

**Submitter :** Mrs. Pamela Lyle

**Date:** 08/21/2006

**Organization :** The Rose

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

CMS-1512-PN

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

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

Sincerely,

Pamela Lyle  
CFO, The Rose  
281-464-5121

**Submitter :** Dr. Samuel Masket  
**Organization :** Amer. Society of Cataract and Refractive Surgery  
**Category :** Health Care Professional or Association

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2200-Attach-1.PDF



OUTPATIENT OPHTHALMIC  
SURGERY SOCIETY, INC.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY  
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

August 21, 2006

Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
ATTN: CMS-1512-PN  
200 Independence Avenue  
Room 445-G  
Washington, DC 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 Dr. McClellan:

The American Society of Cataract and Refractive Surgery (ASCRS) represents over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of over 900 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

ASCRS and OOSS appreciate the opportunity to submit comments on the proposed rule for the five-year review of work relative value units and changes to the practice expense methodology.

**Five-Year Review of Work Relative Value Units**

***Application of the Increased E/M Work RVUs to the 10- and 90- Day Global Codes***

ASCRS and OOSS agree with the agency's proposal to apply the increased E/M work RVUs to E/M services included in the 10- and 90-day global period codes. We maintain that the E/M services performed in conjunction with a 10- and/or 90-day global services are not different from those that are performed distinctly. However, we are concerned that CMS may have used the discounted E/M work

RVUs, rather than the full E/M work RVUs. We urge the agency to ensure that it uses the full E/M work RVUs and not the budget-neutrality-adjusted E/M work RVUs for the 10- and 90-day global codes.

***Budget Neutrality Adjustment for Physician Work***

**ASCRS and OOSS strongly disagree with applying a budget-neutrality adjustment to the work RVUs. The societies urge CMS to preserve the integrity and relativity of the work RVUs and apply the budget neutrality adjustment to the 2007 conversion factor rather than to the work RVUs.**

As CMS explained in the proposed notice, the agency anticipates that budget-neutrality adjustments will be required as a result of significant changes in the RVUs resulting from the five-year refinement of work relative value units, as well as other fee schedule payment policy revisions that will be announced later this year. In addition, CMS explains that it considered two options for making the statutorily required budget-neutrality adjustments to account for the five-year review of physician work: 1) reducing all work RVUs by an estimated 10 % and 2) reducing the physician fee schedule conversion factor by an estimated 5%.

CMS further explains that the application of the budget-neutrality adjustment to the conversion factor would negatively impact all physician fee schedule services, whereas the application of the budget-neutrality adjustment to the work RVUs would affect only services that have physician work RVUs. Because the need for a budget neutrality adjustment is due largely to changes resulting from the five-year review, CMS believes it would be more equitable to apply the adjustment across services that have work RVUs and is thus proposing a budget-neutrality adjustor that would reduce all work RVUs by an estimated 10% to meet the budget-neutrality provisions of the Medicare law.

Again, ASCRS and OOSS strongly disagree with applying a budget-neutrality adjustment to the work RVUs and urge CMS to apply the budget neutrality adjustment to the 2007 conversion factor. The application of a budget neutrality work adjustor to the work RVUs is counterintuitive and halts the progress made by specialty societies, the RUC and CMS, who spent countless hours to develop accurate changes to work RVUs. In addition, the application of a budget-neutrality adjustor to the work RVUs goes against CMS' long-standing policy that adjustments to RVUs to maintain budget-neutrality are ineffective and cause confusion. It is for this reason CMS has been applying budget-neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

As you know, the vast majority of private payers use the Medicare fee schedule in their contracts with physicians, and physicians could be negatively affected if private payers used budget-neutrality-adjusted work RVUs. To maintain two separate work RVUs lists, one adjusted for budget neutrality and one not adjusted for budget neutrality, has great potential to generate needless confusion and administrative hassle.

We note CMS' rationale for proposing to reverse its long-held policy of applying budget neutrality adjustment to the work RVUs; however, we are confused as to why the agency would pursue this option when the agency has admitted that it causes problems and confusion.

Furthermore, CMS explains that it proposes to implement the work adjuster instead of applying budget neutrality adjustments to the conversion factor because it believes it is more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the five-year

**AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY**

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review. This rationale is not plausible because it assumes all work RVUs were involved in the five-year review. As you know, only 422 of the more than 7500 physician codes were involved in this past five-year review. However, many codes will be penalized simply because they have work RVUs. It would only make sense to apply budget-neutrality adjustments to the conversion factor since it is the only monetary factor in the formula.

**Therefore, ASCRS and OOSS, again, urge CMS to reconsider its proposal to make budget-neutrality adjustments to the work RVUs and encourage the agency to apply the budget-neutrality adjustments to the 2007 conversion factor.**

### **Practice Expense Methodology**

#### ***Use of Supplemental Survey Data***

As we noted in our comments last year, we have concerns regarding CMS' acceptance of supplemental survey data. First and foremost, we do not believe it is fair to base practice expense payments for some specialties on updated supplemental data while basing the practice expense payments of other specialties on outdated survey data. Second, the use of current practice expense data for some specialties and outdated practice expense data for others distorts the relativity of the payments. This concern has been raised in the past, most recently by the Medicare Payment Advisory Commission (MedPAC) in its June 2006 *Report to the Congress: Increasing the Value of Medicare*. Specifically, MedPAC states the following with regard to the use of updated supplemental survey data:

Relying on more current practice cost data submitted by some (but not all) specialties raises several issues. Supplemental submissions do not provide a recurring source of information for all specialties. Although the [Balanced Budget Refinement Act of 1998 (BBRA)] gave providers the option to submit more current information, they are not mandated to do so. Since the BBRA, few groups (16 out of more than 60 specialties) have submitted newer data. Groups informed the commission that collecting PE information is costly and time consuming, and that they do so only when it is likely to increase their payment rates.

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 change in a budget neutral manner...As a result, once CMS uses specialties' supplemental data, PE payment for services primarily furnished by them could increase while payments for services furnished by other specialties could decrease.

As you are aware, the medical community is working with the American Medical Association on a new practice expense survey effort. This new multi-specialty survey will provide all medical specialty societies an opportunity to participate and will assist in collecting updated, reliable, and consistent practice expense data that can be used in the PE RVUs for all services.

**Therefore, we urge CMS to postpone accepting any supplemental survey data until all specialties have had a fair opportunity to provide updated practice expense data.**

\* \* \* \* \*

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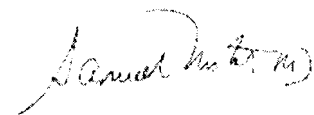
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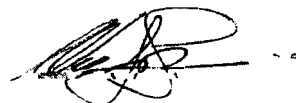
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ASCRS and OOSS look forward to working with CMS and encourage CMS to include the recommendations outlined above in the final rule. Should you have any further questions or comments, please contact Emily L. Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs, at 703-591-2220 or [egraham@ascrs.org](mailto:egraham@ascrs.org), or Michael A. Romansky, OOSS Legal Counsel, at [MRomansky@SHCare.net](mailto:MRomansky@SHCare.net) or 202-626-6872.

Sincerely,



Samuel Masket, MD  
President, ASCRS



William Fishkind, MD  
President, OOSS

**AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY**

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

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**Submitter :** Ms. Virginia McIntosh

**Date:** 08/21/2006

**Organization :** PA Society for Clinical Social Work

**Category :** Social Worker

**Issue Areas/Comments**

**Discussion of comments-HCPAC  
Codes**

**Discussion of comments-HCPAC Codes**

I am a Clinical Social Worker for over thirty years, having worked in one children's agency and two mental hospitals. I now have a private practice and teach occasionally at a Graduate School of Social Work. Social workers have provided mental health services for over 70 years and at one point provided over 60% of all mental health services in the USA. We have more experience and higher standards than any other master level professional. In addition, many clinical social workers have doctorate degrees, graduate supervised experience, and lots of advanced training, i.e., certificate programs, etc. We do this work because it is a very gratifying profession. But if fees are continually reduced, as they have been in the last 15 years, many of us will not be able to continue to support our offices and professional expenses (cost of license, continuing education <subst> expenses to keep abreast of changes in the field, office expenses, cost of billing for services, etc.). As it is, I know several social workers who left the field because they couldn't make enough money to support themselves &/or their families.

Therefore, I'm pleading with you to reconsider your proposal to cut reimbursement by 14%. Please do not reduce work values by 7% for clinical social workers. In addition, I respectfully request that CMS withdraw the proposed increase in evaluation and management codes until they have the funds to increase reimbursement for all Medicare providers. I also request that CMS not approve the proposed "Topdown" formula to calculate practice expense.

Please create a formula that does not create a negative impact for mental health providers. Mental health services have taken a large negative jolt in the last 15 years, so that many citizens are not able to access mental health and substance abuse services when they need them or at all in some regions. We know that good mental health does support maintenance of good physical health and therefore better work focus and attendance. In addition mental health services are a necessity for the seriously mentally ill and chronic substance abusers. We save money when people get adequate mental health and substance abuse services. Again I request you reconsider these proposals and create a formula which does not negatively affect social workers or clients of services.

**Submitter :** Ms. Virginia McIntosh  
**Organization :** PA Society for Clinical Social Work  
**Category :** Social Worker

**Date:** 08/21/2006

**Issue Areas/Comments**

**Discussion of comments-HCPAC  
Codes**

**Discussion of comments-HCPAC Codes**

I am a Clinical Social Worker for over thirty years, having worked in one children's agency and two mental hospitals. I now have a private practice and teach occasionally at a Graduate School of Social Work. Social workers have provided mental health services for over 70 years and at one point provided over 60% of all mental health services in the USA. We have more experience and higher standards than any other master level professional. In addition, many clinical social workers have doctorate degrees, graduate supervised experience, and lots of advanced training, i.e., certificate programs, etc. We do this work because it is a very gratifying profession. But if fees are continually reduced, as they have been in the last 15 years, many of us will not be able to continue to support our offices and professional expenses (cost of license, continuing education & other expenses to keep abreast of changes in the field, office expenses, cost of billing for services, etc.). As it is, I know several social workers who left the field because they couldn't make enough money to support themselves &/or their families.

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Again I request you reconsider these proposals and create a formula which does not negatively affect social workers or clients of services.



**Submitter :** Ms. Jaime Mulligan  
**Organization :** American Chiropractic Association  
**Category :** Chiropractor

**Date:** 08/21/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-1512-PN-2203-Attach-1.DOC

American  
**Chiropractic**  
Association

DEDICATED TO IMPROVING THE HEALTH AND WELLNESS OF AMERICA, NATURALLY.

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August 21, 2006

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  
OTHER ISSUES

This letter is in response to June 29, 2006 Federal Register (71 Fed. Reg. 37170) request for public comments on the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology. The American Chiropractic Association (ACA) would like to express our deep concerns about adopting this rule as written.

The rule proposes increased payment to some physicians to reward management of care and "face time" with providers through increased valuation of higher-level evaluation and management (E/M) services. The ACA agrees that management of care and "face time" is important and that E/M services have been historically undervalued, but we would like any changes to be considered within the context of the larger healthcare community. The projected four billion dollar increase in reimbursement for E/M services triggers a budget neutrality provision. On page 37241, under "Budget Neutrality," CMS discusses their options related to this issue, outlining either the application of ten percent reduction in work RVUs or a five percent across the board reduction in the conversion factor. In the rationale, CMS states "we believe it is more equitable to apply the adjustment across services that have work RVUs" as this "would impact only those services that have physician work RVUs" and the conversion factor method would "negatively impact all PFS services." ACA wishes to state that we do not view this as an either/or proposition, in that CMS does have an opportunity make the negative impact of the proposal much less dramatic by phasing in the new valuation of E/M services. Additionally, while ACA understands that neither of the choices outlined by CMS will make all parties happy, we respectfully disagree with CMS' assessment that their proposed mechanism is equitable.

Specifically, the proposal disproportionately affects those providers who cannot bill or do not frequently use the E/M codes and will derive no benefit from the increased E/M payment, including doctors of chiropractic. The 10% reduction in work RVUs is balanced out for providers who utilize these higher-level E/M codes, but for doctors of chiropractic who spend a considerable amount of face time with patients but are not allowed to bill for these services, the proposal in the five-year review notice fails to recognize the value of our time.

Under the proposed rule, doctors of chiropractic in 2007 in will face a negative eight percent impact due to the combined work RVU reduction and practice expense (PE) revision (seven percent work, one percent PE). Within four years (by 2010), the combined impact of the work RVU and proposed PE changes will total -11%. These would be in addition to the reduction in the fee schedule conversion factor due to the "sustainable growth rate" (SGR) required under current law, which is supposed to result in at least a 4.6% cut in 2007. All things being equal, doctors of chiropractic will be subjected to

a 12.6% decrease in reimbursement next year alone. The ACA will continue to voice our objections to the overall payment system but would specifically ask CMS to reconsider the budget neutrality provision of this proposed rule, as it further aggravates a difficult situation.

The proposed cuts undermine Congress' goal of having a Medicare payment system that preserves patient access and achieves greater quality of care. ACA believes that the proposed system of reimbursement is unfair and potentially jeopardizes access to care for millions of the elderly and disabled. CMS can and should explore ways to value face time without disproportionately reducing patient access to care by some providers. At this time when there is an increased focus by CMS on preventative and well-oriented care, we find it inexplicable that a rule would put an undue burden on providers who provide such services routinely.

Thank you for your consideration. Should you have any questions, please contact Jaime Mulligan at [jmulligan@acatoday.org](mailto:jmulligan@acatoday.org) or 703-812-0246.

Sincerely,



Kevin Corcoran  
Executive Vice President

**CMS-1512-PN-2204 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Ms. Judith Parnes

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

**Organization :** Judith S. Parnes, LCSW, LLC

**Category :** Social Worker

**Issue Areas/Comments**

**GENERAL**

GENERAL

This correspondence reflects my concerns regarding CMS-1512-PN, Fee Reduction for Clinical Social Workers who are Medicare Providers.

I am a Medicare provider for Psychotherapy services and the executive director of a geriatric care management agency, Elder Life Management. Elder Life Management provides psychotherapy services to older adults, including residents of nursing homes and assisted living facilities throughout the state. I strongly believe that a reduction in the rate of reimbursement by Medicare will have a negative impact on my practice as well as on the lives of the nursing home residents who require these services.

If you would like to discuss this matter in person or by telephone please contact my office at 732-493-8080.

Sincerely,

Judith S. Parnes, LCSW

**CMS-1512-PN-2205 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Mr.

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

**Organization :** VNUS Medical Technologies,Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

Please see attached comments

CMS-1512-PN-2205-Attach-1.PDF



August 21, 2006

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

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

Dear Dr. McClellan:

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

- **Work Budget Neutrality-** VNUS Medical Technologies urges CMS to apply as much transparency as possible to their proposed regulations. One area to achieve this would be applying the budget neutrality adjuster to the physician fee schedule conversion factor vs. reducing the overall work RVU's for selected procedures. We believe that applying the budget neutrality adjustment to the conversion factor will be far more transparent than if applied to the work RVU's as it is currently proposed. By applying it to the conversion factor it will enable the physicians to more easily understand the impact of the proposed cuts.
- **PE Methodology-** While VNUS supports CMS's proposal to implement a revised methodology for calculating practice expense (PE) RVUs so that the process is more transparent and more easily understood, VNUS strongly recommends that CMS eliminate the proposed reductions in PE RVUs for endovenous RFA procedures described by CPT codes 36475 and 36476. These recently established CPT codes were surveyed late in 2004 and therefore the current values more closely reflect accurate PE expenses.

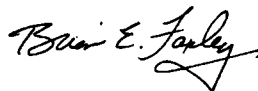
For this reason, we encourage CMS to maintain the current 2006 PE values (listed below) for CY 2007.

CPT	Description	2006 Facility PE RVUs	2006 Non- Facility PE RVUs
<b>36475</b>	Endovenous RFA, 1 <sup>st</sup> vein treated	<b>2.54</b>	<b>51.54</b>
<b>36476</b>	Endovenous RFA, vein add-on	<b>1.14</b>	<b>7.9</b>

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

Thank you for your consideration of this important matter.

Very truly yours,

A handwritten signature in black ink that reads "Brian E. Farley". The signature is written in a cursive style with a prominent loop at the end of the last name.

Brian Farley  
President and CEO  
VNUS Medical Technologies, Inc.

**CMS-1512-PN-2206 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Dr. Donald Quest

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

**Organization :** American Association of Neurological Surgeons

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2206-Attach-1.DOC



AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS  
THOMAS A. MARSHALL, *Executive Director*  
5550 Meadowbrook Drive  
Rolling Meadows, IL 60008  
Phone: 888-566-AANS  
Fax: 847-378-0600  
info@aans.org



American  
Association of  
Neurological  
Surgeons



CONGRESS OF  
NEUROLOGICAL SURGEONS  
LAURIE BEHNCKE, *Executive Director*  
10 North Martingale Road, Suite 190  
Schaumburg, IL 60173  
Phone: 877-517-1CNS  
FAX: 847-240-0804  
info@1CNS.org

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Columbia University  
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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.

**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 *Discectomy, 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 25<sup>th</sup> 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 25<sup>th</sup> 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 25<sup>th</sup> 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 many comments 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, 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 2006 MFS.

## **CONCLUSION**

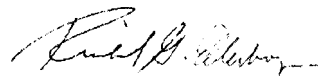
The AANS and CNS appreciate the enormity of work performed by CMS staff for the five year review of the Medicare physician fee schedule. Nevertheless, we disagree with CMS' conclusion that an "error" in the summary of recommendations form resulted in misvaluation by the RUC. The reference codes were 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. 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

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  
Congress of Neurological Surgeons

### **Staff Contact**

Catherine Jeakle Hill  
Senior Manager of Regulatory Affairs  
AANS/CNS Washington Office  
725 15<sup>th</sup> Street, NW  
Suite 800  
Washington, DC 20005  
Office: 202-628-2072  
Fax: 202-628-5264  
Email: [chill@neurosurgery.org](mailto:chill@neurosurgery.org)

**CMS-1512-PN-2207 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Timothy McNichol

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

**Organization :** American College of Osteopathic Internists

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-1512-PN-2207-Attach-1.DOC





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3 Bethesda Metro Center, Suite 508, Bethesda, MD 20814 (301) 656-8877 (800) 327-5183 Fax (301) 656-7133  
www.acoi.org acoi@acoi.org

August 15, 2006

Mark B. McClellan, MD, PhD.  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard, C4-26-05  
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

The American College of Osteopathic Internists appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services Proposed Notice on the Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology.

The American College of Osteopathic Internists (ACOI), which represents the nation's osteopathic internists and medical subspecialists, is dedicated to the advancement of osteopathic internal medicine through excellence in education, advocacy, research and the opportunity for service. Further, the ACOI is committed to assisting its members' efforts to provide the highest level of care possible to their patients. Adoption of the proposed rule published in the *Federal Register* on June 29, 2006 will take an important step in the promotion of access to high-quality care for Medicare beneficiaries.

#### **Evaluation and Management Services**

The ACOI strongly supports CMS's proposed rule to increase the work relative value units (RVUs) for evaluation and management (E&M) services, as recommended by the American Medical Association/Specialty Society RVS Update Committee's (RUC). Due to an incorrect assumption highlighted by findings of the RUC, previous valuation for these services inaccurately reflects the work and complexity associated with providing E&M services.

The complexity and work required in treating the aging American population, and the resulting expansion in the number of Medicare beneficiaries who present higher numbers of chronic conditions, continues to rise. This has been coupled with an expanding recognition of the importance of preventive services under the Medicare program. Full adoption of the proposed rule will correct present inaccuracies in E&M coding and align physician payment with the actual complexity and work associated in providing the highest level of quality care to Medicare

beneficiaries. The ACOI urges CMS to oppose any recommendation to scale-back or eliminate proposed increases in RVUs for E&M services.

**Budget Neutrality**

CMS is required to ensure that expenditures will not differ more than \$20 million from what expenditures would have been absent changes in work RVUs for any given year. The proposed changes in work RVUs for E&M services will increase expenditures and thus require a budget offset. Under the proposed rule, CMS would reduce all work RVUs by 10 percent to achieve the necessary savings. The ACOI is opposed to this approach in light of past experiences with this mechanism. In fact, in 1999 CMS recognized the inherent problems with this approach and stated

We did not find the work adjuster 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).

The ACOI believes the proper way to achieve budget neutrality is to apply an adjustment to the conversion factor. Budget neutrality is a fiscal issue and not one of relativity. To this end, applying an across-the-board 10 percent reduction to work RVUs inappropriately ignores the fiscal rationale for the mandatory adjustments. Therefore, the ACOI recommends that CMS reconsider its proposed approach to achieve budget neutrality and apply an adjustment to the conversion factor.

The ACOI appreciates the opportunity to provide these comments. We look forward to working with CMS in the future on these and other issues of importance impacting the nation's health care delivery system.

Sincerely,



Frederick Schaller, D.O., FACOI  
President

**CMS-1512-PN-2208 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Dr. Monty Menhusen

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

**Organization :** University of Iowa Hospital

**Category :** Physician

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

I am opposed to the CMS-1512-PN proposal

The proposed P/E method would create a huge reduction in payment for services for anesthesiologists and other specialties to supplement the small number of specialties. Secondly, the calculated overhead expenses are out of date and significantly underestimates our actual expenses.

A new expense survey should be completed and current data applied. There should be a 2.8% increase in 2007 as recommended by MedPAC. The SGR formula should be abandoned and the MEI method adopted.

Thank you,  
Monty Menhusen DO MPH JD

**CMS-1512-PN-2209 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Mr. Ron Ashworth

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

**Organization :** Sisters of Mercy Health System

**Category :** Health Care Provider/Association

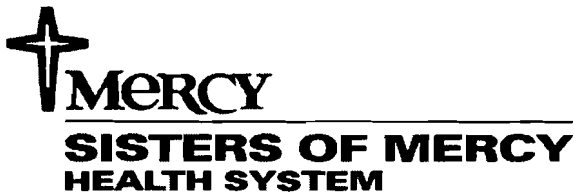
**Issue Areas/Comments**

GENERAL

GENERAL

"See Attachment"

CMS-1512-PN-2209-Attach-1.PDF



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: CMS-1512-PN

Dear Administrator McClellan:

The Sisters of Mercy Health System (Mercy) is a 19-hospital system operating in Missouri, Kansas, Oklahoma and Arkansas. We currently support hospital-based physicians in these four states. Mercy welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled "*Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*", 71 Fed. Reg. No. 125 (June 29, 2006).

Thank you for considering our comments below:

#### **Background**

We recognize the payment system for physicians has evolved over the years. Initially, physician payments were based on physician charges. This system was subsequently revised by limiting payments via the use of the Medicare economic index. In 1992, payments made via a "charge-based" system ceased and the era of the "fee schedule" payment system began. The current fee schedule we utilize is based on the "sustainable growth rate" method.

We believe Congress adopted this method to both ensure Medicare beneficiaries have necessary access to physician services, and to place "controls" on the amount of federal money being expended on physician related services. We understand Part B premiums and transfers from general revenues are established each year to match the following year's estimated costs and that Part B costs are continually rising. Per the 2006 Medicare Trustees Report, physician payment rate reductions are projected to be 4 to 5 percent each year through at least 2015 in order to maintain the sustainable growth rate formula. While we appreciate the need to balance funding with the availability of federal funds, we also appreciate the need for sufficient access to healthcare for the growing number of elderly Americans.

We do not believe physicians will be able to provide "adequate" access to Medicare beneficiaries if cuts continue for these services. Volume and intensity of physician services continue to

increase. At the same time there will be continued increases in the number of Medicare beneficiaries seeking care.

- Medicare enrollment increased 1.6% from 2004 to 2005
- First wave of the 76 million baby boomers expected to reach age 65 in 2011
- Continued increase in average life expectancy
- Continued increase in number of individuals with chronic disease/illnesses

It is apparent that physicians can not continue to sustain overall payment cuts (even no increases would be considered as "cuts" given inflationary factors) while at the same time being expected to dedicate more of their practice to the growing Medicare population.

In a recent American Medical Association (AMA) survey, 45 percent of physicians stated they will either stop accepting or decrease the number of new Medicare patients they accept if Medicare payments are cut for 2007. We request that CMS refrain from any Part B payment cuts in order to ensure physicians remain committed to accepting Medicare beneficiaries for treatment. We do not believe CMS should risk physician accessibility for Medicare beneficiaries. The inability of Medicare beneficiaries to have adequate access to physician services will only promote deterioration in the patient's health status; directly and negatively impacting the cost of care provided in other health care settings such as hospitals and their emergency rooms. Numerous studies have clearly demonstrated this would be significantly more expensive for CMS than ensuring continued access for Medicare beneficiaries to physician care. It is the fiscal responsibility of both CMS and the provider community to ensure all Medicare beneficiaries have adequate access to all levels of care, which would not be supported by payment cuts to physicians.

Thank you for considering our comments. Should you have additional comments please contact Ron Trulove at (314) 364-3561 or me at (314) 628-3685.

Sincerely,



Ron Ashworth  
President/CEO  
Sisters of Mercy Health System

c: Jim Jaacks  
Randy Combs  
Ron Trulove

**CMS-1512-PN-2210 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Dr. Harvey Neiman

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

**Organization :** American College of Radiology

**Category :** Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2210-Attach-1.PDF



August 21, 2006

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

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

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists is pleased to submit comments on the proposed notice "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, 2006. We will address the proposed adjustment of work relative value units (RVUs) to preserve budget neutrality, the need for a transition to full implementation of the proposed work RVUs under the five-year review, the practice expense methodology, the excessive value reduction for some procedures, and the proposed work RVU for CPT® code 76075 Dual energy x-ray absorptiometry (DXA), bone density study.

**Budget Neutrality**

In the Regulatory Impact Analysis section of the proposed notice, the Centers for Medicare and Medicaid Services (CMS) estimates the impact of proposed changes in work RVUs resulting from the five-year review of physician work RVUs to be \$4 billion. Since section 1848(c)(2)(B)(ii) of the Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what the expenditures would have been in the absence of these changes, CMS must make adjustments to preserve budget neutrality. CMS describes the two options that were considered for making these adjustments:

Option 1: Reduce all work RVUs. CMS estimates that all work RVUs would have to be reduced by 10 percent to maintain budget neutrality under this option.

Option 2: Adjust the conversion factor (CF). CMS indicates this option would require an estimated 5 percent reduction in the CF to maintain budget neutrality.

The Agency's stated reason for choosing option 1 was a belief that it may be more equitable to apply the budget neutrality adjustment across services that have work RVUs. However, this is a dramatic departure from previous Five Year Review budget neutral adjustments, and the **ACR recommends that CMS apply the budget neutral adjustment required for the Five Year Review to the Conversion Factor rather than physician work.** We appreciate the opportunity to comment on this proposal.

Unlike the practice expense RVUs, where the methodology and data are undergoing substantial refinement, physician work RVUs have been stable for more than a decade and as such a separate budget neutral adjustment for work is not necessary. Applying the proposed budget neutral adjustment only to



work is no different than directly scaling the work RVUs. We believe adjusting the CF is the more appropriate option for maintaining budget neutrality. The RVU values we have today have withstood the test of time, and have been modified based on three Five Year Reviews. CMS and organized medicine have agreed that maintaining the integrity of the resource based relative value system (RBRVS) is important, and the conversion factor has been the method of choice when making adjustments to physician work. We acknowledge that a budget neutrality adjustment factor was applied to the work RVUs following the first five-year review in 1997, but we believe that CMS recognized the problems this would create since CMS specifically noted in the final rule implementing the first five-year review of relative values that:

“[i]n years subsequent to 1998, we plan to make the budget neutrality adjustments to the CFs [conversion factors]” (Federal Register, November 22, 1996, p. 59533).

And in 1999, the Agency stated:

“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).

There is no reason to believe that this statement is not applicable today. Budget neutrality adjustments required by changes in work RVUs have been applied to the conversion factor since 1999, consistent with the agency’s commitment and the long-standing recommendations of the AMA/Specialty Society Relative Value Scale Update Committee (RUC). CMS provides no compelling argument in the Proposed Notice to justify changing this position.

While not applicable to the Medicare system, CMS should be cognizant that maintaining the stability of the work RVUs is essential since Medicare’s RVUs are used by many other payers. In addition, they are often the basis of physician compensation and productivity analyses. Merely publishing unadjusted work values in Addendum B, does not change the fact that CMS is proposing to scale the work values as a result of the Five Year Review, and while we understand it is not the intention of the Agency, by scaling the RVUs it makes it seem to outside observers that the physician work of the services unaffected by the Five Year Review has decreased as a result of the Five Year Review.

Eventually, we would like to see the conversion factor used to make budget neutrality adjustments for work, practice expense and professional liability insurance (PLI). However, development of practice expense RVUs is far from complete, and we recognize that a separate budget neutral adjustment for practice expense is mandatory until the RVUs are stabilized.

While Interventional Radiologists regularly provide clinical care to their patients and thus utilize E/M codes to a significant degree, the majority of radiologists represented by the ACR do not provide a significant amount of E/M services. Consequently, radiology as a specialty received relatively little benefit from the five-year review as E/M services are provided with a low overall frequency within the specialty on average. And while a budget neutral adjustment to the conversion factor can be explained to our members as part of the regulatory process, the concept of scaling the work RVUs has the effect of devaluing the professional work of our members. Obviously our specialty has a significant number of technical component services and we recognize that the currently proposed global and technical



component (TC) payments will be somewhat negatively impacted by our recommendation to place the budget neutrality adjustment for the Five Year Review on the conversion factor. Nonetheless, **for the reasons stated above and because appropriate recognition of the physician work in radiology services is vitally important to our profession, we urge CMS to make the budget neutrality adjustment to the conversion factor in the final rule.**

#### **Transition for Five-Year Review**

As noted above, CMS estimates the impact of proposed changes in work RVUs resulting from the five-year review of physician work to be \$4 billion. This extraordinary impact is due largely to significant increases in the work RVUs for evaluation and management (E/M) services and the accompanying increases in the post-operative work RVUs for procedures with 10 or 90 day global periods. In this letter, we are not commenting on the proposed RVUs for these services. However, we note that for those specialties that typically do not provide E/M services or perform surgical procedures, the negative impact of the increases in work RVUs for these services will be significant and immediately effective on January 1, 2007.

In the section of the proposed notice dealing with the new practice expense methodology, CMS states "We are concerned that, when combined with a proposed negative update factor for CY 2007 and the proposed changes to the work RVUs under the five-year review, the shifts in some of the practice expense (PE) RVUs resulting from the immediate implementation of our proposals could potentially cause some disruption for medical practices. Therefore, we are proposing to transition the proposed PE changes over a four-year period."

We support this transition and believe the same logic for a transition applies to the work RVUs. **Therefore, we recommend a transition of the work RVUs consistent with the transition CMS has proposed for the practice expense RVUs.** During the transition period, the work RVUs would be calculated on the basis of a blend of the work RVUs that result from the five-year review (weighted by 25 percent during CY 2007, 50 percent during CY 2008, 75 percent during CY 2009, and 100 percent thereafter), and the current CY 2006 work RVUs for each existing code. We see nothing in the statutory requirements for periodic review and adjustments in relative values found at section 1848(c)(2)(B) that would preclude the transition in work values that we are recommending here.

#### **Practice Expense**

In the proposed notice, CMS states that its three major goals with respect to the resource-based practice expense (PE) methodology are: 1) to ensure the practice expense payments under the Medicare Physician Fee Schedule (MFS) reflect the relative resources required for each of the services; 2) to develop a payment system that is understandable so that specialties can better predict the impacts of changes in the practice expense data and 3) to stabilize the practice expense portion of the MFS so that changes in practice expense data does not produce large fluctuations. The ACR believes the practice expense methodology as explained in the proposed rule is not as transparent and understandable as CMS intended. We have two specific issues related to the methodology and a comment on the accuracy of the data used to calculate the PE RVUs that we would like to bring to your attention.

#### Physician Work in the Allocation of Indirect PE RVUs

As described in the proposed notice, the work RVUs that are used in the calculation of the indirect PE RVUs have been reduced by 10 percent as a result of the budget neutrality adjustment associated with the

five-year review. In using the scaled RVUs, this feature of the methodology has the effect of understating the indirect costs of services with physician work and results in a higher proportion of the PE RVUs for global services (i.e., those with both professional and technical components) being attributable to the technical component than would occur if the full work RVUs were used in the allocation of the indirect PE RVUs. We note that if the practice expense methodology was being revised in any year other than a five-year review year that this would not be an issue and the full work RVUs would be used in the allocation.

If our recommendation to make the budget neutrality adjustment to the conversion factor in the final rule is accepted, then the full work RVU will be used in the allocation of the indirect PE RVUs and this problem will be corrected. If CMS decides to finalize its proposal to make the budget neutrality adjustment to the work RVUs, then **the ACR requests that this feature of the methodology be revised so the true (unadjusted) work RVUs are used in the allocation of the indirect PE RVUs.**

#### Assumptions Used in Calculating Equipment Costs

In the proposed rule, CMS provides the formula used to calculate the direct practice expense costs associated with equipment. The formula is complex and takes account various factors, including the hours an office is open, the percent of the time the equipment is in use, the useful life of the equipment, the interest rate on the purchase of equipment and the cost of maintenance. The Medicare Payment Advisory Commission (MedPAC) has suggested that the current assumption that equipment is in use 50 percent of the time an office is open is too low and that the assumption of an 11 percent interest rate is too high. However, other factors such as maintenance costs may also be incorrect. For certain, all of these factors can vary depending on the equipment in question.

In the proposed rule, no proposals are made to revise the formula and comments are not sought on the issue. Consequently, we assume that no changes could be made in the final rule. However, it is possible that CMS will receive some specific recommendations for change in 2007. In the absence of specific CMS proposals for change, **the ACR requests that the acceptance of any recommendations be deferred pending the collection of valid data on all the important factors used in the calculation of equipment costs.** We agree with Herb Kuhn, the Director of the Center for Medicare Management who said in testimony before the House Subcommittee on Health of the Committee on Energy and Commerce on July 18, 2006 that "data to substantiate alternative equipment utilization assumptions are not available." We are prepared to work with CMS in the months ahead to collect the necessary data and we look forward to the opportunity to comment on any proposed changes to the formula in a future Federal Register notice or proposed rule.

#### Practice Expense Per Hour (PE/hr) Figures

The ACR appreciates and applauds CMS's proposal to accept the ACR supplemental survey data to calculate the practice expense values. However, the ACR remains concerned that CMS did not fully utilize the ACR supplemental survey data. The ACR is also concerned with weighting of the data. The ACR followed strict guidelines outlined by CMS and used an approved contractor, Doane Marketing Research, to submit the data. The ACR invested significant financial resources, staff time and physician volunteer time to complete the survey.

The ACR's original supplemental survey data resulted in a practice expense per hour of \$194.82 as calculated by Doane, but through a series of steps the final value being used by CMS has fallen to \$174.20. This is well out of proportion to the adjustments for other specialty societies that conducted supplemental surveys over the same period as that for the ACR. One adjustment involves a reduction of

the original \$194.82 to \$185.72 by CMS's contractor, The Lewin Group. The difference is due to how total patient care hours are calculated. In the supplemental survey, Doane collected data on the number of full and part-time physicians in the practice and the total number of clinical patient care hours they provided in a typical week. The mean number of hours was approximately 21 per part-time physician, compared with approximately 37 per full-time physician. Doane used the complete survey data on both full-time and part-time physicians in obtaining an accurate sum of total hours for all physicians in the practice and thus, precise mean total expenses per hour.

In calculating total hours for all physicians in the practice, The Lewin Group chose not to use the complete set of acquired survey data, disregarding the survey data on part-time hours and, instead, imputed hours for part-time physicians by an incorrect methodological decision to assign full-time hours to all part-time physicians. Lewin's changes resulted in an increase in total hours for 47 percent of practices, a decrease for 4 percent of practices, and no change for 49 percent of practices. These changes also resulted in total annual hours for all physicians in the 171 practices surveyed being 220,907 higher by The Lewin Group's method, compared with the direct calculation by Doane. The higher hours used by The Lewin Group accounts for mean expenses per hour being lower (\$185.72) than that obtained by Doane (\$194.82). It violates sound statistical practice to discard valid data and substitute imputations based on incorrect suppositions. We have reviewed The Lewin Group's written justifications for its methods and strongly disagree with their rationale for inflating the physician hours. Despite The Lewin Group claim that the standard methodology is to allocate full-time hours to part-time physicians, The Lewin Group has, in at least one prior instance, used the complete data set and has allocated appropriate part-time hours to part-time physicians. Since precedent for our suggested methodology has been established by The Lewin Group and accepted by CMS, **the ACR requests that CMS implement the full set of data from the ACR supplemental survey as accurately analyzed by Doane Marketing Research.**

Another adjustment involves weighting the data, which further devalued the figure from \$185.72 to \$159.42. There was no transparency in this process, particularly in regard to sampling stratification, and the ACR would greatly appreciate having the opportunity to examine and comment on the methods used by The Lewin Group and adopted by CMS.

We look forward to working closely with CMS to ensure appropriate practice expense per hour for radiology procedures. In developing final policies, we believe that CMS must ensure that no errors have been made in computing the PE/hr value for radiology.

#### Accuracy of the Data

Based on a briefing on the proposed notice that was provided by CMS staff at the offices of the American Medical Association after publication of the proposed notice, it is our understanding that there may have been errors in the PE/hr data for some specialties that did not submit supplemental PE data. If that is the case, it is possible that the PE RVUs published in the proposed notice are not correct. We believe it is incumbent on CMS to identify and correct any errors as soon as possible and **the ACR asks that CMS be willing to accept additional comments from the ACR and any other interested parties after the close of the comment period if it turns out that corrected RVUs are significantly different from those that were published in the proposed notice.**

#### Impact on Practice Expense Values

The ACR believes the practice expense methodology as explained in the proposed rule is not as transparent and understandable as CMS intended. When comparing the 2006 practice expense values to



the proposed 2007 and to the proposed fully transitioned 2010 values, the ACR discovered a wide range of reductions and increases for radiology codes. While some of these codes are infrequently used, there are many frequently used services that are significantly reduced in value, to the point where physicians may find it untenable to continue providing those services, resulting

in a negative impact on access to care for Medicare beneficiaries. Examples include services such as DXA, CAD mammography, stereotactic breast biopsy, interventional, nuclear medicine and certain radiation oncology procedures. **The ACR strongly believes that the new practice expense methodology used should provide more consistent RVU assignment across all radiology procedure codes, particularly those that have unique characteristics, such as medical physics.** We note that the two medical physics TC only codes will be adversely impacted by the proposed changes. These reductions (-68.9% for 77336 and -32.6% for 77370) are, we believe, an unintended consequence of the revised methodology. These codes from the non-physician work pool have no equipment cost and suffer significantly from the new methodology. Such a large decrease in value will impair adequate funding for the safe and effective delivery of radiation therapy services to cancer patients. **We urge CMS to review the factors that have caused this devaluation.**

Of additional concern to the ACR is the striking variability of RVU changes among procedures in the same family. It seems illogical that unilateral and bilateral diagnostic mammography would experience a much needed, and generally agreed appropriate, increase in value while screening mammography would experience a decrease. **The ACR is very concerned with this wide range of variability in practice expense values in all modalities and seeks explanation and additional information from CMS.** If, upon further analysis, we find the need to modify PE inputs, we will bring them to the Practice Expense Review Committee (PERC) and request the agency to consider correcting the inputs ahead of any scheduled review of practice expense data.

#### Assignment of Equipment Room Time for Interventional Imaging Services

The ACR is concerned that the equipment room time assigned to interventional radiology services (i.e., 74XXX and 75XXX codes) may not be appropriate. **The ACR recommends CMS revisit the method used to determine the equipment room time for these services to ensure accuracy.** The ACR supports comments submitted by Society of Interventional Radiology (SIR) on this issue and **encourages CMS to work with the ACR and SIR on this issue to get it corrected before the final rule is implemented.**

#### **Medical Physicist Salary**

The American Association of Physicists in Medicine (AAPM) conducted a survey on Medical Physicist salary. The current hourly wage of a Medical Physicist may not be accurate as CMS based it on the Department of Labor data for a health physicist and not a medical physicist. Accordingly, **the ACR recommends that CMS base hourly wage of a Medical Physicist on the 2005 AAPM Salary data with an inflation adjustment for 2006.** The total income for a Medical Physicist averaged at \$152,100 in 2005. This amount included consulting fees, but no benefits.

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

As part of the five-year review process, CMS referred 24 codes in the radiology section of CPT to the RUC. These codes are listed in Table 27 of the proposed notice. The RUC recommended that the current work RVUs be maintained for 21 of the 24 codes. The ACR appreciates the CMS decision to accept the RUC recommendations for all but 3 of these codes. Two of the codes for which the RUC

recommendations were not accepted are provided primarily by cardiologists (78478 and 78480) and will not be addressed in these comments. The third code is 76075 [Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (eg, hips, pelvis, spine)]. CMS proposes to accept the RUC recommendation that the work RVU be decreased from 0.30 to 0.20.

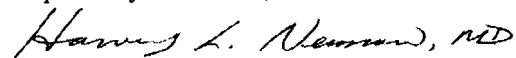
At the beginning of the five-year review process, the ACR was the only specialty to express interest in conducting a survey for this code. As a result, other specialty societies that provide DXA, such as internal medicine, rheumatology and family practice did not participate in the survey. In addition, other organizations that are not part of the RUC process such as the International Society of Clinical Densitometry have members who also perform DXA. We understand that some of these specialty societies and organizations may be submitting comments on the proposed notice requesting that the work RVUs be restored to the current level of 0.30.

CMS in the past has stated that it wants to ensure that all stakeholders are represented in the determination of physician work. **The ACR encourages CMS to consider any comments from any of the other specialty societies and organizations performing DXA so that their views may be taken into account in the determination of the final work RVUs for 2007.** If CMS decides to include this code on the agenda for a refinement panel, the ACR would appreciate the opportunity to participate.

#### **Conclusion**

Thank you for the opportunity to comment on this proposed notice. The ACR encourages CMS to continue to work with physicians and their professional societies in order to create a stable and equitable resource-based payment system. The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at [achoe@acr.org](mailto:achoe@acr.org).

Respectfully Submitted,



Harvey L. Neiman, MD, FACR  
Executive Director

cc: Herb Kuhn, CMS  
Ken Simon, MD, CMS  
Carolyn Mullen, CMS  
Pamela West, CMS  
Rich Ensor, CMS  
Ken Marsalek, CMS  
John A. Patti, MD, FACR, Chair, ACR Commission on Economics  
Bibb Allen, Jr., MD, FACR, Vice-Chair, ACR Commission on Economics  
Pamela J. Kassing, ACR  
Maurine Spillman-Dennis, ACR  
Angela J. Choe, ACR

**CMS-1512-PN-2211 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Mr. Martin O'Neill

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

**Organization :** The Heart Group PC

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2211-Attach-1.DOC

August 21, 2006

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

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

Dear Dr. McClellan:

On behalf of The Heart Group, PC (THG) and our eighteen (18) individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Located in Evansville, IN, THG currently operates an outpatient cath lab that is joint-ventured with one of the local hospitals. Our cath lab performs approximately 500 cardiac and peripheral procedures per year. If the proposed reimbursement cuts are implemented, Medicare reimbursement would be less than our direct costs and force us to close the cath lab.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1% reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 T C and 93556 T C would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes



would fall from 94% of the proposed 2007 APC rate for these three codes to 34% of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

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

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19-step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

#### **Direct Costs**

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

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51% of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49% of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate

more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51% of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

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

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

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

<b><i>Direct Cost Category</i></b>	<b><i>Included In RUC-Determined Estimate</i></b>	<b><i>Excluded From RUC-Determined Estimate</i></b>
Clinical Labor	<ul style="list-style-type: none"> <li>• Direct Patient Care For Activities Defined by RUC</li> <li>• Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery)</li> </ul>	<ul style="list-style-type: none"> <li>• Direct Patient Care For Activities Not Defined by RUC</li> <li>• Actual Staff Allocation Based on Patient Needs</li> </ul>
Medical Supplies	<ul style="list-style-type: none"> <li>• Supplies Used For More Than 51% of Patients</li> </ul>	<ul style="list-style-type: none"> <li>• Supplies Used For Less Than 51% of Patients</li> </ul>
Medical Equipment	<ul style="list-style-type: none"> <li>• Equipment Used For More Than 51% of Patients</li> </ul>	<ul style="list-style-type: none"> <li>• Equipment Used For Less Than 51% of Patients</li> </ul>
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> <li>• Approximately 55% of the direct costs are included in the RUC estimate</li> </ul>	<ul style="list-style-type: none"> <li>• Approximately 45% of the direct costs are included in the RUC estimate</li> </ul>

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

### **Indirect Costs**

The “bottom-up” methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities (“IDTFs”), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24%. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

### **Solutions**

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

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance (“COCA”) to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Sincerely,

Martin B. O’Neill, MHS, CMPE  
Chief Executive Officer

**CMS-1512-PN-2212 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Dr. Jose R Garcia

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

**Organization :** Dr. Jose R Garcia

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

GENERAL

GENERAL

ie "See Attachment"

CMS-1512-PN-2212-Attach-1.DOC

#2212

August 18, 2006

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

To Whom It May Concern:

It has come to my attention that you have recently proposed changes to the Physician Fee Schedule (CMS-1512-PN, RIN 0938-AO12, Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology). My understanding is that these changes will result in an 80% reduction in the technical portion and 50% reduction in the professional component for DXA of the axial skeleton (CPT 76075) reimbursement.

As I am sure you are aware, osteoporosis is more common; especially as the general age of the population increases and Americans are living longer. The use of *fan beam* DXA systems enables physician as myself to screen and detect bone mineral density loss. This detection is detrimental to preserving the health of my patients, specifically females.

The decrease in reimbursement, which already excludes DXA vertebral assessment (CPT 76077), will negatively impact access to this vital test. The operation and utilization cost for providing and maintaining the *fan beam* DXA screen is much higher than the estimated \$38 reimbursement that is being recommended for each exam. If this reduction is approved, my overhead cost for providing the DXA exam will be far too expensive and will require me to discontinue the service.

Please consider, if the screening capability provided by the DXA is decreased due to costly maintenance and low reimbursement, the early detection of osteoporosis will decrease. If the disease detection decreases, bone injury and fractures will increase. Increased injury will result in increased hospitalizations and surgeries that could have likely been avoided with detection and treatment of the underlying cause, commonly osteoporosis. I would hope you agree the cost of, what could be unnecessary hospitalizations and surgeries, far outweighs the cost of continuing current reimbursement rates of CPT 76075.

I urge you to continue current reimbursement rates and help me in my effort to provide above adequate care for our growing, aging population.

Cordially,  
Jose R. Garcia, M.D.  
Brittany Fuller, PA-C  
bf/JG

**CMS-1512-PN-2213 Five Year Review of Work Relative Value Units Under the Physician Fee Schedule**

**Submitter :** Ms. Kelli Barron

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

**Organization :** Community Oncology Alliance

**Category :** Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2213-Attach-1.DOC

CMS-1512-PN-2213-Attach-2.DOC

# Community Oncology Alliance

*Dedicated to high quality, affordable, and accessible cancer care*

August 21, 2006

Mark B. McClellan, MD, PhD, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1512-PN  
Room 445-G Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. McClellan:

On behalf of the Community Oncology Alliance (COA), we believe that it is imperative to file comments and to voice our concerns relating to the 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), published as a Proposed Notice with comment, in the June 29, 2006 Federal Register.

On the surface, it appears that the proposed increases to Evaluation and Management Service Codes for 2007 are a positive for community oncology clinics—where 84% of cancer patients are treated—reimbursed under Medicare Part B. Additionally, it appears that the combined impact of Practice Expense (PE) and Work Changes will benefit the specialty of hematology/oncology by increasing aspects of reimbursement by 3% in the transitional year 2007, which will actually then decrease 2% by 2011. However, this stated increase is deceptive and does not accurately portray the fact that since 2004, reimbursement to the community oncology clinics under Medicare Part B has been substantially cut through 2006. The combined impact of the proposed changes commencing 2007, and the current reimbursement situation, is truly creating a crisis in this country relating to the delivery of cancer care. We base this on the following facts:

- Any recommended increases by CMS will be stymied by a budget neutrality adjustor, reducing the work Relative Value Units (RVUs) by as much as 10%.
- The Geographic Practice Cost Indices (GPCI) will be eliminated on December 31, 2006, removing the protected floor put in place in 2004.
- The 2007 Proposed Physician Fee Schedule released August 8, 2006 shows yet another proposed decrease of 5.1%.
- The expiration of the oncology demonstration project will further cut at least \$150 million from cancer care funding by Medicare.
- We understand that the current conversion factor of \$37.8975, set in 1995, is being reduced by 5% to \$34.5030. This, in effect, means you are applying an eleven year old factor to data that will in and of itself be three years old when implemented and continue to use that aged data for the next several years.
- None of the temporary G codes implemented in 2005 and made permanent in 2006 are being considered for RVU adjustment per Addendum C. There are numerous problems experienced with these new codes due to interpretational difficulties, rule changes, carrier discretion, coding errors, drug classifications, inappropriate denials and delayed MedLearn Educational Tools, to identify just a few. Additionally, it is unclear how CMS acquired the PE data for the G codes and how or even if the codes

#2213

1101 Pennsylvania Ave., NW  
Suite 700  
Washington, DC 20004  
(202) 756-2258

1790 Kirby Parkway, #130  
Memphis, TN 38138  
[communityoncology.org](http://communityoncology.org)

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*Georgia*

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*Alabama*

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*Texas*

Robert Hermann, MD  
*Georgia*

Dawn Holcombe, MBA  
*Connecticut*

Paul Kaywin, MD  
*Florida*

Grace Kendrick, JD, MHA  
*Ohio*

Mary Kruczynski  
*Pennsylvania*

Donna Krueger, RN, OCN  
*Illinois*

Lynn Kuhn, BBA, CPA  
*Texas*

Steve Leibach, MD  
*Illinois*

Lance Miller, MD  
*Oklahoma*

Carol Murtaugh, RN, OCN  
*Iowa & Nebraska*

Ricky Newton, CPA  
*Virginia*

William Nibley, MD  
*Utah*

John Ogle, MBA, CPA  
*Tennessee*

Wendy Smith, MSN, ACNP  
*Mississippi*

Kurt Tauer, MD  
*Tennessee*

Annette Theis, MHSA  
*Florida*

Tammy Thiel  
*Alaska*

Mark Thompson, MD  
*Ohio*

Steve Tucker, MD  
*California*



were cross walked in some fashion from years 2004 to 2005 to 2006. If CPEP data from 2004 was used, it is already outdated for implementation three years later in 2007.

- Medicare Part B drug reimbursement based on Average Selling Price (ASP) is inadequate for three important reasons not included in an analysis by CMS or other agencies. First, community oncology clinics are subsidizing the Medicare program for each drug increased in price because of the 6-month lag in updating drug reimbursement rates. Second, the inclusion of prompt payment discounts between the manufacturer and wholesaler effectively reduces the real Medicare drug reimbursement rate to ASP+4%. Third, the impact of bad debt, which CMS refuses to acknowledge, effectively reduces drug reimbursement to below cost.
- Pharmacy facility costs are not reimbursed, especially in light of increased regulation and cost. For example, the United States Pharmacopeia's proposed changes to Chapter 797, Pharmaceutical Compounding-Sterile Preparations, will place considerable burdens on community oncology clinics if suggested modifications for drug preparation are adopted. There is a stipulation that states if preparation time exceeds one hour for any chemotherapy compounded sterile preparation, the drug must be discarded. This will result in considerable waste and, as a result, cost. Additionally, USP797 is also recommending clean rooms and even anterooms in every clinic that could cost upwards of \$85,000.00.
- Treatment planning costs are not reimbursed.

While Medicare Part B reimbursement continues to decline, community cancer clinics are facing escalating costs. Administrative costs are increasing with more personnel needed to implement new programs (e.g., Part D) and increasing regulations (HIPAA, pre-certification, et cetera).

It is important to note that as the payer of close to 50% of cancer care in this country, Medicare influences the actions of private payers. Specifically relating to coding and fee schedule changes, because most payers use the Medicare system, changes to Medicare Part B reimbursement impacts have a leveraging affect.

During 2006, more community oncology clinics report not being able to treat patients in increasing situations where Medicare drug and services reimbursement is being reduced. Clinics report closing facilities and reducing staff. The inappropriate and unrealistic ratcheting down of Medicare Part B funding is dismantling the cancer care delivery system in this country. If you believe that this claim is unfounded and "crying wolf", I invite you to visit our clinic or any other community cancer clinic in this country. Unfortunately, it will be too late by the time that CMS is forced to believe that this is true. The number of new oncologists is now not keeping pace with the oncologists retiring or simply leaving active patient care. This is a direct result of the draconian changes to Medicare reimbursement.

Unfortunately, a harbinger of the situation facing cancer care can be seen in the tragedy facing immuno-compromised patients depending on IVIG. Ever since changes to Medicare Part B drug reimbursement based on ASP were implemented in 2005, the cost, reimbursement and availability of IVIG have been unstable. As a result, patients have literally died.

We request that CMS consider the impact of the changes it is making. The agency's conclusion that there is no impact on oncology is simply incorrect and not based on market fact.

We submit as an attachment, the transcript from a recent hearing on Medicare Part B reimbursement conducted by the Ways and Means Health Subcommittee.

Sincerely,

A handwritten signature in black ink that reads "Fred Schnell". The signature is written in a cursive, slightly slanted style.

Dr. Fred Schnell

President

Community Oncology Alliance

**Written Testimony Submitted to the Ways & Means Subcommittee on Health  
Medicare Reimbursement on Physician-Administered Drugs  
July 13, 2006**

**Submitted by the Community Oncology Alliance (COA)**

Medicare Part B reimbursement for cancer care is insufficient in 2006. The implications of insufficient reimbursement are that community cancer clinics report sending more patients to the hospital for treatment, closing satellite facilities and practices, reducing staff, and being pressured to factor economic decisions into the cancer treatment plan in order for clinics to continue treating patients. Additionally, clinics report considering dropping out of the Medicare program. Already, in 2006, there are reports about access problems from community cancer clinics in over 37 states.

The fundamental problem with Medicare Part B reimbursement in 2006 is that drug administration reimbursement has decreased by over 20% since 2004 while drug reimbursement has decreased by over 30%. So, during a time period when underlying medical costs are increasing approximately 4% per year, reimbursement for both essential services and drugs required to treat seniors covered by Medicare Part B continues to decrease. Relating to services reimbursement, certain services such as cancer treatment planning and pharmacy facilities are not reimbursed. Relating to drug reimbursement, Medicare reimbursement of Average Sales Price (ASP) + 6% appears in cases to cover drug acquisition costs. However, reimbursement for most cancer drugs is actually less than cost when including the realities of pharmacy facilities, prompt pay wholesaler discounts, bad debt, and manufacturer price increases. Community cancer clinics, where 84% of the cancer patients in the United States are treated, cannot continue to operate in an environment where costs are exceeding reimbursement.

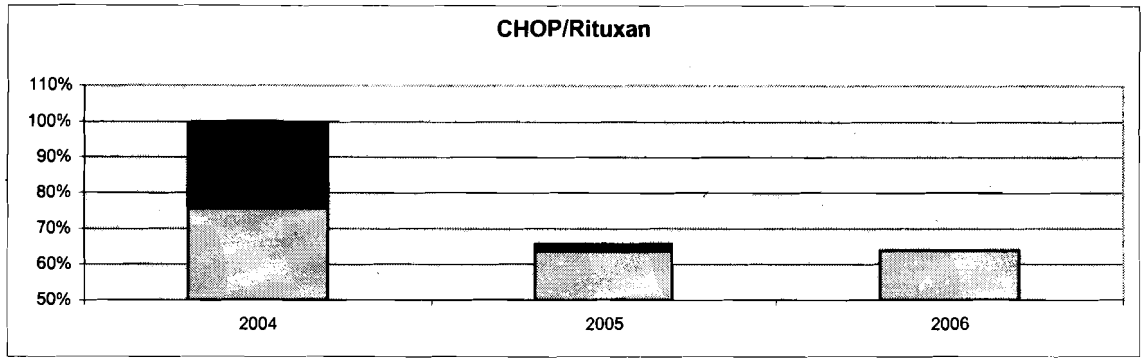
The specific problems with Medicare reimbursement are three-fold.

**Problem #1: Medicare payment for drug administration is inadequate and is decreasing.**

The Medicare Modernization Act (MMA) increased drug administration payments by 110% starting in 2004. The MMA also created a lump-sum transition increase of 32% that further raised drug administration payments in 2004. This transition increase decreased to 3% in 2005 and was eliminated in 2006. The purpose of this transition increase was for the Centers for Medicare & Medicaid Services (CMS) to ascertain the adequacy of existing payment codes and to create new codes for un-reimbursed services, such as treatment planning.

Unfortunately, in 2004 no new major payment codes were created by CMS for 2005; only temporary "G codes" were created. Instead, CMS developed a chemotherapy demonstration project for 2005 that retained at least \$300 million in Medicare funding for cancer care. This stopgap funding, along with the 3% transition fee and averted cut in the physician fee schedule, minimized any impact on community oncology during 2005. However, the chemotherapy demonstration project and transition increase both expired at the end of 2005, which resulted in lower Medicare reimbursement in 2006. Additionally, CMS replaced the temporary "G codes" with new codes at a lower relative value unit (RVU) rate and with no clear "cross walk" (i.e., translation) from the "G codes." This resulted in an additional decrease in drug administration reimbursement. Exhibit A shows a coding analysis performed by expert coders from around the country. Analyzing some commonly used cancer treatment regimens, it is clear that reimbursement for drug administration only (this analysis excludes drug reimbursement) on a treatment-by-treatment basis has decreased substantially from 2004 to 2006. This decrease is estimated to be in excess of 20% overall.

The graph below illustrates the components of declining drug administration for the CHOP/Rituxan treatment regimen presented in Exhibit A. The purple portion of the bar in 2004 and 2005 illustrates the impact of the transition increases—32% in 2004 and 3% in 2005. The blue portion represents the underlying RVU-based payment.



It is illogical that Medicare drug administration reimbursement has decreased over 20% from 2004 to 2006 in light of the fact that medical human resource and supply costs have actually increased by approximately 4% per year during this period. It must be noted this has occurred when drug reimbursement has decreased by over 30% with the change from the prior AWP system to the new ASP-based reimbursement system.

**Problem #2: Certain essential cancer care services and costs are not reimbursed.**

The prior AWP-based reimbursement system resulted in drug reimbursement overpayments that subsidized essential cancer services that were either under-reimbursed or not reimbursed. Under the ASP-based system there is neither a subsidy nor a direct or indirect reimbursement for certain essential services. For example, cancer treatment planning is not reimbursed as part of any existing Medicare payment mechanism. It is ironic that radiation oncology treatment planning, which is typically part of the overall cancer treatment plan, is reimbursed by Medicare, whereas medical oncology treatment planning is not reimbursed. As another example, all of the direct drug costs of a pharmacy are not reimbursed. These include storage, inventory, pharmacy operations, and waste disposal. In light of increasing regulations dealing with chemotherapy and other toxic drug handling, the costs of maintaining a pharmacy are increasing. However, these costs are not reimbursed directly or indirectly.

Although some argue that many costs are “bundled” in the drug administration payment codes, there is no evidence that this is true or that these costs are appropriately covered by payment codes. In fact, the existing codes for drug administration have not been updated—even with the 2004 MMA 110% increase—to reflect the increasing costs of simply administering cancer drugs, much less cover any other facets of cancer treatment, such as treatment planning.

**Problem #3: ASP + 6% may only barely cover drug acquisition costs. It does not cover all direct drug costs.**

A clinic’s total drug costs are comprised of drug acquisition costs, pharmacy costs, billing and overhead, and bad debt. Analyzing a clinic’s drug acquisition costs in comparison to ASP + 6% reimbursement and concluding that reimbursement covers cost is a faulty analysis, which is the problem with studies completed by the Office of the Inspector General (OIG) and the Government Accountability Office (GAO). The table below shows both OIG’s estimated purchase price by drug (column a) along with the corresponding drug reimbursement rate (column b). If all of the patient’s

co-insurance was paid, most of the drug acquisition cost is covered by the reimbursement (column c). However, factoring in bad debt of 5.3% most of the drug acquisition costs are not covered by the reimbursement (column d). On a case-by-case basis, the impact of non-payment of the 20% co-insurance is substantial (column e). If you factor in bad debt and selected other direct drug costs, the result is a further under-reimbursement of drug costs.

	(a)	(b)	(c)	(d)	(e)	(f)
Drugs	OIG Estimated Average Purchase Price	4th Quarter Medicare Payment Rate	If Total Amount Paid	Bad Debt Factor of 5.30%	If No Co-pay Collected	Bad Debt Factor and Other Drug Costs
Carboplatin	16.24	35.25	19.01	17.14	11.96	14.67
Dexamethasone	0.05	0.11	0.06	0.05	0.04	0.05
Cisplatin	2.05	2.37	0.32	0.19	(0.15)	0.03
Vinorelbine	35.71	42.83	7.12	4.85	(1.45)	1.85
Dolasetron Mesylate	4.04	6.52	2.48	2.13	1.18	1.68
Cyclophosphamide	2.03	2.12	0.09	(0.02)	(0.33)	(0.17)
Epoetin Alfa	9.20	9.22	0.02	(0.47)	(1.82)	(1.11)
Filgrastim	245.46	279.57	34.11	19.29	(21.80)	(0.28)
Darbepoetin alfa	15.61	15.06	(0.55)	(1.35)	(3.56)	(2.40)
Flourouracil	1.49	0.64	(0.85)	(0.88)	(0.98)	(0.93)
Leucovorin	1.16	1.32	0.16	0.09	(0.10)	(0.00)
Palonosetron hydrochloride	16.38	17.99	1.61	0.66	(1.99)	(0.60)
Granisetron hydrochloride	6.39	7.14	0.75	0.37	(0.68)	(0.13)
Vincristine	3.18	3.60	0.42	0.23	(0.30)	(0.02)
Pegfilgrastim	2,080.71	2,078.07	(2.64)	(112.78)	(418.25)	(258.24)
Etoposide	0.46	0.49	0.03	0.00	(0.07)	(0.03)
Docetaxel	280.71	293.64	12.93	(2.63)	(45.80)	(23.19)
Pamidronate disodium	56.50	40.63	(15.87)	(18.02)	(24.00)	(20.87)
Gemcitabine hydrochloride	111.40	115.89	4.49	(1.65)	(18.69)	(9.76)
Fludarabine	263.12	262.87	(0.25)	(14.18)	(52.82)	(32.58)
Bevacizumab	55.27	57.11	1.84	(1.19)	(9.58)	(5.18)
Zoledronic acid	192.95	200.03	7.08	(3.52)	(32.93)	(17.52)
Trastuzumab	51.80	54.39	2.59	(0.29)	(8.29)	(4.10)
Oxaliplatin	8.07	8.53	0.46	0.01	(1.25)	(0.59)
Irinotecan	123.00	126.92	3.92	(2.81)	(21.46)	(11.69)
Mitoxantrone	316.10	323.80	7.70	(9.46)	(57.06)	(32.13)
Doxorubicin J9001	353.30	364.53	11.23	(8.09)	(61.68)	(33.61)
Topotecan	730.88	763.80	32.92	(7.56)	(119.84)	(61.03)
Octreotide	84.40	87.31	2.91	(1.72)	(14.55)	(7.83)
Diphenhydramine	0.93	0.72	(0.21)	(0.25)	(0.35)	(0.30)
Sargramostim	21.44	21.87	0.43	(0.73)	(3.94)	(2.26)
Amifostine	414.00	439.31	25.31	2.03	(62.55)	(28.73)
IVIg non-lyophil	56.26	56.30	0.04	(2.94)	(11.22)	(6.88)
Fulvestrant	79.97	81.33	1.36	(2.95)	(14.91)	(8.64)
Rituxan	440.10	455.92	15.82	(8.34)	(75.36)	(40.26)
Paclitaxel	16.71	13.33	(3.38)	(4.09)	(6.05)	(5.02)
Leuprolide	279.34	224.42	(54.92)	(66.81)	(99.80)	(82.52)
Enoxaparin Sodium	6.45	5.45	(1.00)	(1.29)	(2.09)	(1.67)
Doxorubicin J9000	5.48	5.84	0.36	0.05	(0.81)	(0.36)

It is unreasonable to simply look at drug acquisition costs in isolation without considering all direct drug costs. The stated Medicare drug reimbursement rate is ASP + 6%. However, factoring in other costs, the effective real rate is ASP - 3.8%. These include the MMA-mandated inclusion of prompt payment discounts between the pharmaceutical manufacturer and the wholesaler into the ASP calculation; the impact of the lag between a manufacturer's price increase and inclusion in the drug reimbursement rates; and the bad debt factor.

Stated Medicare Drug Reimbursement Rate	ASP + 6%
<i>Less Prompt Pay Discount</i>	2.00%
<i>Less Price Increase Lag</i>	2.50%
<i>Less Bad Debt</i>	5.30%
<b>Effective Medicare Drug Reimbursement Rate</b>	<b>ASP - 3.8%</b>

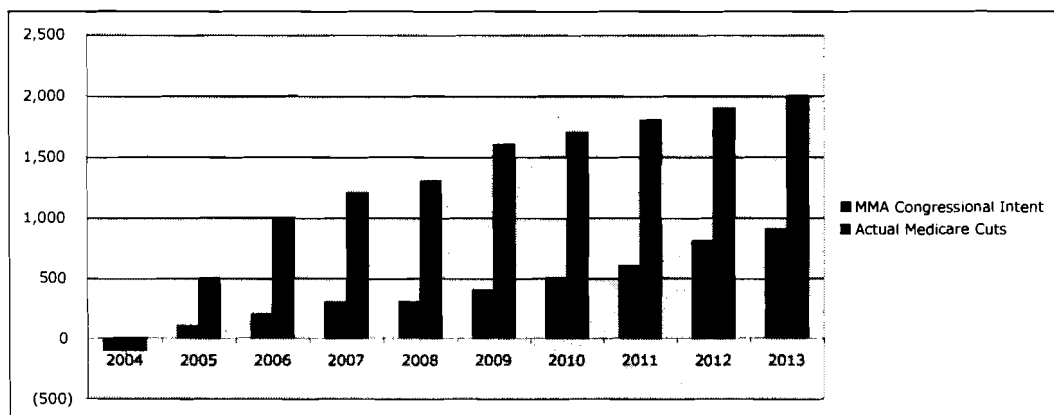
Bad debt is a real cost incurred by community cancer clinics. COA estimates bad debt at 5.3% nationally. An estimated 12% of patients have no secondary co-insurance and in many states Medicaid—as the secondary insurer—does not cover the patient’s co-insurance obligation. As the cost of cancer drugs escalate, patients are increasingly unable to cover co-insurance payments that can run over \$20,000. Bad debt is a reality of operating a community cancer clinic, yet it is ignored as a reality by CMS. Community cancer clinics historically have been willing to treat patients rather than turn them away or hand them over to a collection agency. However, community cancer clinics now are increasingly unable to subsidize cancer care for seniors covered by Medicare with no secondary insurance coverage.

This analysis does not include pharmacy costs. MedPAC estimated pharmacy costs at 26-28% of total drug costs in analyzing actual costs from outpatient facilities in Maryland. This analysis also does not include the cost of capital in purchasing very expensive cancer drugs or the costs of billing and overhead. Once again, under the AWP-based system these costs were part of drug reimbursement. However, under the ASP-based system only acquisition cost is reimbursed.

Some believe that the Competitive Acquisition Program (CAP) is a solution to drug reimbursement problems. However, CMS has struggled to find only one CAP vendor—after delaying the program because initially there were no vendors—and few if any community cancer clinics will trust an unproven, untested system to deliver the correct drugs on time to their patients. The CAP will create multiple patient inventories, risk treatment errors, and result in treatment delays. Additionally, the CAP will actually increase pharmacy and billing costs because of the procedures, tracking, and record keeping requirements. Analyzing the top reimbursed cancer drugs, COA estimates that Medicare will actually pay over 3% more for drugs to the CAP vendor than to community cancer clinics.

These three problems have resulted in Medicare now becoming the lowest payer for cancer care services. Medicare, with its considerable market clout, has set reimbursement rates artificially low for private payers to follow. In many cases, this is exactly what is happening.

The congressional intent of the MMA was to save Medicare \$4.2 billion from 2004-2013 by changing the reimbursement system for cancer care, according to the Congressional Budget Office in a letter dated November 20, 2003, to Chairman Thomas. Unfortunately, actual implementation by CMS is resulting in substantially more cuts to Medicare reimbursement for cancer care. Exhibit B is a report from PricewaterhouseCoopers that estimates the cuts to cancer care reimbursement to be \$13.8 billion, far in excess of the \$4.2 billion intended by Congress. The graph below shows this discrepancy in projected cuts (congressional intent) versus actual implementation by CMS. The reasons for this discrepancy are the three problems previously outlined in this document.



There is bipartisan recognition of this problem in both the House and the Senate. The entire cancer community supports solutions to this problem. There are currently three bills in the House addressing aspects of this overall problem, including one with over 70 sponsors that was introduced by Congressman Jim Ramstad, a member of the Ways and Means Subcommittee on Health. There is an identical Senate bill that was introduced by Senator Arlen Specter.

Some have suggested waiting to see more substantial patient access problems before fixing the problems with Medicare Part B reimbursement for cancer care. That is simply not acceptable because actual lives of Americans are already being negatively impacted. Furthermore, we risk dismantling a system of cancer care that has been built during the past 15-20 years. Rescuing the cancer care delivery system when it is too late will not be feasible because the damage will be done. Already, the incidence of cancer is increasing while the number of oncologists is flattening. Reimbursement problems should not be motivating older oncologists to retire, which is starting to happen, or discouraging new physicians from pursuing a specialty in oncology, which is also happening at the medical school and fellowship levels.

On behalf of community oncology, we ask the Congress to immediately fix the problems of insufficient Medicare reimbursement for cancer care by at least accomplishing the following:

- Eliminate “prompt payment” discounts from pharmaceutical manufacturers’ calculation of ASP. Prompt payment discounts are financing discounts between the manufacturer and the wholesaler—these are not incentive purchasing discounts to community cancer clinics. Inclusion of these discounts in the ASP calculation artificially lowers Medicare drug reimbursement by approximately 2%.
- Immediately increase Medicare reimbursement for those drugs increased in price by the manufacturer. Community cancer clinics are currently subsidizing Medicare for all drug price increases for 6 months, on average.
- Create payment mechanisms for un-reimbursed services such as treatment planning and pharmacy facilities. Medicare reimbursement needs to more realistically cover the essential services provided to seniors by community cancer clinics.
- Reevaluate existing drug administration payment codes to restore adequate reimbursement that covers the costs of the materials and human resources required to administer drugs.
- Address the growing bad debt problem of Medicare patients without adequate secondary insurance.

An independent analysis of the plight facing community oncology appeared as a research article in the Journal of the National Comprehensive Cancer Network (*Surviving the Perfect Storm: An RVU-Based Model to Evaluate the Continuing Impact of MMA on the Practice of Oncology*; Volume 4, Number 1, January 2006). The authors write, “*The emotional and financial pressures facing the medical oncologist in private practice are enormous, with no relief in sight. The complexity of managing private practice oncology rivals that of managing cancer care.*” “*Will the planned changes in Medicare reimbursement, exacerbated by the loss of operational inefficient medical oncology practices, lead to irreparable changes in the oncology delivery system (e.g., access, availability, continuity, and quality)?*” “*Will the United States abrogate its leadership in clinical cancer care and research and default to a specialty of algorithm followers rather than algorithm creators? Are the unintended consequences of changes in regulation and reimbursement fully appreciated? And lastly and most importantly, what are the risks to the cancer patient resulting from the heuristic approach promulgated by regulators and legislators?*”

Exhibit C presents a sample of quotes received from community cancer clinics across the country.

### Exhibit A

HCPCS	Treatment Description	Total Dose Based 1.7 BSA/68 kg	Admin. Time	Administration Code Description	2003 and 2004 Administration Code	2006 Administration Code	Reimb 2004	Reimb 2006	2004 2006 Diff	2004- 2006% Diff
	<b>CHOP/Rituxan</b>	<b>Non-Hodgkins Lymphoma</b>								
J9000	Adriamycin 50mg/m2	85mg	10minutes	Sequential Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J9370	Vincristine 2mg	2mg	10 minutes	Sequential Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J9070	Cytosan 750mg/m2	1275mg	1hr	Initial IV Chemo Inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
J99310	Rituxan 375mg/m2	637.5mg	3hrs	Seq. IV Chemo Inf + 2hrs	96412 x 3	96417,96415x2	\$144.90	\$162.57	\$17.67	12.19%
J2469	Aloxi 0.25mg	0.25mg	15 minutes	Short infusion	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	15 minutes	In same bag with Decadron	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							<b>\$789.56</b>	<b>\$504.03</b>	<b>-\$285.53</b>	<b>-36.16%</b>
	<b>Folfox 6 + Avastin</b>	<b>Colorectal Cancer</b>								
J9263	Oxaliplatin 100mg/m2	170mg	2hrs	Initial IV Chemo Inf+ 1hr	96410/96412	96413, 96415	\$265.65	\$211.84	-\$53.81	-20.26%
J0640	Lecovorin 400mg/m2	680mg	2hrs	Concurrent IV Infusion	Not coded	90768	\$0.00	\$24.63	\$24.63	
J9190	5FU 400mg/m2	680mg	10 minutes	Sequential Chemo IVP	CCI edit	96411	\$0.00	\$70.87	\$70.87	
J9190	5FU 2400mg/m2	4080mg	46hrs	Continuous Chemo IV inf.	96414-59	96416	\$269.59	\$185.70	-\$83.89	-31.12%
J9035	Avastin 5mg/kg	340mg	1hr	Seq. IV Chemo inf.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20minutes	Seq. IV Infusion	Not coded	90767	\$33.02	\$42.45	\$9.43	28.56%
J1100	Decadron 20mg	20mg	20minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
							<b>\$734.35</b>	<b>\$671.54</b>	<b>-\$62.81</b>	<b>-8.55%</b>
	<b>Carbo/Taxol Low Dose</b>	<b>Lung Cancer, Breast Cancer</b>								
J9045	Carboplatin AUC 2	175mg	1hr	Initial IV Chemo Inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
J9265	Taxol 80mg/m2	136mg	1hr	Seq. IV Chemo inf.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.45	\$42.45	
J1100	Decadron 20mg	20mg	20minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							<b>\$383.44</b>	<b>\$351.31</b>	<b>-\$32.13</b>	<b>-8.38%</b>
	<b>Carbo/Taxol q3weeks</b>	<b>Lung Cancer, Breast Cancer</b>								
J9045	Carboplatin AUC 5	425mg	1hr	Initial IV Chemo Inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
J9265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo Inf + 2hrs	96412 x 3	96417,96415x2	\$144.90	\$162.57	\$17.67	12.19%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.45	\$42.45	
J1100	Decadron 20mg	20mg	20minutes	Piggy backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							<b>\$480.04</b>	<b>\$429.37</b>	<b>-\$50.67</b>	<b>-10.56%</b>



**Exhibit A (continued)**

HCPCS	Treatment Description	Total Dose Based 1.7 BSA/68 kg	Administration Time	Administration Code Description	2004 Administration Code	2006 Administration Code	Reimb 2004	Reimb 2006	2004 2006 Diff	2004- 2006% Diff
	<b>Dose Dense AC-Taxol</b>	<b>Breast Cancer</b>					USA			
J9000	Adriamycin 60mg/m2	102mg	1-3 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J9070	Cytosan 600mg/m2	1020mg	1hr	Initial Chemo inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
J9265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo Inf + 2hrs	96412 x 3	96417,96415x2	\$144.90	\$162.57	\$17.67	12.19%
J2469	Aloxi 0.25mg	0.25mg	10minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	20minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.45	\$42.45	
J2780	Zantac 50mg	50mg	20minutes	Piggy backed with Decadron	Not coded	90768	\$0.00	\$24.63	\$24.63	
							<b>\$634.80</b>	<b>\$500.24</b>	<b>-\$134.56</b>	<b>-21.20%</b>
	<b>TAC</b>	<b>Breast Cancer</b>								
J9170	Taxotere 75mg/m2	127.5mg	1 hr	Initial IV Chemo Inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
J9000	Adriamycin 50mg/m2	85mg	1-3 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J9070	Cytosan 500mg/m2	850mg	1hr	Seq. Chemo Inf.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	10 minutes	In bag with Aloxi	Not coded	Not billed	\$0.00	\$0.00	\$0.00	
							<b>\$538.20</b>	<b>\$355.10</b>	<b>-\$183.10</b>	<b>-34.02%</b>
	<b>Herceptin</b>	<b>Breast Cancer</b>								
J9355	Herceptin 2mg/kg	136mg	1hr	Initial Chemo inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
	<b>Taxol/Herceptin</b>	<b>Breast Cancer</b>								
	Taxol 80mg/m2	136mg	1hr	Initial IV Chemo Inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%
	Herceptin 2mg/kg	136mg	1hr	Seq. Chemo Inf.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J1200	Benadryl 50mg	50mg	15 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							<b>\$383.44</b>	<b>\$284.23</b>	<b>-\$99.21</b>	<b>-25.87%</b>
	<b>Taxol/Gemzar</b>	<b>Lung Cancer</b>								
J9265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo Inf + 2hrs	96410/96412 x2	96417,96415x2	\$313.95	\$162.57	-\$151.38	-48.22%
J9201	Gemzar 1250mg/m2	2125mg	1hr	Initial IV Chemo inf.	96412	96413	\$48.30	\$172.81	\$124.51	257.78%
J2469	Aloxi 0.25mg	0.25mg	5 minutes	Seq. IVP	Not paid	90775	\$0.00	\$26.91	\$26.91	
J1200	Benadryl 50mg	50mg	20minutes	Seq. IV Infusion in one bag	90780	90768	\$117.79	\$24.63	-\$93.16	-79.09%
J1100	Decadron 20mg	20mg	20minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	20minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							<b>\$480.04</b>	<b>\$386.92</b>	<b>-\$93.12</b>	<b>-19.40%</b>
	<b>Gemzar</b>	<b>Pancreatic Cancer</b>								
J9201	Gemzar 1250mg/m2	2125mg	1hr	Initial IV Chemo inf.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.49%

## Exhibit B

President Bush signed the Medicare Modernization Act (MMA) on December 8, 2003. This legislation made significant changes in payment for Part B prescription drugs. Under Section 303 (oncology) of the MMA, Part B drugs, which previously were reimbursed at 95 percent of Average Wholesale Price (AWP), were reimbursed at 85 percent of AWP in 2004 and then, in 2005, reimbursed at a new pricing system called "Average Sales Price" (ASP), under which reimbursement was set at ASP+6 percent. Finally, in 2006 and beyond, physicians will have a choice between providing the drugs and being reimbursed at ASP+6 percent or having these drugs provided by vendors selected in a competitive bidding process.

PricewaterhouseCoopers (PwC), at the request of the Community Oncology Alliance, estimated savings to the Medicare program from changes in Part B reimbursement rates for covered outpatient oncology drugs and oncology-related services under the MMA. Based on the most recent information from the Medicare program, we estimate the savings of \$4.1 billion for the five-year period of 2004-2008 and \$13.7 billion for the ten-year period of 2004-2013 (as shown in Table 1 below).

These estimates are considerably higher than those estimated by the Congressional Budget Office (CBO) in 2003 at the time of enactment of the MMA. CBO estimated savings from Section 303 of the MMA at \$0.9 billion for the 2004-2008 period and \$4.2 billion for the 2004-2013 period, or about one-third PwC's estimate for the same period.<sup>1</sup> The differences in estimates are not surprising. CBO's 2003 estimate was based on their best information at that time, which did not include any specific information on ASP. In constructing our estimate, we had access to actual ASP information for 2005-2006 from the Centers for Medicare and Medicaid Services (CMS).<sup>2</sup>

**Table 1.**  
**Federal Budgetary Cost of the MMA Payment Changes to**  
**Oncology Outpatient Drugs and Biologicals**  
**(Fiscal Years 2004-2013, in \$ billions)**

	2004	2005	2006	2007	2008	2004-2008	2004-2013
PwC's 2006 estimate	0.1	(0.5)	(1.0)	(1.3)	(1.4)	(4.1)	(13.7)
CBO's 2003 estimate	0.1	(0.1)	(0.2)	(0.3)	(0.3)	(0.9)	(4.2)
<i>Difference</i>	(0.0)	(0.4)	(0.8)	(0.9)	(1.1)	(3.2)	(9.5)

PricewaterhouseCoopers estimate, July 10, 2006.

<sup>1</sup> Congressional Budget Office. *H.R. 1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. November 20, 2003.

<sup>2</sup> Our savings estimate does not include indirect effects on the federal outlays for the Medicare Part B premium, Medicare Advantage, and the Medicaid program. CBO did not show these offsets separately for individual sections of the MMA but, instead, folded together all the offsets of dozens of other programs and reported the overall offset.

## **Methodology**

In 2004, Part B oncology drugs were reimbursed at 85 percent of AWP under the MMA, compared to 95 percent of AWP in absence of the MMA. To calculate the spending after the change in drug pricing, we took the drug portion of the baseline and applied the 85 percent in place of the previous 95 percent for branded drugs. This reduced drug spending by \$0.5 billion. However, the reduction in drug payments was offset by the increase in payments to physician fee schedules under the MMA. Consequently, estimated payments in 2004 were virtually unchanged by the MMA.

In 2005, we estimated the new ASP+6 percent pricing system would reduce oncology drug payments by about 30 percent, based on new information from CMS. We applied this percentage to the baseline 2005 drug spending. This price reduction resulted in savings of \$1.8 billion in drug spending. In the meantime, physician fees spending was increased by \$0.4 billion. The combined impact of the MMA on oncology Part B spending would be gross savings of \$1.4 billion. These gross savings would result in fiscal year savings of \$0.5 billion to the Medicare program for 2005 after accounting for behavioral offsets, cost sharing, and conversion from calendar year to fiscal year.

Starting in 2006, physicians will have a choice of whether they purchase drugs and receive the ASP pricing system or have the drugs distributed by vendors selected through a competitive bidding process. We have assumed that all physicians will be reimbursed by the ASP pricing system. This is a conservative estimate of potential savings because our assumption is that Medicare would pay ASP+6 percent rather than the lower competitive amount. In 2006, the reduction in drug spending was estimated at about 35 percent, based on the first three quarters of ASP + 6 percent information. Total impact of the MMA on oncology Part B spending was estimated to be gross savings of \$2.2 billion, or \$1.0 billion in fiscal year savings to the Medicare program after accounting for behavioral offsets and cost sharing.

In 2007 and thereafter, the reduction in drug spending was assumed at 32 percent, the average of that of 2005 and 2006. We have also incorporated in our estimate proposed changes by CMS in work relative value units (RVUs) and practice expense (PE) RVUs affecting payments to physician services. These revisions are proposed to be effective starting January 1, 2007. Specifically, CMS estimated that the combined impact of work and PE RVUs changes would increase oncology physician fee schedules by 3 percent in 2007 (first year of PE transition) and by 2 percent in 2010 with full PE implementation.

We estimated the total savings over the five-year period (2004-2008) to the Medicare program would be about \$4.1 billion and the ten-year period (2004-2013) would be about \$13.7 billion, as reported in Table 1.

## EXHIBIT C

*"On an average we are sending 25-30 patients to the hospital a month for their chemotherapy treatment and growth factor support due to an overwhelming percentage of 20% coinsurance turning into bad debt. Facilities, however, are providing a very limited number of open chairs for patients which means patients are being delayed a week or two waiting on an open chair."*

*"We have only been able to send one patient to our local hospital due to the fact that they are refusing to accept Medicare, Medicaid, self pay, and managed care Medicaid patients based on the following factors: they are not set up for chemotherapy infusion; they do not have the staff needed; and lastly, they are not budgeted for the additional financial burden. We are still in negotiations with these hospitals and will let you know when/if we have a resolution."*

*"We have a practice that is unable to take on every referral. Two years ago we stopped doing second opinions, and rarely had to turn down new patients. This year we have turned down more new patients than ever in the history of our 15 years in this town--we no longer do self-referred patients, and cannot always take on new patients referred by physicians. Thus, we do not take any HMO's or any MediCal. Because chemotherapy is so expensive, we have stopped taking any dual eligibles. Many more patients have been hospitalized for chemo in our town than were three years ago, and that clearly is because the drugs are unaffordable, both to patients and doctors. If one of five Avastin patients fails to pay their 20%, our practice could go out of business."*

*We are looking toward closing one of our offices. We can no longer cover the overhead of the practice due to the inadequate payments of ASP+6%. The other reimbursement schedules are grossly inadequate. We have already cut staff. Medicare D for oncology patients is a catastrophe. Most cannot afford the co-pays on these very expensive drugs. They are priced out of effective medications such as the TK inhibitors, Revlamid, etc. THERE IS A NEW WRINKLE! Medicare is now not denying our claims but "PENDING" all claims for Rituxan, Aranesp, and Herceptin – thus they delay payment for three to four months. This has wiped out all of our money. We cannot purchase any more drugs! We will now be sending all patients to the hospital 10 miles away for chemotherapy. Does Medicare wish to eliminate the private practice of Medical Oncology?*

*"It seems that CMS excluded our specialty number 98 from yet another fix in their system. We still have not been paid from the first oversight which was the 2006 demonstration project, but to add insult to injury, a much worse problem has occurred and it seems that I cannot make any progress no matter what I do. Medicare has been pending all of our claims that include Aranesp, Procrit or Neulasta charges. They request medical records. They pend the entire claim to include any chemo drugs that may be included. We have not been paid this entire year for these drugs. I have stopped sending my claims for these services hoping to prevent this process and hold up on any additional claims."*

*"We did cost analyses on each chemo protocol based on each drug cost and overhead. This was done using our most common secondary reimbursements. Based on this, a list was sent to staff indicating which protocols were underwater. These are the treatments sent out. What was found was that without a secondary, in most cases with Medicare, we were underwater with some exceptions."*

*"We can't afford to treat patients that cannot pay their 20%. Right now 26 of 64 drugs we commonly give are underwater at 100% of Medicare. Also, the hospitals are seeing more and more patients in their outpatient units. We are in a high competition area, and a lot of the Oncologists in this area are sending patients to the hospital for treatment."*

*"When we treat patients without secondary coverage we put a financial burden on these patients. This is not the time to cause more stress; this is the time to allow the patient to heal. One example of financial stress is colon cancer; the treatment cost is \$8,000 every two weeks for 12 treatments. Patient responsibility is 20%, or \$1600 per treatment or \$3,200 per month. If they cannot afford secondary insurance, how can they afford \$3,200 per month for six months (\$19,200)? The clinic is to collect this amount. The clinic is not a collection agency. A pharmacist once said to me as I tried to call in a drug that cost \$1,200, why would I loan the patient a thousand dollars while the government decides to pay me? This \$19,200 is a loan that many times is paid in \$50 and \$100 installments. Maybe the government could loan the money to these patients so we can go back to assisting the patient in health care."*

*"We do see the Medicare only patients for OV and labs but refer them to the hospital for any treatment because most of our drugs will be in the red if we receive only 80% of the Medicare allowable. Most of our patients who only have Medicare do so because they cannot afford a secondary/supplemental – thus, cannot afford or will not pay the co-pay. We service western Kentucky which has a lot of the "working poor" who cannot even afford their employer's healthcare premiums and southern Illinois that is just poor with a very high percentage of Medicaid."*

**CMS-1512-PN-2214 Five Year Review of Work Relative Value Units Under the  
Physician Fee Schedule**

**Submitter :** Mr. William Dwight

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

**Organization :** Dwight Orthopedic Rehabilitation Company

**Category :** Physical Therapist

**Issue Areas/Comments**

**Other Issues**

Other Issues

William H. Dwight, PT  
Dwight Orthopedic Rehabilitation Company  
1432 East Twelve Mile Road  
Madison Heights, MI 48071  
248 544 8779  
Fax: 248 543 0479

August 21, 2006

CMS

RE: Proposed reduction in relative work value units for physical therapy services provided to Medicare Beneficiaries.

To the Policy Makers:

I would like to urge CMS to reconsider proposed cutback in relative value assessments assigned to services provided by physical therapists.

As a Therapist for 26 years, I have only seen growth in the education and skill level of therapists providing care to patients. Our profession has advanced from bachelors to Masters and now Doctorate in Physical Therapy to achieve entry level eligibility. As a result, therapists are able to provide highly skilled and capable services. Further cutbacks in reimbursement for those services is not only inconsistent with advancing skill levels, it also creates an unsustainable reimbursement system to allow our profession to encourage the participation of current and future individuals to choose to become therapists without adequate reimbursement for the services they provide. Individuals will choose other fields where their level of skill and education are commensurate with their ability to make a living.

I fully understand CMS to be fiscally responsibility. I might suggest first looking at abuses as outlined in the OIG report of May 1, 2006.

Please do not punish the highly skilled and educated providers of the physical therapy profession. There is absolutely no objective support to reduce our relative work values.

Thank you for your consideration.

Sincerely,

William H. Dwight, PT

CMS-1512-PN-2214-Attach-1.PDF



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

MAY 1 2006

Washington, D.C. 20201

# 2214

**TO:** Leslie V. Norwalk  
Deputy Administrator  
Centers for Medicare & Medicaid Services

**FROM:** *Brian Tatchell for*  
Stuart Wright  
Deputy Inspector General  
for Evaluation and Inspections

**SUBJECT:** Physical Therapy Billed by Physicians

In 2002, the Office of Inspector General (OIG) initiated work associated with Medicare payments for physical therapy. In October 2003, we reported interim results to your office detailing aberrant billing patterns by certain physicians and carrier efforts to target physicians' physical therapy claims. Since the issuance of our 2003 memorandum, we have completed the results of our medical review of claims paid by Medicare in the first 6 months of 2002 and we have updated our claims data analysis of physicians who show aberrant billing patterns for physical therapy claims.

Based on a simple random sample of 70 physical therapy line items billed by physicians and rendered in the first 6 months of 2002, we found that 91 percent of physical therapy billed by physicians and allowed by Medicare during the first 6 months of 2002 did not meet program requirements, resulting in \$136 million in improper payments. In addition, we analyzed Medicare claims data from 2002 to 2004 and identified aberrances in physicians' billing patterns and unusually high volumes of claims. Finally, based on our review, we identified a number of issues associated with physical therapy billed by physicians under the "incident to" rule.

During the course of our review, the Centers for Medicare & Medicaid Services (CMS) took actions that addressed many of our findings. First, in November 2004, CMS issued a final rule to address the skill level of staff that provides physical therapy "incident to" physician services. Additionally, in May 2005, CMS issued a change request that clarifies CMS policy with respect to physical therapy services (Publication 100-02, Transmittal 36, Change Request 3648). Finally, CMS recently posted provider education materials regarding physical therapy services on its Web site ([www.cms.hhs.gov/providers/therapy/](http://www.cms.hhs.gov/providers/therapy/)). In light of these changes, we have decided not to issue a report that would include formal recommendations to CMS. Instead, we are transmitting this summary of our review in the event that the information will be useful in CMS's review of the physical therapy benefit and future considerations of the "incident to" rule.

## BACKGROUND

Physical therapy is the treatment of functional limitations to prevent the onset and/or slow the progression of physical impairments after an illness or injury. Physical therapy includes: (1) examining patients with impairments, functional limitations, disabilities, or other health-related conditions to determine a diagnosis, prognosis, and intervention; (2) alleviating

impairments and functional limitations by designing, implementing, and modifying therapeutic interventions; and (3) preventing injury, impairment, functional limitation, and disability, including the promotion and maintenance of fitness, health, and quality of life.<sup>1</sup> Common treatments performed in physicians' offices include therapeutic procedures, manual therapy, electrical stimulation, and ultrasound therapy.

Physical therapy billed directly by physicians represented approximately \$158 million out of a total of approximately \$528 million for physical therapy claims billed to the Part B carriers and allowed by Medicare in the first 6 months of 2002. Medicare allows physicians to submit claims for physical therapy that they do not perform personally, as long as the services are an "integral, although incidental, part of the physicians' personal professional services in the course of diagnosis or treatment of an injury or illness."<sup>2</sup> The total allowed for physicians' physical therapy claims has increased from \$353 million in 2002 to \$509 million in 2004, and the number of physicians who billed for more than \$1 million in physical therapy has more than doubled, from 15 to 38 in the same 2-year period.

General provisions of the Social Security Act (the Act) govern Medicare reimbursement of all services, including physical therapy. Section 1862(a)(1)(A) of the Act states that ". . . no payment may be made [under the Medicare title for services that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Specific coverage requirements for physical therapy are in section 1861(p) of the Act, which requires that:

- The patient must be under the care of a physician (a doctor of medicine, osteopathy, optometry, or podiatric medicine).
- The services must be furnished under a plan of care. The plan of care indicates the type, amount, frequency, and duration of the services.
- The plan of care must be recertified periodically by a physician.

The implementing regulations at 42 CFR §§ 410.60 and 410.61 restate these coverage requirements and further specify that the plan of care must include the diagnosis and anticipated goals of the therapy that a physician must recertify every 30 days. Section 2218 of the Medicare Carriers Manual<sup>3</sup> states that the plan of care must contain:

- the patient's significant past history;
- patient's diagnoses that require physical therapy;
- related physician orders;
- therapy goals and potential for achievement;

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<sup>1</sup> For a more complete definition of physical therapy, see American Physical Therapy Association, "Model Definition of Physical Therapy for State Practice Acts in the Guide to Physical Therapy Practice," 1997, chapter 1, p. 2.

<sup>2</sup> Centers for Medicare & Medicaid Services, Medicare Carriers Manual, section 2050.1.

<sup>3</sup> Online Centers for Medicare & Medicaid Services Manual System, Publication 100-2, chapter 15, section 220.2.



- any contraindications;
- patient’s awareness and understanding of diagnoses, prognosis, treatment goals; and
- when appropriate, the summary of treatment provided and results achieved during previous periods of physical therapy services.

Section 1833(e) of the Act requires that providers furnish “such information as may be necessary in order to determine the amounts due” to receive Medicare payment. Related regulations at 42 CFR §§ 411.15(k) and 424.5(a)(6) reflect these provisions of Federal law.

Section 1861(s)(2)(A) of the Act provides for Medicare coverage of services and supplies furnished “incident to” the professional services of a physician. This section defines covered medical and other health services as “. . . services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills.” The implementing regulations at 42 CFR §§ 410.10(b) and 410.26 restate this language. Section 2050 of the Medicare Carriers Manual<sup>4</sup> provides examples of services and supplies covered under the “incident to” rule. Examples of services include taking blood pressures and temperatures, giving injections, and changing dressings. Examples of supplies include gauze, ointments, bandages, and oxygen.

The “incident to” rule allows physicians to bill for physical therapy performed by any nonphysician staff (including, but not limited to, licensed physical therapists). The rule allows physician reimbursement for physical therapy at the full physician fee schedule amount for physical therapy provided by nonphysician staff, if the services are:

- commonly furnished in a physician’s office and are an integral, although incidental, part of the physician’s covered services;
- included in a treatment plan for an injury or illness, where the physician personally performs the initial service and is involved actively in the course of treatment; and
- furnished under the direct supervision of a physician.<sup>5</sup>

Section 1862(a)(20) of the Act permits payment for therapy services furnished “incident to” a physician’s professional services only if the practitioner meets the standards and conditions that would apply to such therapy services if they were furnished by a therapist, with the exception of the licensing requirement. Under the “incident to” rule, licensed physical therapists need not perform the services, and Medicare currently does not require licensure or certification of staff that perform “incident to” physical therapy. However, in all other settings, including nursing homes, independently practicing physical therapists’ offices, and rehabilitation facilities, Medicare requires that only licensed physical therapists can render physical therapy. In addition, licensed physical therapist assistants, performing within their scope of practice, may render Medicare physical therapy under the direct supervision of a physical therapist.

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<sup>4</sup> *Ibid.*, sections 60.1-60.4.

<sup>5</sup> Direct supervision means that the physician must be present within the office suite and immediately available to render assistance in person, if necessary. Physicians do not need to be present in the room when the services are rendered. The incident to” rule does not limit the number of services physicians can bill concurrently (42 CFR § 410.26).

### **Training, licensure, and direct billing for physical therapists**

Physical therapists are college-educated and State-licensed health care professionals. To qualify for a State physical therapy license, candidates must have completed a post-baccalaureate professional education program from an accredited institution.<sup>6</sup> Generally, the education includes a 4-year college degree and at least 2 additional years of full-time study in physical therapy. Therapists must pass a State-administered national examination in order to practice. Additional requirements may vary according to individual State practice acts. For example, in California, physical therapists must complete an additional 18 weeks of clinical experience under the supervision of a licensed physical therapist to become licensed.

To bill Medicare directly, physical therapists must be licensed by the State in which they practice and must adhere to Medicare's coverage guidelines for outpatient physical therapy. Physical therapists can provide services in their own offices, a physician's office, a nursing home, a hospital, or a rehabilitation facility. When physical therapy is rendered "incident to" physicians' professional services, unlicensed individuals can render the services.

In November 2004, CMS issued a final rule to address the skill level of staff that provides physical therapy "incident to" physicians' services. CMS now requires that staff providing these services must meet the same standards and conditions as qualified therapists, with the exception of the licensing requirement. For example, unlicensed staff furnishing "incident to" physical therapy services must meet the existing training standards for licensed physical therapists. In May 2005, CMS issued a change request (Publication 100-02, Transmittal 34, Change Request 3648) that reorganizes and clarifies current CMS policy with respect to physical therapy services. The change request includes:

- clarification of conditions of coverage for physical therapy services;
- descriptions of plan of care, certification, and recertification requirements;
- description of reasonable and necessary requirements;
- description of supervision requirements for physical therapy services; and
- clarification of "incident to" physical therapy services.

In addition, CMS has posted provider education materials regarding physical therapy services on its Web site ([www.cms.hhs.gov/providers/therapy/](http://www.cms.hhs.gov/providers/therapy/)).

### **Previous Office of Inspector General Work**

OIG began reviewing Medicare rehabilitation therapy (including physical therapy) in 1994. Our evaluations, which have focused on therapy provided in physicians' offices and nursing homes, found that significant compliance and quality of care problems persist, including overutilization, services rendered by unskilled staff, and services billed that do not meet Medicare's coverage rules.

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<sup>6</sup> Graduates from 1960 to the present must have graduated from an institution accredited by the Commission on Accreditation in Physical Therapy Education (CAPTE). Beginning in 2002, the CAPTE limited its accreditation to only those programs offering a post-baccalaureate degree in physical therapy.

In 1994, OIG reported that approximately 78 percent of physical therapy rendered in physicians' offices did not represent true physical therapy, as defined by Medicare.<sup>7</sup> The services were mostly palliative in nature or did not represent the complexity required by Medicare's coverage guidelines.

In 1999, OIG issued two reports<sup>8</sup> addressing therapy provided to Medicare beneficiaries in skilled nursing facilities during 1998, prior to implementation of the prospective payment system. We found that while most nursing home patients were proper candidates for physical and occupational therapy, approximately 13 percent of the services were billed improperly. These improper billings represented almost \$1 billion reimbursed to nursing homes in 1998.

In 2001, OIG issued two reports<sup>9</sup> addressing physical therapy for nursing home patients. We found that the \$1,500 financial limitation on therapy in 1999 did not prevent nursing home patients from receiving necessary and appropriate services. We also found that, despite the limitation, 14 percent of the therapy (representing \$28 million during the first 6 months of 1999) was not medically necessary.

## **METHODOLOGY**

We used multiple methodologies to accomplish our objectives:

1. medical review of a random sample of claims,
2. analysis of Medicare claims and billing patterns, and
3. interviews with physicians in our sample and Medicare carrier personnel.

For this review, we selected a simple random sample of 70 physical therapy line items billed by physicians and rendered in the first 6 months of 2002. We eliminated two line items from our sample because one line item was for respiratory therapy and a physician we could not locate submitted the other. The total allowed amount in our sample of 68 line items was \$2,176.62. We selected the line items from the population of all line items billed by physicians with service dates between January 1 and June 30, 2002.<sup>10</sup> We selected line items in order to project our findings to the total Medicare allowed amounts for physicians' physical therapy during the sample timeframe.

A line item is a single current procedural terminology (CPT) code within the claim; however, it may reflect multiple units of the same procedure. For example, CPT 97110 represents a therapeutic procedure, one or more areas, each 15 minutes. The line items ranged from one to

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<sup>7</sup> Office of Inspector General, "Physical Therapy in Physicians' Offices," OEI-02-90-00590.

<sup>8</sup> Office of Inspector General, "Physical and Occupational Therapy in Nursing Homes: Medical Necessity and Quality of Care" (OEI-09-97-00121) and "Physical and Occupational Therapy in Nursing Homes: Cost of Improper Billings" (OEI-09-97-00122), both issued in August 1999.

<sup>9</sup> Office of Inspector General, "Physical, Occupational, and Speech Therapy for Medicare Nursing Home Patients: Medical Necessity, Cost, and Documentation Under the \$1,500 Caps" (OEI-09-99-00560) and "Physical, Occupational, and Speech Therapy for Medicare Nursing Home Patients: Medical Necessity and Quality of Care Based on the Treatment Diagnosis" (OEI-09-99-00563), both issued in August 2001.

<sup>10</sup> The total population of line items is 5,669,575 representing \$164.4 million.

three units each (15 to 45 minutes). Each line item, regardless of the number of units, is weighted equally when we report aggregate claim percentages. We used the actual allowed amount for each line item, which reflects the number of units for each CPT code to estimate total allowed Medicare dollars. A claim may contain multiple line items with multiple units. Throughout this report, we use the term “claim” to refer to single physical therapy line items (a single CPT code).

We requested complete medical records from the physicians for each beneficiary for the dates reflecting the physical therapy episode of care during which the sampled claim was rendered. In addition, we requested the Medicare billing records, physician and staff schedules for each day the beneficiary received medical services, and all licenses and credentials for the staff that provided services to the beneficiary. The episodes of care varied in length and occurred from July 2001 through December 2002. We made four requests for the records. We received 54 valid responses (79 percent). The confidence intervals at the 95 percent level are in Appendix A.

We contracted with licensed physical therapists to review each service according to a standard protocol, which was based on Medicare coverage guidelines and requirements. The review instrument solicited information about the beneficiary’s physical therapy as a whole and about the individual sampled service in particular. This enabled the reviewers to determine if the services billed to Medicare were covered and properly documented. This level of information would not generally be available to carriers unless they were to conduct a comprehensive medical review of a particular physician or patient.<sup>11</sup> After completing their review, the contractors returned the completed instruments to us for data entry. We analyzed the medical review results using the statistical software packages SAS and SUDAAN.

When we requested medical records from a physician and received no response after four requests, we considered the claim undocumented. This is consistent with 42 CFR § 424.5(a)(6), which states that Medicare providers must furnish to the Medicare carriers sufficient information to determine whether or not payment is due. In our final written request to the physicians, we informed them that if we did not receive the requested documentation, we would not be able to confirm the appropriateness of payment, and we would refer the matter to the appropriate Medicare carrier for resolution. Carriers could collect overpayments from the physicians and determine if fraud or abuse investigations are warranted.

#### **Data Analysis and Interviews**

We analyzed all physicians’ Medicare Part B physical therapy claims for 2002, 2003, and 2004. We analyzed and reviewed physicians’ billing patterns. Our analysis included:

- total allowed amounts for physicians’ physical therapy;
- total allowed amounts for physical therapy per physician;
- total allowed amounts for physical therapy per beneficiary;
- geographic dispersion of Medicare’s physical therapy; and

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<sup>11</sup> We recognize that our methodological approach differs from that of CMS’s Comprehensive Error Rate Testing (CERT) program. The CERT paid claims error rate is based on the review of a single claim, while our review elicited information about the beneficiaries’ episode of physical therapy care in addition to an evaluation of the individual sampled service.

- relationships among physicians, including physicians who share the same beneficiaries with other physicians.

We interviewed, in person and by telephone, selected Medicare Part B carriers that have conducted reviews and investigations of physicians' physical therapy claims. The carriers provided summaries of their work, including the total dollar amounts for therapy that was paid inappropriately.

We conducted telephone interviews with 32 of the 54 physicians who responded to our medical record request and consented to an interview. We asked to what extent they personally render physical therapy and who on their staff render physical therapy.

## 2002 MEDICAL REVIEW RESULTS

**Ninety-one percent of physical therapy billed by physicians and allowed by Medicare during the first 6 months of 2002 did not meet program requirements, resulting in \$136 million in improper payments.** During the first 6 months of 2002, Medicare allowed approximately \$158 million for physical therapy billed by physicians (Table 1). Based on our medical review, 26 percent of the therapy during this period was not medically necessary, and 34 percent was undocumented. Fifty-seven percent of the services were furnished under incomplete plans of care or had no plan of care documented. All of the services that were not medically necessary also were furnished under incomplete plans of care or had no plans of care documented.

Type of error	Sample		Projected	
	Services	Allowed Amount	Services (Percent)	Allowed Amount (Millions)
<b>Not medically necessary</b>	<b>18</b>	<b>\$455.65</b>	<b>26%</b>	<b>\$33.0</b>
Undocumented:				
-Nonresponse	14	466.58	*	*
-Missing documentation	9	209.56	*	*
<b>Total undocumented</b>	<b>23</b>	<b>\$676.14</b>	<b>34%</b>	<b>\$49.0</b>
Incomplete/No plan of care:				
-Incomplete plan of care	23	\$802.40	34%	\$58.2
-No plan of care	16	\$397.50	24%	\$28.8
<b>Total incomplete/no plan of care</b>	<b>39</b>	<b>\$1,199.90</b>	<b>57%</b>	<b>\$87.0</b>
<b>Overlapping errors</b> (Both not medically necessary and incomplete/no plan of care)	<b>(18)</b>	<b>(\$455.65)</b>	<b>&lt;26%&gt;</b>	<b>&lt;\$33.0&gt;</b>
<b>Total</b>	<b>62</b>	<b>\$1,876.04</b>	<b>91%</b>	<b>\$136.0</b>

Source: Medical Review of Physical Therapy Billed by Physicians January to June 2002.

\* Indicates the n for that cell is too small to reliably project. Totals may not equal the sum of individual rows due to rounding.

Not medically necessary. Pursuant to section 1862(a)(1)(A) of the Act, services that are not reasonable and necessary are not covered by Medicare. Twenty-six percent of the physical therapy billed by physicians and allowed in the first 6 months of 2002, totaling \$33 million, did not meet Medicare criteria for medical necessity. Medical reviewers found that there were no objective bases for care, no identified outcomes, and/or no change in the patients' conditions to justify ongoing therapy.

Undocumented. Physicians did not provide substantiating documentation for approximately 34 percent of the services billed to Medicare. Despite repeated requests, we did not receive the medical records related to 14 of the services in our sample. The physicians who billed for an additional nine of the services provided us with records that did not substantiate that any service was rendered on the date claimed. Based on these findings, we estimate that Medicare may have allowed approximately \$49 million during the first 6 months of 2002 for undocumented physical therapy services billed by physicians. Although some cases of missing documentation may be attributable to billing errors (e.g., putting the wrong date on the claim form), others might represent services not rendered. In any case, claims for services that lack sufficient documentation to show that care was provided do not meet the requirements of section 1833(e) of the Act.

No plan/incomplete plan of care. Separate from the completely undocumented services previously discussed, 57 percent of physical therapy services were furnished without a plan of care or under an incomplete plan of care, contrary to the requirements of section 1861(p) of the Act. Approximately 24 percent of the services were furnished under no plan of care, and 34 percent were furnished under incomplete plans.<sup>12</sup> The incomplete plans did not contain information concerning the amount, frequency, or duration of the therapy, and/or physician certification. When projected to the national population of therapy billed by physicians, we estimate the services furnished without a plan of care or under an incomplete plan of care represent \$87 million that Medicare allowed during the first 6 months of 2002.

Overlapping errors. All of the services that were not medically necessary also were furnished under incomplete plans of care or had no plans of care documented.

**Because of inadequate documentation, reviewers had difficulty assessing the quality of the therapy services.** Reviewers could not assess the quality of care for 33 of the 54 records they reviewed. However, 12 records contained enough documentation for the reviewers to question the quality of care and note that some services “lacked an objective basis for care.” They also noted that massage therapy alone, which was the only service provided in three cases, is not considered “a skilled intervention or restorative care.”

Most medical records did not indicate the skill level of the individual who rendered the therapy. The reviewers could not determine the skill level of the staff who rendered physical therapy in 32 of the 54 records. Persons with the appropriate skill levels, including physicians, physical therapists, and physical therapist assistants appear to have rendered the services in 18 of the 54 records. Persons who lacked appropriate skill levels,<sup>13</sup> such as an acupuncturist, a “certified

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<sup>12</sup> These approximations total 58 percent due to rounding.

<sup>13</sup> According to the judgment of our medical reviewers.

disability examiner,” a massage therapist, and a physical therapist aide, appear to have rendered the services for four of the claims.

Of the 32 physicians we interviewed, 24 told us that their staff render some or all of the physical therapy for which they bill Medicare. According to these physicians, therapy in their offices is rendered by:

- podiatrists,
- chiropractors,
- physical therapists,
- physical therapist assistants,
- massage therapists, and
- physical therapist aides.

Fourteen of the physicians we interviewed reported that they personally render some or all of the therapy for which they bill; however, we could not verify through Medicare claims data what proportion of the physicians’ physical therapy claims were rendered personally by the physician.

*Some physicians in our sample billed Medicare for extensive physical therapy without developing a plan of care.* Twenty-three of the fifty-four beneficiaries in our sample received physical therapy with no plan of care. These beneficiaries received a mean average of 30 days of physical therapy in 2002 from the physicians in our sample. Medicare allowed a mean average of \$2,691 for each beneficiary for physical therapy from the physicians in our sample. In total, physicians for these 23 beneficiaries billed physical therapy for more than 8,000 beneficiaries in 2002 for which Medicare allowed approximately \$7.8 million.

One beneficiary in our sample received 15 months of physical therapy for lumbago and osteoarthritis, for which Medicare allowed \$39,126. The beneficiary’s physician did not document a plan of care and did not establish medical necessity for the services. The physician, a general practitioner, billed physical therapy to Medicare for 672 patients in 2002, an average of 27 patients per day. In 2002, Medicare allowed \$752,531 for this physician’s physical therapy claims.

## **ANALYSIS OF PHYSICIAN BILLING PATTERNS FOR PHYSICAL THERAPY**

We identified aberrances in physicians’ billing patterns and unusually high volumes of claims that suggest physical therapy is vulnerable to abuse. Using 100 percent of Medicare’s claims data for 2002, 2003, and 2004, we analyzed physicians’ billing patterns for physical therapy. The following are examples of what we found that raise questions about physicians’ physical therapy billing patterns:

- Approximately 4 percent of all physicians who submitted physical therapy claims account for more than half of all allowed claims in 2004 (Table 2).
- Medicare allowed between \$1 million and \$7.6 million in physical therapy claims for each of 15 physicians in 2002, 29 physicians in 2003, and 38 physicians in 2004. (See Appendix B.)

- For an additional 992 physicians, Medicare allowed more than \$100,000 each in physical therapy claims alone in 2004.
- One hundred thirty-four physicians each billed Medicare for physical therapy for more than 500 patients in 2004. In contrast, the median number of patients receiving physical therapy for the entire physician population (that rendered physical therapy in 2004) is eight. Of the 134 physicians, 97 shared at least 50 of their patients with another of the 134 physicians who also billed physical therapy for the same patient.
- We identified 13,090 beneficiaries whom Medicare allowed at least \$5,000 each in physical therapy billed by physicians in 2004. In contrast, for the entire beneficiary population, Medicare allowed a median of \$305 each for physical therapy billed by physicians in 2004.
- The aberrances in billing patterns we observed cannot be explained by the specialties of providers who bill for excessive services. For example, only 4 of the 51 physicians who billed Medicare more than \$1 million for physical therapy in 2002, 2003, or 2004 were physical medicine and rehabilitation or osteopathic manipulative therapy specialists. (See Appendix B.)

**Table 2: Selected Statistics for Physical Therapy Billed by Physicians in 2004 by Categories of Medicare Allowed Amounts**

Allowed per physician	\$1 to \$99,999	\$100,000 to \$499,999	\$500,000 to \$999,999	\$1 million or more
Total physicians	23,777	885	107	38
Percent of physicians	95.85%	3.57%	0.43%	0.15%
Percent of allowed physical therapy	38.85%	34.26%	13.92%	12.97%
Median allowed per physician	\$987	\$163,127	\$623,091	\$1,419,803

Source: Office of Inspector General analysis of Medicare claims data, 2005.

### THE “INCIDENT TO” RULE

Physicians are not required to indicate on their claims if services were rendered “incident to” their professional services, and thus, the claims appear as if the physician personally rendered the services. Therefore, in our medical review and our analysis of billing patterns, we could not measure the proportion of physicians’ claims that were rendered “incident to” nor could we determine whether qualified therapists rendered the service.

Under the “incident to” rule, a physician can bill for an unlimited amount of physical therapy rendered at the same time, as long as the physician is “directly supervising” the staff rendering the services. However, based on the medical record documentation provided by the sampled physicians, we could not confirm that physicians directly supervised the provision of the service because they are not required to document “direct supervision” of therapy. In our analysis of billing patterns, we found that some physicians are billing physical therapy for dozens of beneficiaries daily, but we could not determine how many receive therapy at the same time, and therefore could not determine whether direct supervision for all of these services was physically possible. For example, 1 physician in our sample billed Medicare for physical therapy for an



average of 51 patients per day in 2002. Among all physicians who billed Medicare for physical therapy in 2002,<sup>14</sup> 110 billed at least once for more than 50 patients per day.

Finally, under Medicare, although staff that render physical therapy “incident to” physicians’ services need not be licensed, they are required to adhere to the same standards of care<sup>15</sup> as independently practicing physical therapists. However, because physicians’ medical records were documented inadequately, we could not confirm their compliance with these standards of care.

## **CONCLUSION AND ITEMS FOR CONSIDERATION**

Under the “incident to” rule, Medicare allows physicians to bill for physical therapy that is rendered either by the physicians themselves or by their staff. Until 2005, staff who rendered physical therapy in physicians’ offices did not have to be trained or licensed. In 2005, CMS implemented a regulation that requires staff who render physical therapy in physicians offices have the same training as licensed physical therapists. They still do not need to be licensed. In addition, under the “incident to” rule, there is no limit on the number of therapy staff that physicians can supervise concurrently. These conditions represent a vulnerability that could partially account for the noncovered and undocumented care described above and could be placing beneficiaries at risk of receiving services that do not meet professionally recognized standards of care. Therefore, we believe that the requirements for physical therapy rendered in physicians’ offices, including licensure, should not differ with the requirements for therapy rendered in other settings, such as independently practicing physical therapists’ offices and nursing homes.

In addition, given the vulnerabilities identified in our medical review as well as our analysis of physician billing patterns for physical therapy, CMS should consider revisions, clarifications, and further study of the “incident to” rule to ensure that Medicare beneficiaries are receiving skilled services from appropriately trained and licensed staff and that the services meet professionally recognized standards of care. Under separate cover, we will forward information on the noncovered and undocumented services identified in our sample to CMS for appropriate action.

We plan to continue to monitor Medicare payments for physical therapy and will conduct additional reviews in this area as warranted.

If you have any questions about this summary of our review, please do not hesitate to call me or one of your staff may contact Tricia Davis, Director, Medicare and Medicaid Branch, at (410) 786-3143 or through e-mail [Tricia.Davis@oig.hhs.gov].

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<sup>14</sup> This includes, but is not limited to, the physicians who appeared in our random sample of claims.

<sup>15</sup> Effective June 6, 2005, CMS requires that staff providing physical therapy “incident to” physicians’ services must be graduates of a qualified program of training in physical therapy. (Online CMS Manual System, Publication 100-02, chapter 15, section 230.5. Accessed November 21, 2005.)

APPENDIX A

Confidence Intervals for Selected Statistics

Selected Statistics		Estimates		Estimated Allowed Services (percent)		Estimated Allowed Dollars (in millions)	
Estimates	Point Estimate (in millions)	Lower	Upper	Lower	Upper	Lower	Upper
What Medicare allowed	100%	\$157.8				\$148.5	\$167.1
Inappropriately paid services	91.2%	\$136.0	84.4%	98.0%		\$115.8	\$156.3
-Not medically necessary	26.4%	\$33.0	15.9%	37.0%		\$15.7	\$50.4
-Undocumented services	33.8%	\$49.0	22.5%	45.2%		\$29.2	\$68.8
-Incomplete or no plan of care	57.4%	\$87.0	45.5%	69.2%		\$64.2	\$109.8

Source: Office of Inspector General analysis of Medicare claims data, 2005.

**APPENDIX B**

**Physician Profiles: Physicians Allowed More Than \$1 Million for Physical Therapy Claims in 2001 and 2002**

Physician		Total Part B Allowed Physical Therapy Claims			Part B Beneficiary Statistics (2004)	
No.	Specialty	2002	2003	2004	Total Beneficiaries Who Received Physical Therapy	Average Allowed Physical Therapy Claims Per Beneficiary
1	Internal Medicine	\$ 1,876,782	\$ 2,067,335	\$ 3,901,621	389	\$ 10,030
2	Osteopathic Manipulative Therapy	\$ 163	\$ 1,727,941	\$ 3,873,463	221	\$ 17,527
3	Pediatric Medicine	\$ -	\$ 260,663	\$ 3,569,459	138	\$ 25,866
4	Family Practice	\$ 378,670	\$ 742,025	\$ 3,160,019	328	\$ 9,634
5	Internal Medicine	\$ 137,437	\$ 2,355,194	\$ 2,991,062	251	\$ 11,917
6	Internal Medicine	\$ 174,925	\$ 1,379,520	\$ 2,770,288	198	\$ 13,991
7	Family Practice	\$ 414,089	\$ 2,943,860	\$ 2,745,495	131	\$ 20,958
8	Obstetrics/Gynecology	\$ -	\$ -	\$ 2,304,814	185	\$ 12,458
9	Family Practice	\$ 1,282,524	\$ 7,629,540	\$ 2,021,617	456	\$ 4,433
10	Internal Medicine	\$ 1,414,012	\$ 1,698,609	\$ 1,775,549	400	\$ 4,439
11	Internal Medicine	\$ -	\$ -	\$ 1,765,782	103	\$ 17,144
12	Physical Medicine and Rehabilitation	\$ 377,629	\$ 1,328,291	\$ 1,683,338	699	\$ 2,408
13	Family Practice	\$ -	\$ 549,832	\$ 1,675,719	980	\$ 1,710
14	General Practice	\$ -	\$ 152,757	\$ 1,671,809	899	\$ 1,860
15	Family Practice	\$ 5,395	\$ 6,368	\$ 1,620,016	577	\$ 2,808
16	Family Practice	\$ 809,255	\$ 150,485	\$ 1,604,205	717	\$ 2,237
17	General Practice	\$ 421,882	\$ 610,184	\$ 1,578,111	751	\$ 2,101
18	Internal Medicine	\$ 638,291	\$ 1,609,510	\$ 1,496,640	278	\$ 5,384
19	Family Practice	\$ 1,354,725	\$ 2,237,009	\$ 1,445,758	112	\$ 12,909
20	Internal Medicine	\$ 519,960	\$ 1,010,853	\$ 1,393,847	62	\$ 22,481
21	Internal Medicine	\$ 2,016,524	\$ 1,631,839	\$ 1,338,885	510	\$ 2,625
22	Family Practice	\$ 945,352	\$ 1,665,354	\$ 1,319,578	1564	\$ 844
23	General Practice	\$ 452,046	\$ 1,183,474	\$ 1,278,525	742	\$ 1,723
24	Physical Medicine and Rehabilitation	\$ 99,221	\$ -	\$ 1,273,308	622	\$ 2,047
25	Internal Medicine	\$ 327,561	\$ 1,068,519	\$ 1,247,487	585	\$ 2,132
26	General Surgery	\$ 290,313	\$ 755,328	\$ 1,234,159	841	\$ 1,467
27	Family Practice	\$ 1,170,425	\$ 1,234,733	\$ 1,222,831	663	\$ 1,844
28	Family Practice	\$ 1,432,369	\$ 1,762,887	\$ 1,214,077	925	\$ 1,313
29	General Practice	\$ -	\$ 51,062	\$ 1,149,140	464	\$ 2,477
30	Family Practice	\$ -	\$ 3,613	\$ 1,122,661	869	\$ 1,292
31	Internal Medicine	\$ 1,097,949	\$ 1,110,347	\$ 1,116,834	311	\$ 3,591

## APPENDIX B

## Physician Profiles: Physicians Allowed More Than \$1 Million for Physical Therapy Claims in 2001 and 2002 (continued)

Physician		Total Part B Allowed Physical Therapy Claims			Part B Beneficiary Statistics (2004)	
No.	Specialty	2002	2003	2004	Total Beneficiaries Who Received Physical Therapy	Average Allowed Physical Therapy Claims Per Beneficiary
32	General Practice	\$ -	\$ 2,252	\$ 1,110,650	702	\$ 1,582
33	General Practice	\$ 160,478	\$ 56,733	\$ 1,099,092	527	\$ 2,086
34	General Practice	\$ 756,197	\$ 1,004,757	\$ 1,072,267	648	\$ 1,655
35	Osteopathic Manipulative Therapy	\$ 108	\$ 360,466	\$ 1,043,992	84	\$ 12,428
36	Internal Medicine	\$ 109,675	\$ 477,074	\$ 1,039,833	331	\$ 3,141
37	Ophthalmology	\$ 652,059	\$ 1,097,927	\$ 1,022,585	267	\$ 3,830
38	Internal Medicine	\$ 50,956	\$ 287,431	\$ 1,003,409	670	\$ 1,498
39	Internal Medicine	\$ 1,167,398	\$ 1,201,513	\$ 939,284	450	\$ 2,087
40	Internal Medicine	\$ 115,999	\$ 1,029,026	\$ 873,985	341	\$ 2,563
41	Internal Medicine	\$ 1,073,827	\$ 514,978	\$ 563,536	386	\$ 1,460
42	General Practice	\$ 921,636	\$ 1,090,810	\$ 525,272	565	\$ 930
43	Internal Medicine	\$ 1,203,828	\$ 2,056,425	\$ 301,632	343	\$ 879
44	Family Practice	\$ 407,647	\$ 2,124,714	\$ 300,544	217	\$ 1,385
45	Internal Medicine	\$ 1,283,553	\$ 230,010	\$ 100,357	129	\$ 778
46	General Practice	\$ 1,725,638	\$ 1,318,579	\$ 80,004	711	\$ 113
47	General Practice	\$ 732,566	\$ 1,165,387	\$ 52,367	55	\$ 952
48	Internal Medicine	\$ 1,088,169	\$ 808	\$ 5,368	12	\$ 447
49	Family Practice	\$ 589,697	\$ 1,382,912	\$ 131	1	\$ 131
50	General Practice	\$ 1,878,761	\$ -	\$ -	0	\$ -
51	Internal Medicine	\$ 2,362	\$ 1,605,499	\$ -	0	\$ -
	<i>Averages</i>	\$ 595,510	\$ 1,055,442	\$ 1,315,178	439	\$ 5,129
	<i>Totals</i>	\$ 31,562,055	\$ 55,938,437	\$ 69,704,410	18,887	

Source: Office of Inspector General analysis of Medicare claims data, 2005.