS object to CMS's proposal not to increase the work values for two spine procedures, CPT Codes 22612 and 63048. We support the values which were recommended by the American Medical Association (AMA) Relative Value Update Committee (RUC). We urge CMS to accept the RUC recommended work values of 22.00 for CPT Code 22612 and 3.55 for CPT Code 63048 In addition, we disagree with the values for three aneurysm procedures, CPT codes 61697, 61700, and 61702, based on the fact that the post operative work for these codes has not been fully acknowledged and incorporated.

- **Budget Neutrality Adjustment.** The AANS and CNS believe that a budget neutrality adjustment to account for the changes in work should be made to the conversion factor and not to the work relative values, as CMS has proposed.

- **Resource-Based Practice Expense RVUs**. The AANS and CNS request that CMS delay acceptance of supplemental practice expense data until such time as a new practice expense survey of all physician specialties can be completed.

- **Publication of RUC-recommended work values for all CPT Codes**. The AANS and CNS request that CMS publish the RUC-recommended values in the Medicare Fee Schedule, whether or not the service is covered by Medicare.

WASHINGTON OFFICE
KATIE O. ORRICO, *Director*
725 Fifteenth Street, NW, Suite 800 Washington, DC 20005
Phone: 202-628-2072 Fax: 202-628-5264 E-mail: korrico@neurosurgery.org

DISCUSSION OF COMMENTS—GYNECOLOGY, UROLOGY, PAIN MEDICINE, AND NEUROSURGERY (FR p. 37202-03; Section II. B. 3. a. and e.)

Spine Surgery -- CPT Codes 22612 and 22648

As part of the five year review, CMS requested a reevaluation of the work values for seven spine procedure codes: CPT code 22520 *Percutaneous vertebroplasty*; CPT code 22554 *Arthrodesis anterior interbody technique*; CPT code 22612 *Arthrodesis, posterior or posterolateral technique*; CPT code 22840 *Posterior non-segmental instrumentation*; CPT code 63047 *Laminectomy, facetectomy and foraminotomy*; CPT code 63048 *Laminectomy, facetectomy and foraminotomy additional segment*; and 63075 *Diskectomy, anterior.* On page 37202 and 37203 of the Notice of Proposed Rulemaking (NPRM), CMS provides a discussion of the alternative survey methodology utilized by the specialty societies conducting RUC surveys for these codes. CMS choose to accept the RUC recommended values for codes 22520, 22554, 22840, 63047 and 63075. However, CMS rejected the RUC-passed values for CPT Codes 22612 and 63048. We believe that CMS misinterpreted the data we presented in support of our recommended values for these codes, which were accepted by the workgroup and the full RUC without revisions. We appreciate the opportunity to further clarify both the survey methodology and the data derived through our survey, as we believe the values passed by the RUC are correct and therefore urge CMS to accept the RUC-passed values.

As the rule notes on page 37202, the RUC recommended an increase in the relative work value (RVW) for CPT code 22612 from 20.97 to 22.00. A value of 22.00 was the survey's 25th percentile value, and as the NPRM notes, the survey process yielded well over 100 responses (208 responses total) which increases the validity and reliability of the data that were presented. As part of the rationale for rejecting this value, CMS states that the workgroup's recommendation was based largely on a typographical error that listed the primary reference code, CPT code 22595, as having a work value of 23.36.

Although we acknowledge that this value was not the CMS published value, it does actually reflect the value given by the survey respondents for this reference code. The survey respondents were not given the work values for either code in the survey. Consequently, the survey respondents were unaware that they gave a value for 22595 that was higher than the CMS published value, reflecting their assessment that the work value has in fact increased for both 22612 and 22595. However, since only 22612 was brought forth by CMS, we could not additionally bring forth 22595 for reconsideration. We anticipate bringing forth this code in the next five year review process. Perhaps it would have been clearer if both the CMS value and surveyed value for 22595 were noted in the RUC Summary of Recommendation form. The Five Year Review Workgroup required the survey of a comparable code that was not included in the five year review process as a reference code. The workgroup used the reference code to assess validity of the mini-survey process, but did not base its work value recommendation on the reference code itself. Instead, the workgroup based its recommendation on the validity of the survey data and the building block methodology presented in the additional rationale section of the Summary of Recommendation form. Our additional rationale explained the results from our survey in detail because our survey methodology was a variation of the standard RUC survey instrument. The workgroup was able to understand that the survey respondents based their decisions on a comparison of the work currently involved in a spinal fusion and the work involved in a spinal fusion five years ago. Furthermore, as CMS noted, a value of 22.00 was the 25th percentile value from the survey results and not the median value. Our expert panel believed that 22.00 was an appropriate value for 22612 and that it maintained appropriate rank order with not only 22595 but other, equally comparable codes from the family of spinal fusion codes.

In changing the recommended value for CPT code 63048 from 3.55 to 3.26, we also believe that CMS misinterpreted our survey and presentation process. Again, we appreciate the opportunity to clarify

this process for CMS. CMS states on page 37203 of the NPRM, that no information is given that compares the respondents' estimates of complexity and intensity between CPT code 63048 and the reference code because the summary of recommendation form did not list a reference code. Based upon the RUC-approved requirements for the mini-survey, only two reference codes were requested for the entire group of codes surveyed, and were to be used as a validation of the mini-survey process. For the code 63048, our respondents compared the complexity and intensity currently involved in the work of 63048 with the complexity and intensity involved in the work of 63048 five years ago. Just as we did in our summary of recommendation forms for the other six codes, we outlined this process in the additional rationale section of the form and also clarified that a value of 3.55 was very near the 25th percentile value from our survey results. Therefore, we believe that a value of 3.55 as a measurement of the current level of complexity and intensity is an appropriate comparison to the complexity and intensity of performing the work involved in 63048 five or more years ago.

As a final point, we would like to emphasize that the same methodology and the same summary of recommendation forms used for CPT codes 22612 and 63048, for which CMS rejected the RUC recommended values, were also used for the five spine procedure codes, for which CMS accepted the RUC recommended values. We believe that by accepting the RUC–passed values for the five other spine codes, CMS has demonstrated sufficient confidence in the methodology of the survey and the presentation of the results. CMS is inconsistent to claim that a reference code work value "error", which actually represented the survey respondents work value estimate of the reference code as required by the Five Year Review Workgroup, should result in a rejection of two codes for which the RUC recommended an increase, but not be relevant to the five codes for which the RUC recommended no change or a decrease. Since the respondents were not given work values for any of the codes (survey or reference), there could be no influence of these values upon the survey respondents, as these were obtained after the survey was completed. Given that CMS accepted the work value recommendations for the three procedures that the RUC recommended a decrease in the existing work RVUs (CPT Codes 22554, 63047, and 63075) and the two procedures that the RUC recommended no change (CPT Codes 22520 and 22840) based upon the RUC-accepted mini-survey methodology, we believe CMS must also accept the RUC-passed values for CPT Codes 22612 and 63048.

Aneurysm Procedures – CPT Codes 61697, 61700, and 61702

During the five year review workgroup meeting, the AANS and the CNS had concerns about the changes in post service evaluation and management (E/M) work recommended by the workgroup for three cerebral aneurysms procedures. Last September, we asked that CPT Codes 61697, 61700, and 61702 be extracted from the workgroup's recommendations and be considered by the full RUC. The concerns regarding all three codes were essentially the same: that the post service E/M work was not adequately accounted for in the work values assigned to the codes by the workgroup. We did not request that CPT code 61698 (which is within the same family of codes) be extracted because we agreed with the workgroup's recommended changes to the work RVU as well as the pre and post service time and visits.

The workgroup recommended "changes to standardize the pre-service and post-service times" and the work associated with these changes was taken out of the AANS/CNS recommended RVW. We do not agree that 60 minutes of pre-service evaluation is the "standard" for a complex neurosurgical procedure. Our survey indicated that the preservice evaluation time is typically 90-120 minutes. Some members of the workgroup felt that due to the urgent nature of the typical patients receiving these procedures, part of the pre-service evaluation would be a separately billable E/M service. We disagreed with this assertion and therefore asked that the RUC database rationale note that the

preservice times were reduced because some of the surveyed time was thought to be captured in a separately billable E/M service with the appropriate modifier. However, this underestimates the preservice time for treatment of unruptured aneurysms, which are also described using these codes. Based upon the previously Practice Expense Advisory Committee (PEAC)-approved pre-service times for neurosurgical procedures, these codes would be allocated 75 minutes of preservice time when treatment entails management of an unruptured aneurysm. Current advances in endovascular treatment of ruptured aneurysms now requires a more extensive and complicated discussion and comparison of the risks and benefits of endovascular treatment versus craniotomy treatment of ruptured aneurysms. Moreover, an interdisciplinary discussion among an interventional neuroradiologist and neurosurgeon typically occurs. Consequently, even if a separately-identifiable E/M service is billed, the complex nature of this disease process and its management clearly warrants the 75 minutes of preservice time allocated by the PEAC for complex neurosurgical procedures. This is supported by the survey respondents who reported even longer preservice times.

The workgroup also recommended adjustments to the level and number of postoperative visits. The discussion regarding the post-op visits, and the subsequent adjustments to those visits, centered on the delivery of Critical Care (CPT code 99291) in the post-operative period. It was our understanding that the workgroup did not believe that the visits met the criteria for Critical Care Services. The typical patient as described in the vignettes for these codes has suffered a subarachnoid hemorrhage and is critically ill with acute impairment of the central nervous system. In such circumstances many of these patients will require critical care services that would be appropriately described by CPT code 99291. This is reflected in the RUC database when these codes were previously surveyed in 1995. However, we realize that not all patients will require this level of service and we were therefore willing to accept the workgroup's recommendations to change the post-operative 99291 visits to subsequent hospital care visits, as long as the physician time remains accounted for in the subsequent hospital care codes. We disagreed with the methodology that was used to accomplish this, however. For codes 61697, 61700 and 61702, each post-op 99291 visit was changed to a single 99233 visit. The RUC acknowledged that a prolonged service code could be a method to account for the additional time beyond that reflected in the highest value subsequent hospital visit code. However, the RUC was unable to resolve how to include 2 E/M service codes for the same day. Acceptance of a single 99233 significantly understates the post-operative time and intensity of the work that was described by our survey respondents.

CPT code 99291 is a time-based code that accounts for the delivery of critical care services for a duration of 30 to 74 minutes over a twenty-four hour period. The critical care services may be delivered over any number of visits to the patient on that day. We believe that typically these patients are seen more than one time each day in the early post-op period. Survey respondents chose 99291 on the basis of the critical care services provided as well as the total time of multiple visits to the patient over a 24-hour period. This assumption is supported by the fact that most of the survey respondents who did not choose 99291 as the level of visit on the first post-operative day chose two subsequent hospital care visits to account for the total E/M service delivered in that 24 hour period. The survey instructions clearly state that a patient can have more than one E/M visit in a single 24 hour period and our survey responses demonstrate that this was typical in these patients in the first post-operative days.

We agreed to the workgroup's assertion that the post-op visits reported as 99291 may not reflect the *intensity* of critical care in all patients. However, in order to account for the *time* spent with these very ill patients, we believe that the surrogate to the critical care service is accurately described by **two** 99233 visits, thereby reflecting a lesser intensity but appropriate duration of care given to these patients in the 24-hour period covered by the 99291 code.

The AANS and CNS asked the full RUC to adjust the work RVUs for CPT codes 61697, 61700 and 61702 to account for the time and work of an additional CPT code 99233 in the early postoperative period for these codes.

The full RUC discussed the issue for over an hour and generally seemed to acknowledge that the surveys showed that a significant amount of time is spent with these critically ill patients in the post operative period and that there was work performed that was not captured in the codes. However, the RUC had difficulty determining how to assign evaluation and management code proxies to this work and therefore the full RUC did not agree to change the workgroup's recommendation.

The RUC has struggled with the issue of the appropriate methodology to account for the post-operative work performed by surgeons for critically ill patients. Despite the difficulty in finding a perfect E/M proxy to account for this work, we believe it is essential to value the work as closely as possible. Therefore, we urge CMS to adjust the work RVUs for CPT codes 61697, 61700 and 61702 by adding the time and RVW of an additional CPT code 99233 to these codes. The RUC database lists the median intraservice time for 99233 as 35 minutes and the RVW as 1.51 and therefore these values should be added to the RUC-approved (and CMS proposed) values for each of these codes.

OTHER ISSUES (FR p. 37241; Section II. C. 4.)

Budget Neutrality

The AANS and CNS strongly recommend that CMS account for any necessary budget neutrality adjustments in the conversion factor, rather than applying the neutrality adjuster to the relative value units. We, along with the AMA, RUC, and many other medical societies, have held this position since the inception of the Medicare Fee Schedule and have reiterated it in our past comments to CMS (and its predecessor agency, the Health Care Financing Administration). Pursuant to these recommendations, CMS has historically made the budget neutrality adjustments to the conversion factor. By making budget neutrality adjustments to the relative value units, CMS is essentially negating the RUC and practice expense processes that objectively measured the relative values of all the procedures in the Medicare Fee Schedule. Once these values are recommended by the RUC and accepted by CMS, it is inappropriate to reduce the RVUs for budget neutrality purposes. The purpose of the conversion factor is to allow for budgetary adjustments so as to preserve the measured value of the RVUs themselves.

Furthermore, applying a neutrality factor to the RVUs is not transparent and hides the real impact of the budget neutrality adjustments. While the reduction in the conversion factor may be steep to account for budget neutrality limits, we believe that physicians and policymakers must be fully aware and capable of readily identifying such reductions. Congress must fully understand and appreciate that not only are physicians facing a 5.1 percent cut in reimbursement due to the flawed SGR formula, but that significant reductions due to the adjustments in work and practice expense RVUs loom large as well. The only real way to fully appreciate these facts is to make the budget neutrality adjustments to the conversion factor.

PRACTICE EXPENSE (FR p. 37241-52; Section II. D. 2. b.)

Supplemental Practice Expense Survey Data

The AANS and CNS request that CMS delay acceptance of supplemental practice expense data until such time as a new practice expense survey of all physician specialties can be completed. While we agree that Medicare's practice expense payment system, which accounts for nearly 45 percent of

reimbursement under the Medicare physician fee schedule, should be based on accurate data, we believe that a delay is justified for a number of reasons.

The validity of the supplemental survey data is questionable. We find it hard to believe that over the past several years practice costs have risen so dramatically for the specialties that submitted this survey data (e.g., radiology and radiation oncology have had their practice expense per hour rates increased by approximately 200%). In addition, the surveys' response rates were fairly low; the highest of which was only 27 percent. The Medicare Payment Advisory Commission (MedPAC), in its June 2006 report to Congress, raised concerns about this problem as well.

Even assuming that the supplemental survey's produced valid data, it is inequitable to accept more recent data from only a few specialties, while the majority of physicians will continue to be reimbursed based on data that was collected in 1999. The vast differences between the practice expense per hour rates for those specialties that have conducted new surveys versus those that have not clearly demonstrates that the data are "apples and oranges", calling into question the fairness of the proposed reimbursement rates. As MedPAC noted in its June 2006 report:

> Using more current information from some but not all specialties could cause significant distortions in relative PE payments across services. When CMS uses supplemental submissions, a redistribution of PE RVUs occurs because it generally implements the changes in a budget neutral manner...As a result, once CMS uses specialties' supplemental data, PE payments for services primarily furnished by them could increase while payments for services furnished by other specialties could decrease.

We realize that CMS wants to use the supplemental survey data, but because of budget neutrality it is simply unreasonable for CMS to base practice expense reimbursement for these specialties on new data, while the other specialties are reimbursed based on the original survey data.

Finally, as CMS is aware, the AMA is currently moving forward with designing and conducting a multi-specialty practice expense survey that will provide updated data for *all* specialties, not just the few that submitted supplemental survey data. The AANS and CNS, and many more specialty societies have committed to help fund this initiative and we understand that CMS is entirely supportive of this effort. We hope that such new data will be available to incorporate into the fee schedule in 2008 or 2009 at the latest. Therefore, CMS should wait until this survey is completed so all specialties can have their practice expense reimbursement based on a uniform set of updated practice expense data.

ADDENDUM B (FR p. 37258-37423)

Publication of RUC-Recommended Work Values for all CPT Codes

The AANS and CNS request that CMS publish the RUC-recommended values in the Medicare Fee Schedule (MFS), whether or not the service is covered by Medicare. The rigorous process of the RUC has led third-party payers to use the MFS when establishing their own fee schedules. Therefore, while Medicare may not cover a particular service, it is crucial that CMS publish the values of all services for which the RUC has made RVU recommendations so as to facilitate the dissemination of relative value information to all physicians and payers who use the RVU system. This issue has been discussed by the Practicing Physicians Advisory Council (PPAC), which supports our request. Five codes for intracranial stenting or balloon angioplasty (61630, 61635, 61640, 61641, and 61642) have been valued by the RUC, but despite working through PPAC with CMS representatives, Dr. Rogers and Mr. Bennett, values are only listed for 61630 and 61635. We are grateful for the efforts and support shown by Dr. Rogers and Mr. Bennett in recommending that CMS

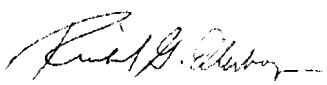
publish these values and urge the agency follow this recommendation and publish the RVUs of all RUC valued services in the final 2007 MFS.

CONCLUSION

The AANS and CNS appreciate the enormity of work performed by CMS staff for the five year review of the Medicare physician fee schedule. Nevertheless, we disagree with CMS' conclusion that an "error" in the summary of recommendations form resulted in misvaluation by the RUC. The reference codes were surveyed as required by the RUC for the mini-survey methodology. The same validity applied to codes that received recommendations for decreases or no change by the RUC and accepted by CMS should apply to those codes (22612 and 63048) for which increases were recommended. In addition, we urge CMS to review the assessment of E/M work in the three cerebral aneurysm codes described above. We also disagree with CMS's proposal to apply a budget neutrality factor to the RVUs, and join the AMA, the American College of Surgeons, and other medical specialty societies in recommending that budget neutrality adjustments for five year review changes be made to the conversion factor. The agency should also delay acceptance of any supplemental practice expense survey data, until a new multi-specialty survey of all physicians is completed. Finally, the AANS and CNS request that CMS publish the RUC-recommended values in the fee schedule, whether or not the service is covered by Medicare, to assist other payers who use the RVU system.

Thank you for the opportunity to comment on these important issues.

Sincerely,



Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
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Submitter : **Ms. Barbara Lifton** **Date: 08/21/2006**

Organization : **New York State Assembly**

Category : **State Government**

Issue Areas/Comments

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

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

Re: proposed cuts for CAD for mammography and DXA bone density scans.

As a Member of the New York State Assembly and Chair of the Assembly Task Force on Women's Issues, I urge the modification or elimination of these cuts. The New York State Legislature has worked hard to create and fund prevention programs for breast cancer and osteoporosis that stress the value of early diagnosis. The proposed cuts are directly at odds with public health messages encouraging women to get screened, and are likely to restrict access to tests that are critical to women's health.

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2234-Attach-1.DOC

CMS-1512-PN-2234-Attach-2.DOC

ATTACHMENT 1 TO # 2234

ASSEMBLY

STATE OF NEW YORK

Albany, New York

Barbara Lifton
Member of Assembly
125th District

Chair
Legislative Task Force on Women's Issues

August 21, 2006

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

Dear Dr. McClellan,

As Chair of the New York State Assembly Task Force on Women's Issues, I wish to express my concern about your cuts to reimbursement for Computer Assisted Detection (CAD) for mammography, and for DXA scans for osteoporosis, as proposed in CMS 1512-PN – *Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology.*

The New York State Legislature has worked hard to create and fund prevention programs for breast cancer and osteoporosis that stress the value of early diagnosis. The proposed cuts are directly at odds with public health messages encouraging women to get screened, and are likely to restrict access to tests that are critical to women's health. I urge you to modify or eliminate the reductions in reimbursement.

Sincerely,

Barbara S. Lifton

Hon. Barbara S. Lifton, Chair,
New York State Assembly Task Force on Women's Issues

CC: Hon. Vivian Cook, Assembly Task Force on Women's Issues
Hon. Sam Hoyt, Assembly Task Force on Women's Issues

ALBANY OFFICE: Rm. 555, Legislative Office Building, Albany, NY 12248 (518) 455-5444
DISTRICT OFFICE: 106 E. Court St., Ithaca, NY 14850 (607) 277-8030

Hon. Rhoda S. Jacobs, Assembly Task Force on Women's Issues
Hon. Catherine T. Nolan, Assembly Task Force on Women's Issues
Hon. Susan V. John, Member of Assembly
Hon. Richard N. Gottfried, Chair, Assembly Committee on Health
Hon. Aileen M. Gunther, Chair, Assembly Subcommittee on Women's Health
Hon. Patricia Eddington, Chair, Legislative Women's Caucus
Leslie R. Wolf, President, Center for Women Policy Studies

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ATTACHMENT 2 TO #2234

ASSEMBLY

STATE OF NEW YORK

Albany, New York

Barbara Lifton
Member of Assembly
125th District

Chair
Legislative Task Force on Women's Issues

August 21, 2006

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

Dear Dr. McClellan,

As Chair of the New York State Assembly Task Force on Women's Issues, I wish to express my concern about your cuts to reimbursement for Computer Assisted Detection (CAD) for mammography, and for DXA scans for osteoporosis, as proposed in CMS 1512-PN – *Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology.*

The New York State Legislature has worked hard to create and fund prevention programs for breast cancer and osteoporosis that stress the value of early diagnosis. The proposed cuts are directly at odds with public health messages encouraging women to get screened, and are likely to restrict access to tests that are critical to women's health. I urge you to modify or eliminate the reductions in reimbursement.

Sincerely,

Barbara S. Lifton

Hon. Barbara S. Lifton, Chair,
New York State Assembly Task Force on Women's Issues

CC: Hon. Vivian Cook, Assembly Task Force on Women's Issues
Hon. Sam Hoyt, Assembly Task Force on Women's Issues

Hon. Rhoda S. Jacobs, Assembly Task Force on Women's Issues
Hon. Catherine T. Nolan, Assembly Task Force on Women's Issues
Hon. Susan V. John, Member of Assembly
Hon. Richard N. Gottfried, Chair, Assembly Committee on Health
Hon. Aileen M. Gunther, Chair, Assembly Subcommittee on Women's Health
Hon. Patricia Eddington, Chair, Legislative Women's Caucus
Leslie R. Wolf, President, Center for Women Policy Studies

ALBANY OFFICE: Rm. 555, Legislative Office Building, Albany, NY 12248 (518) 455-5444
DISTRICT OFFICE: 106 E. Court St., Ithaca, NY 14850 (607) 277-8030

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

Organization : Medical Center LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attacnment

CMS-1512-PN-2235-Attach-1.DOC

#2235

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,

Mark J. Samson, MD

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

Organization : **Conceptus, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Practice Expense

Practice Expense

See attachment

CMS-1512-PN-2236-Attach-1.DOC

#2236

August 19, 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

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:

Conceptus, Inc. welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology proposed notice for calendar year 2007.

Founded in 1992, Conceptus (CPTS) is engaged in the design, development and marketing of innovative medical products for use in the field of women's health. Conceptus is currently focused on marketing its Essure® permanent birth control system. The Essure procedure is a non-incisional alternative to tubal ligation, which is the leading form of birth control worldwide.

Conceptus looks forward to working with CMS to address the concerns we have articulated below regarding the proposed change to a "bottom-up" practice expense methodology. We support CMS' three major goals for its resource-based PE methodology. However, we are concerned that elements of the methodology do not ensure that the PE portion of the Physician Fee Schedule (PFS) payments reflect, to the greatest extent possible, the relative resources required for each of the services on the PFS. Our comments and recommendations regarding this proposed notice are outlined and discussed below.

I. Summary

- Five-Year Review of Work Relative Value Units:

- 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.

- Proposed Changes to Practice Expense Methodology:

  - We recommend that prior to the implementation of the proposed "top-down" methodology that CMS meet with interested parties regarding those office-based procedures with supplies costing over $200 to discuss whether the use of the median versus the average direct PE percentage from the SMS and supplementary specialty survey data would allow for procedures with high cost supplies to not be "discounted" by greater than 30%. We are assuming that a median would not be so heavily weighted, as an average would be, to office visit codes.

  - We urge 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.

  - Everyone involved in facilitating health care to Medicare beneficiaries appreciates the efforts by CMS to create a more accurate, intuitive and stable Practice Expense (PE) methodology. One way that CMS can improve accuracy is if they demonstrate clearly and openly the PE/per hour figures for all specialties. Many groups believe that CMS has numerous mistakes in the PE per hour calculation to bring the entire PE per hour figures to the 2005 values. CMS needs to show for each PE per hour the increase in number for each year, rolling up to 2005.

II. Detailed Discussion

A. Five-Year Review of Work Relative Value Units

1. 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%	**0.31**
99212	Office/outpatient visit, est.	0.45	-33%	0.45	-51%	**0.61**
99213	Office/outpatient visit, est.	0.67	0%	0.92	0	**0.92**
99214	Office/outpatient visit, est.	1.10	64%	1.42	54%	**1.51**
99215	Office/outpatient visit, est.	1.77	164%	2.00	117%	**2.43**

- 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.

B. Practice Expense (PE)

1. Direct Costs PE RVUs – Budget Neutrality

One of CMS' three major goals for its proposed resource-based PE methodology is 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. We applaud this goal and believe that previous CMS statements regarding the concern that practice expense inputs be paid dollar for dollar what they cost a physician is also important and contribute to the creation of this goal. However, the methodology that CMS' has proposed with regard to the split between direct and indirect costs and then how those numbers are used to determine a budget neutrality adjustment for direct costs does not support CMS' goal and previous statements.

Instead, the proposed changes in practice expense methodology seeks to reallocate the split between direct and indirect practice expense costs based on the average direct PE percentage from the SMS and supplementary specialty survey data. The use of an average PE percentage is inherently unfair to those procedures within a specialty that have a high cost disposable or higher than average equipment costs. The use of an average PE percentage weights the split between direct and indirect costs towards office visit practice expenses, because these would be the majority, by volume of type of code billed, for any specialty. For example, hysteroscopy with fallopian tube cannulation procedures have significantly higher supply costs then many other office-based procedures thus a 33% direct costs versus 67% indirect, where it is more heavily weighted towards indirect costs, leaves inadequate dollars in the direct cost pool forcing a budget neutrality adjustment of higher than necessary portions to those procedure costs with high cost disposables.

CPT Code	Descriptor	Direct Costs	33% of 2010 PE Dollars	Difference	2010 Direct/Indirect Split if CMS Recognized all Direct Costs

58565	Hysteroscopy w/ fallopian tube cannulation	$1,148.35	$434.34	-$714.01	87% - Direct and 13% Indirect
99213	Office visit	$16.58	$9.50	-$7.08	58% - Direct and 42% Indirect

Given the bottom-up nature of the proposed methodology, starting with a sum of the costs of each direct input followed by a budget neutrality adjustment to the direct inputs of greater than 30%, it in effect is causing physicians to assume a 30% discount off the cost of the disposables, costs physicians have already incurred to perform the procedure. In the previous "top-down" methodology, there were only a few specialties that did not have a supply scaling factor of close to or greater than one. Thus the cost of the supplies to the physician was included in the PE calculation. Under this proposed methodology, physicians are forced to "pay" CMS a discount. CMS just recently updated the costs associated with all such supplies, particularly those costing $200 and over. Costs of disposable supplies in the CPEP database are accurate and well-documented.

Physicians will not be able to absorb the discounts assumed in the budget neutrality formula and subsequent adjustment on top of significant other reductions, such as the budget neutrality adjustments on work RVUs due to the 5 year review changes and the 5.1% reduction in the conversion factor that they are facing. Many procedures that are now safely and effectively being provided in a physician's office will likely migrate to other more costly settings. A shift of services back to a potentially inefficient setting does not seem to be a goal that Medicare would want to achieve.

Procedure code	Descriptor	2006 PE RVU	2007 PE RVU	Fully transitioned PE RVU	2007 % change	Fully transitioned % change
58565	Hysteroscopy w/ fallopian tube cannulation	49.7	45.85	34.73	-.7.72	-29.12
99213	Office visit	.69	.71	.76	2.89	10.14

We recommend that prior to the implementation of the proposed "top-down" methodology that CMS meet with interested parties

regarding those office-based procedures with supplies costing over $200 to discuss whether the use of the median versus the average direct PE percentage from the SMS and supplementary specialty survey data would allow for procedures with high cost supplies to not be "discounted" by greater than 30%. We are assuming that a median would not be so heavily weighted, as an average would be, to office visit codes.

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.

B. PE Per Hour

Everyone involved in facilitating health care to Medicare beneficiaries appreciates the efforts by CMS to create a more accurate, intuitive and stable Practice Expense (PE) methodology. One way that CMS can improve accuracy is if they demonstrate clearly and openly the PE/per hour figures for all specialties. Many groups believe that CMS has made numerous mistakes in the PE per hour calculation while bringing the entire PE per hour figures to the 2005 values. CMS needs to show for each PE per hour the increase in number for each year, rolling up to 2005. This needs to be corrected prior to the final rule and CMS needs to publish again and

ask for comments on these numbers. Given that the swings in dollars from one specialty to another could be significant this needs to be corrected so that the impact will be known.

Many groups are grappling to determine their specific information on their own. Since Medicare is the primary source of the most current data and understands better then anyone else the new methodology, it is important that they update and provide this important information as soon as possible. Providing this information will also help groups to determine if the impacts portrayed by CMS in Table 54 are appropriate since there is considerable speculation of errors. It will also go a long way in achieving CMS' expressed goal of increased accuracy.

Conceptus, Inc. appreciates your attention to our comments and would be pleased to provide additional information or discuss any of these issues in greater detail. Do not hesitate to contact me at 650-962-4051 or Mark_Sieczkarek@Conceptus.com or Carla Monacelli, our Senior Director for Healthcare Affairs at 651-436-3360 for additional information or to invite us to a meeting at CMS regarding high cost supplies, including implantable devices and disposables, and the impact of the proposed "bottom-up" practice expense methodology.

Sincerely,

Carla Monacelli
Senior Director, Healthcare Affairs
Conceptus, Inc.
331 East Evelyn Avenue
Mountain View, CA 94041

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

Organization : Medical Center LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2237-Attach-1.DOC

H2237

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,

Monty B. Shuman, MD

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

Organization : Medical Center LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2239-Attach-1.DOC

2239

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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Thank you in advance for your reconsideration in this matter.

Sincerely,

D Tate MD

David L. Tate, MD

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

Organization : NATIONAL ASSOCIATION OF PORTABLE X-RAY PROVIDERS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT"

CMS-1512-PN-2240-Attach-1.WPD

CMS-1512-PN-2240-Attach-2.WPD

CMS-1512-PN-2240-Attach-3.WPD

ATTACHMENT 1 TO # 2240

HALSEY, RAINS & ASSOCIATES, LLC
415 2ND STREET, NE
SUITE 100
WASHINGTON, DC 20002

August 21, 2006

Mark McClellan
Administrator
CMS
The Humphrey Building
200 Independence Avenue
Washington, DC 20515

Dear Administrator McClellan:

On behalf of the National Association of Portable X-Ray Providers (NAPXP), I am submitting formal comments to the notices proposing changes to the Medicare Physician Fee Schedule (MPFS) that is anticipated to improve accuracy of payments to physicians for the services furnished.

Under the proposed notice, the portable x-ray industry received an increase of 8% over a four-year period. The increase is appreciated, although overdue as our code has not received an appropriate update in over 14 years. Until we have the information regarding the zero work pool changes and the conversion factor for this schedule, we are unsure of the outcome.

We have worked over the last year and one-half with your staff on creating a new formula for evaluating the Q0092 code for set-up. We appreciate the time and effort spent by your staff in working with the industry and look forward to continued relations. Although, to date, the numbers and calculations for this industry have yet to be put into place as discussed.

We look forward to the final rule and our opportunity to comment at that time.

Thank you,

Steven C. Halsey
Partner

Cc: Bruce Cotti, President, NAPXP
Zach Evans, Chairman of the Board, NAPXP
Norman Goldhecht, Executive Director, NAPXP

ATTACHMENT 2 TO # 2246

HALSEY, RAINS & ASSOCIATES, LLC
415 2ND STREET, NE
SUITE 100
WASHINGTON, DC 20002

August 21, 2006

Mark McClellan
Administrator
CMS
The Humphrey Building
200 Independence Avenue
Washington, DC 20515

Dear Administrator McClellan:

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We look forward to the final rule and our opportunity to comment at that time.

Thank you,

Steven C. Halsey
Partner

Cc: Bruce Cotti, President, NAPXP
Zach Evans, Chairman of the Board, NAPXP
Norman Goldhecht, Executive Director, NAPXP

ATTACHMENT 3 TO # 2240

HALSEY, RAINS & ASSOCIATES, LLC
415 2ND STREET, NE
SUITE 100
WASHINGTON, DC 20002

August 21, 2006

Mark McClellan
Administrator
CMS
The Humphrey Building
200 Independence Avenue
Washington, DC 20515

Dear Administrator McClellan:

On behalf of the National Association of Portable X-Ray Providers (NAPXP), I am submitting formal comments to the notices proposing changes to the Medicare Physician Fee Schedule (MPFS) that is anticipated to improve accuracy of payments to physicians for the services furnished.

Under the proposed notice, the portable x-ray industry received an increase of 8% over a four-year period. The increase is appreciated, although overdue as our code has not received an appropriate update in over 14 years. Until we have the information regarding the zero work pool changes and the conversion factor for this schedule, we are unsure of the outcome.

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We look forward to the final rule and our opportunity to comment at that time.

Thank you,

Steven C. Halsey
Partner

Cc: Bruce Cotti, President, NAPXP
Zach Evans, Chairman of the Board, NAPXP
Norman Goldhecht, Executive Director, NAPXP

Submitter : Mrs. Sandra Souza **Date:** 08/21/2006

Organization : Medical Center LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2241-Attach-1.DOC

2241

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,

Sandra L. Souza, MD

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

Organization : AAPM, ABS, ACRO, ASTRO, AFROC, RBMA, SROA

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

The attached letter is a joint submittal by the American Assoc. of Physicists in Medicine, American Brachytherapy Society, American College of Radiation Oncology, American Society for Therapeutic Radiology and Oncology, Assoc. for Freestanding Radiation Oncology Centers, Radiology Business Management Assoc., and Society for Radiation Oncology Administrators

CMS-1512-PN-2242-Attach-1.PDF

2242

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:

The undersigned organizations are writing to you to urge that the Centers for Medicare and Medicaid Services (CMS) incorporate into its proposed practice expense methodology the radiation oncology practice expense per hour (PE/hr) revisions set forth in the report prepared by Direct Research (the "Direct Research Report") and submitted under separate cover by the Association for Freestanding Radiation Oncology Centers (AFROC).

The PE/hr for radiation oncology is determined differently from that of other specialties. In general, the PE/hr for other specialties is based on a single survey; however, in the case of radiation oncology, the Lewin Group recommended that CMS "blend" the PE/hr for hospital-based radiation oncologists from the survey conducted by the American Society for Therapeutic Radiology (ASTRO) and the PE/hr for radiation oncologists practicing in non-hospital settings from the survey conducted by AFROC. Based on its estimate of the proportion of hospital-based vs. non hospital-based radiation oncologists, The Lewin Group recommended that this data be "blended" in the proportion 75% (hospital-based)/25% (freestanding).

The Direct Research Report indicates that the 75/25 "blend" recommended by The Lewin Group is inaccurate. That Report indicates that the Lewin Group's methodology is flawed, and that the more accurate methodology for blending the AFROC and ASTRO survey results yields an uninflated PE/hr for radiation oncology of $213.07/hr, rather than $161.08, the uninflated PE/hr recommended in the Lewin Report. Even if the same methodology used by the Lewin Group is used, the more accurate "split" between hospital-based and non-hospital based radiation oncologists is 64/36 rather than 75/25, and use of this more accurate "split" results in an uninflated radiation oncology PE/hr of $205.19 rather than $161.08. We respectfully request that CMS modify the radiation oncology PE/hr in accordance with the findings of the Direct Research report when the final rule is published.

Please note that, in addition to this statement, each of the undersigned organizations is also submitting separate comments on other aspects of the proposed practice expense revisions. We hope that this letter is

helpful and look forward to working with CMS to address this and other important methodological and data issues as the practice expense revisions move forward over the next several years.

Respectfully submitted,

American Association of Physicists in Medicine
American Brachytherapy Society
American College of Radiation Oncology
American Society for Therapeutic Radiology and Oncology
Association for Freestanding Radiation Oncology Centers
Radiology Business Management Association
Society for Radiation Oncology Administrators

Radiation Oncology Centers: Analysis of Weights Used for Medicare Practice Expense Per Hour Calculation.

Final Report
May 4, 2006

Submitted to:
Association of Freestanding Radiation Oncology Centers (AFROC).
C/O Diane Millman
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye Street, N.W., 12th Floor
Washington, DC 20006-5409

Submitted by:
Christopher Hogan, Ph.D
President, Direct Research, LLC
506 Moorefield Rd, SW
Vienna, VA 22180

Executive Summary

The Centers for Medicare and Medicaid Services (CMS) relies in part on survey data when it sets practice expense relative values in its physician fee schedule. Surveys are used to show the average practice expense per hour of physician work, separately by physician specialty. When multiple surveys are available, CMS may take a weighted average of different survey data sources.

The Association of Freestanding Radiation Oncology Centers (AFROC) asked for an analysis of the weighting that was used by Lewin, Incorporated (and adopted by CMS) to generate an average practice expenses per hour for radiation oncology. The Lewin analysis combined practice expense for hospital-based and non-hospital based radiation oncologists, using two different practice expense surveys.

The choice of weights is important because hospital-based physicians have very low practice expenses. (Most of their expenses are paid by the hospital, not the physician.) Modest changes in the weight assigned to hospital-based physicians may have a significant impact on the estimated average practice expense per physician work hour.

I looked at this issue using two different approaches (percent of physicians, percent of physician time) and several years of data. My analysis consistently suggests that the Lewin study overstated the fraction of radiation oncology in hospital-based settings. Where Lewin assumed 75 percent of radiation oncologists were hospital-based, I found that 64 percent of radiation oncologists were hospital-based in 2004, and that 62 percent of radiation oncologists' time was in hospital-based settings (based on their Medicare fee-for-service bills and CMS' 2002 estimates of physician time per procedure). Re-weighting the Lewin-published data to reflect these proportions would raise average total practice expense for radiation oncology from roughly $161 per physician work hour to slightly more than $200 per physician work hour.

1) The Lewin Study.

The Lewin study referred to here is: Recommendations Regarding Supplemental Practice Expense Data Submitted for 2006, Evaluation of Survey Data for: Urology, Dermatology, Gastroenterology, Allergy/Immunology, Diagnostic Imaging Centers, Freestanding Radiation Oncology Centers", by Alan Dobson, Ph.D. et al., dated June 8, 2005.

For radiation oncology, the Lewin study ended their analysis by taking a 75%/25% weighted average of the practice expense per hour for hospital-based and non-hospital-based radiation oncologists. The Lewin weights were described as reflecting the *fraction of physicians* who were hospital-based and non-hospital-based, based on the majority of Medicare fee-for-service claims by site of care, for every unique provider identification number (UPIN).

1.1 Provisionally accept the Lewin method, re-examine the data on fraction of radiation oncology physicians who are hospital-based.

The first task was simply to count physicians, following the approach described briefly in the Lewin study. I did the following:

- Start with the 5 percent sample standard analytic file (SAF) physician supplier claims (limited data set version) for 2002 to 2004.
- Extract all claims for radiation oncology (CMS specialty code 92).
- Flag site of service as hospital-based using the site-of-service codes:
  - 21 hospital inpatient
  - 22 hospital outpatient
  - 23 hospital ER
- For the 2004 file, the count of claims lines showed that I did not miss any significant volume of claims by ignoring the more obscure sites of service that might be counted as inpatient (e.g., psychiatric facilities).
  - 44% were in office (site 11)
  - 35% were in hospital OPD (site 22)
  - 16% were in hospital inpatient (site 21)
  - 3% were in hospital ED (site 23)
  - 2% were in all other sites
- This claim line count should not be taken as indicative of the share of relevant services provided in these locations due to the presence of technical-component-only claims (discussed later).
- Summarize various measures of claims volume (claims, claims lines, units of service, allowed charges) by UPIN and site (hospital and non-hospital)
- Assign a UPIN as hospital-based if 50% or more of service volume was provided in the hospital setting.

Results from this analysis differ significantly from the Lewin analysis. Where Lewin identified 75 percent of UPINS as hospital-based, I found 66 percent (in 2002), with a slight downward trend from 2002 to 2004. By 2004, only 64 percent of the UPINs in the file, for specialty code 92 (radiation oncology), would be counted as hospital-based physicians.

Table 1: Hospital-Based Radiation Oncologists, Based on Site Where Majority of Medicare Services Were Provided

	Count of UPINSs			Percent of UPINs		
Data Year	Not hospital based	Hospital based	Total	Not hospital based	Hospital based	Total
2002	948	1808	2756	34%	66%	100%
2003	1003	1843	2846	35%	65%	100%
2004	1046	1897	2943	36%	64%	100%

Source: Analysis of Medicare 5 percent sample standard analytic file physician supplier file, LDS version, claims lines with CMS specialty code "92", radiation oncology.

This finding was robust to several alternative ways of measuring procedure volume. The percent of radiation oncologists who were hospital-based did not change more than 1 percentage point from the figures above, whether I:

- counted claims or lines or services;
- used all services or only those in the radiation oncology range (e.g, excluded office visits), or
- ignored bills for technical-component-only services.

The reason for this robustness is simple: the distribution was essentially bimodal: most physicians either did all hospital care or nearly all non-hospital care. For example, the median physician had 100% of services in the hospital. Further, this was not due to small numbers of claims. The median physician had 60 services in the 5 percent sample file.

The overall count of physicians is somewhat lower than might be expected based on other data sources. The Health Resources and Services Administration (HRSA), for example, counted just under 4,000 radiation oncologists in 2000, although the fraction involved in direct patient care was not cited (http://bhpr.hrsa.gov/healthworkforce-/reports/factbook02/FB202.htm). The 2003 UPIN registry showed about 4400 UPINs with specialty 92 (although roughly 30 percent also had a record showing radiology (specialty 30) for the same UPIN). Thus, the roughly 3,000 UPINs appearing on the 5 percent sample claims file is a modest undercount of the actual number of radiation oncologists, based on other sources. This is plausibly attributable to a number of factors, including physicians with multiple Medicare-registered specialties (so the UPIN registry may overcount this specialty), physicians not involved in active patient care or not treating Medicare fee-for-service patients (e.g., administrators, Permanente employees), presence of group UPINs (a single UPIN for a physician group), and similar factors.

My firm conclusion is that, by 2004, if we accept the method of using a weighted average based on counts of physicians, then we should be using 64 percent hospital-based and 34 percent non-hospital-based, in place of the Lewin study's 75%/25% blend.

1.2 A better methodology: time-weighted average.

An alternative method provides good corroboration for the estimates above. CMS is calculating a per-hour practice expense. Given that, if we must construct a weighted average of hospital-based and non-hospital-based practice expense data, it seems better to weight by the fraction of physician hours in those settings rather than the fraction of physicians.

To do that, I used the 2002 physician time data by CPT code, as posted by CMS with the 2002 practice expense revisions. There, the total physician time per procedure (MDTTIMRG) was provided for roughly 8,000 CPT and modifier combinations.

It is worth noting that the physician time for technical component services (-TC modifier, or radiation treatment delivery services that do not involve physician work) is zero. So this physician-time-weighted analysis properly drops the -TC bills and drops the treatment delivery codes (CPT 77401-77418) that involve no physician work. This

is reasonable to do because those codes (-TC and the CPT range 77401-77418) are billed in the carrier file only from non-hospital sites and will not appear in the carrier files billed from hospital-based sites.

Table 2 shows that the fraction of radiation oncologists' time attributable to hospital and non-hospital settings is nearly the same as the fraction of physicians found above. Using 2004 100% claims summary data, 62 percent of radiation oncologists' time was in hospital-based settings, based on the volume of services billed to Medicare by site of service.

Table 2: Share of Radiation Oncologists' Time Treating Medicare Patients, by Site of Service

Site	Total Services	Total Minutes	Percent of Minutes
Total	6,613,227	448,415,010	100%
Hospital	4,110,520	277,862,595	62%
Non-Hospital	2,502,707	170,552,415	38%

Source: Analysis of 2004 Medicare physician/supplier procedure summary master file data for specialty 92 (radiation oncology), matched to 2002 physician time data by CPT and modifier (as posted by CMS for the 2002 practice expense revisions).

1.3 Re-weighting the practice expense data.

The hospital/non-hospital fractions calculated above can be used to re-weight the practice expense data (Lewin study, page 50). Table 3 shows that the higher fraction of physicians or physician time allocated to non-hospital settings raises the weighted average practice expense significantly. I believe that weighting by hours of patient care is most nearly consistent with the underlying CMS methodology. Therefore, I believe that the figures in the rightmost column ($213.07 total) would be the correct weighted average to use in the CMS practice expense calculations, given this basic approach of taking a weighted average of the hospital and non-hospital values.

Table 3: Re-computing Weighted Average Practice Expenses

			Weighted Average		
	Hospital-based	Non-Hospital Based	Lewin Study	Using Table 1 Data, 2004 proportion of physicians	Using Table 2 data, 2004 proportion of physician time
Memo: Proportion hospital-based			0.75	0.64	0.62
Memo: Proportion non-hospital-based			0.25	0.36	0.38
Direct PE per hour					
Clinical Payroll	$ 9.93	$ 153.24	$ 45.47	$ 61.52	$ 64.39
Medical Equipment	$ 3.64	$ 91.04	$ 25.32	$ 35.10	$ 36.85
Medical Supplies	$ 1.56	$ 13.11	$ 4.42	$ 5.72	$ 5.95
Indirect PE Per Hour					
Office Expense	$ 19.31	$ 87.88	$ 36.32	$ 44.00	$ 45.37

Clerical Payroll	$ 12.04	$ 59.56	$ 23.82	$ 29.15	$ 30.10
Other Expense	$ 16.92	$ 52.43	$ 25.73	$ 29.70	$ 30.41
Total PE Per hour	$ 63.40	$ 457.26	$ 161.08	$ 205.19	$ 213.07

Source: Lewin study (cited in text), analysis of 2004 5 percent sample SAF data (Table 1, physician counts), and 2004 100% summary file data (Table 2, physician time).
Notes: The Lewin weighted average is as-published in the Lewin report, and appears to reflect slightly less than 75.0% in hospital-based settings.

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

Organization : **Hoffman La-Roche Inc.**

Category : **Drug Industry**

Issue Areas/Comments

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

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

Attached please find Hoffman La-Roche's comments on changes to Medicare reimbursement for dual-energy x-ray absorptiometry.

CMS-1512-PN-2243-Attach-1.DOC

#2243

Roche

August 21, 2006

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

Re: CMS-1512-PN; Comments to the Proposed Changes to the Practice Expense Methodology

To Whom It May Concern:

Hoffman-La Roche Inc. (Roche) respectfully submits these comments in response to the proposed notice regarding changes in the practice expense methodology published in the Federal Register on June 29, 2006 (71 FR 37170). These changes would significantly reduce Medicare reimbursement for the "gold standard" method for determining bone mass status required for the diagnosis of osteoporosis and osteopenia known as dual-energy x-ray absorptiometry (DXA). Roche is one of the leading manufacturers of pharmaceutical products in the United States with specific research and development interests in osteoporosis as well as marketed products for its treatment and prevention. Roche is committed to developing life-saving medications, as well as taking steps to treat and prevent the development of serious medical conditions such as osteoporosis. We appreciate the opportunity to comment on this issue, and we urge CMS to take action to ensure that patients have access to this "gold standard" of osteoporosis screening.

Despite the fact that the U.S. Surgeon General, the U.S. Preventive Services Task Force, and the National Osteoporosis Foundation all assert that that screening of individuals over the age of 65 is essential to the treatment and prevention of osteoporosis,[1] the recent proposed notice would drastically reduce payments to physicians conducting such screening exams for Medicare beneficiaries. Under the proposed CMS methodology, the practice expense portion of DXA reimbursement would be cut significantly over the next several years, with payments dropping an estimated 50 – 75% percent depending on the exam performed. This severe reduction in reimbursement clearly could threaten patient access to DXA technology in the physician office setting. Without appropriate reimbursement, physicians will be unable to purchase or maintain DXA equipment, leaving them unable to provide this important health care service to patients in need of osteoporosis screening.

[1] *The 2004 Surgeon General's Report on Bone Health and Osteoporosis* (October 2004); U.S. Preventive Services Task Force, AHRQ Publication No. APPIP02-0025, September 2002.

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Furthermore, CMS recently acknowledged the importance of the DXA technology in its proposed regulations for coverage of bone mass measurement services in the Proposed Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 released by CMS on August 8, 2006 (CMS-1321-P). In its discussion of various methods for measuring bone mass, CMS acknowledged that DXA "is precise, safe, and low in radiation exposure, and permits more accurate and reliable monitoring over time." Additionally, CMS noted that not only is DXA the superior method for determining bone mass, but that DXA of the femoral neck is the best validated test to predict hip fracture. In fact, under its proposed conditions for coverage for bone mass measurement procedures, CMS added a requirement that, in some cases, a medically necessary bone mass measurement may be covered for an individual only if the service is performed using the DXA method. As such, it seems inconsistent for CMS to propose significant reductions in payment for DXA services while acknowledging that it is the superior method for measuring bone mass and, in some cases, even requiring its use.

Osteoporosis ranks as one of the most serious conditions facing many Medicare beneficiaries today. The National Osteoporosis Foundation (NOF) reports that osteoporosis and osteopenia affect approximately 44 million men and women age 50 and over. Osteoporosis leads to approximately 1.5 million fractures a year – fractures that often result in much more serious medical conditions, including permanent disability, institutionalization and even death.[2] By 2020, one in two Americans over the age of 50 will have, or be at risk of developing, osteoporosis.[3] **The treatment of this disease places a significant burden on the health care system that will only increase as the population ages, and early screening and treatment are essential to stemming the cost of advanced osteoporosis and maintaining the health and quality of life for Medicare beneficiaries.**

Osteoporosis-related injuries not only jeopardize the health and independence of Medicare beneficiaries, but they also lead to significant health expenses. The 2004 Surgeon General's *Report on Bone Health and Osteoporosis* states that medical expenses for treating broken bones from osteoporosis are as high as $18 billion a year.[4] These expenses significantly impact the Medicare program as well, with one estimate reporting that Medicare pays for about 75% of hospital costs associated with osteoporosis-related admissions among adults age 45 and older.[5]

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[2] National Osteoporosis Foundation "Fast Facts," *available at* http://www.nof.org/osteoporosis/diseasefacts.htm.

[3] *The 2004 Surgeon General's Report on Bone Health and Osteoporosis* (October 2004).

[4] *The 2004 Surgeon General's Report on Bone Health and Osteoporosis* (October 2004).

[5] Testimony before the USP of the National Osteoporosis Foundation, the American Society for Bone and Mineral Research and the International Society for Clinical Densitometry, August 27, 2004, citing Max W, Sinnot P, Kao C, Sung HY, Ride DP. The burden of osteoporosis in California, 1998. Osteoporosis Int. 2002; 13(6): 493-500.

DXA bone density testing is the most accurate method available for the diagnosis of osteoporosis, detecting bone loss much earlier than conventional x-rays. Low-bone density is used to predict risk for fracture as well as to diagnose osteoporosis. Once detected, osteoporosis can be effectively treated or prevented by several means including appropriate proven pharmacologic intervention. In understanding the potential healthcare burden of undiagnosed and untreated osteoporosis in the US population, the NOF or Surgeon General's Report recommend the routine screening for osteoporosis.

Health care providers rely on DXA technology to treat and protect patients at risk for the development of osteoporosis and low bone density. We urge CMS to closely review and address the potential impact of the proposed DXA reimbursement policy. CMS should make any necessary revisions to ensure that physicians are appropriately reimbursed for DXA services and patients have access to the osteoporosis screening tools supported by current clinical guidelines.

Sincerely,

Lars E. Birgerson, MD, PhD
Vice President, Medical Affairs
Roche