**Submitter :** **Mrs. Carol Knieriem** **Date: 08/21/2006**

**Organization :** **Mrs. Carol Knieriem**

**Category :** **Social Worker**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Carol Knieriem
1500 Union Street
Manchester, NH 03104
August 21, 2006

Re: CMS-1512-PN
Dear Sirs;

I am writing to the proposed notice on the Physicians Fee Schedule and the 14% reduction in reimbursement you are proposing for social workers.

I am in a practice associated with our local hospital. Social Workers are the only providers who are able to see Medicaare clients for therapy. If the reimbursement rate is reduced lower than it already is, it will not be financially possible for us to see these clients. The psychiatrists do not provide therapy and so these clients may get medication but they will not receive therapy. Most people don?t need medication. They need practical help, someone to listen and workout issues. Also best practice is therapy and medication when it is prescribed.

I sincerely hope you will withdraw the proposed increase in evaluation and management codes until you have the funds to increase payment for all Medicare providers. Please do not select a formula that penalizes Social Workers.

I am a medicare client and I?ve been impressed with this program but I will not have the same opinion if you implement this change because I know what a disservice you will do to those of us on medicare.

Sincerely,
Carol Knieriem

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

**Organization :**

**Category :** **Other Practitioner**

**Issue Areas/Comments**

**Other Issues**

Other Issues

I am writing as a physical therapist assistant and as someone who may be a Medicare client in the next ten years or so. I am concerned about some of the legislation which in place and is being considered to cut payments for physical therapy services. I am especially concerned with the June 29th proposed noice that sets forth proposed revisions to work relative units and revises the methodology for calculating practice expense RVUs under the Medicare physician fee schedule.

I am urging that severe Medicare payment cuts do not take place in 2007. As a physical therapist assistant I have seen the hardship that limitations in rehabilitation can lead to for our seniors. These include extensive pain which limits function, the lack of function caused by stiff joints which have not been treated after surgeries, and weakness caused by the aging and disease process in general not addressed by exercise as offered by allied health professionals. All of these conditions often lead to the deteriorating health and loss of autonomy of our clients. Many of these people end up in our hospitals and long term care facilities suffering from fractures, pneumonia, urinary tract infections and bed sores due to deconditioning, loss of function, or balance deficits.

I would ask that you and your colleagues transition the changes to the work relative value units over a four year period to ensure that these patients continue to have access to valuable health care services.

Thank you.

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

**Organization :** Kidney Care Partners

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please See Attachment

CMS-1512-PN-2097-Attach-1.DOC

Attachment
2097


August 21, 2006

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

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); Notice

Dear Dr. McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

KCP's comments will address the implementation of RVU revisions to evaluation and management (E&M) service codes and our recommendations for the potential use of these revised values to determine RVU levels for nephrologist services provided to dialysis patients. We will also discuss the potential ramifications of the proposed physician payment revisions on vascular access services provided to kidney patients.

[1] A list of Kidney Care Partners coalition members is included in Attachment A.

## I. KCP SUPPORTS REVISIONS FOR EVALUATION AND MANAGEMENT SERVICES

KCP agrees with the Agency's decision to incorporate the recommendations from the American Medical Association's Relative Value Update Committee (RUC) into the work RVUs for E&M services. We believe the values proposed in the Five-Year Review notice more appropriately replicate the actual physician work involved when nephrologists provide these services to dialysis patients. Further, we are encouraged by the proposed increases in E&M services. These changes should encourage physicians to provide care earlier to patients with chronic kidney disease (CKD). If early stages of CKD are managed correctly, the progression to kidney failure can be significantly delayed. We are pleased with this policy change because it recognizes a more appropriate way to allocate Medicare funds and represents a step forward in the care and treatment of patients with chronic illness, such as CKD.

KCP supports the Renal Physicians Association (RPA) recommendation that outpatient and inpatient dialysis services that use E&M codes as "building blocks" or components of their valuation should have the full increases for the E&M codes incorporated into their values as well. The monthly dialysis codes should be revised to correspond to the sum of their E&M building blocks based on the mid-level adult G-code (G-0318) and extrapolated proportionately to other codes in the family. The inpatient dialysis code should be revised upward to reflect the increases of their E&M elements. These services are surrogates for the E&M care that would be provided to dialysis patients in the absence of these services. These changes are necessary because there are a limited number of nephrologists who serve this critically ill population. It is consistent with the intent and spirit of the RUC recommendations and the CMS notice to apply the E&M code increases to both the outpatient and inpatient dialysis codes.

## II. KCP IS CONCERNED ABOUT PROPOSED REDUCTIONS BECAUSE THEY THREATEN THE GOALS OF THE FISTULA FIRST INITIATIVE

KCP is extremely concerned about the potential impact of changes included in the notice on vascular access services commonly provided to kidney patients. These services play an integral role in the Agency's Fistula First Program, which is intended to ensure that kidney patients receive the most optimal form of vascular access and to avoid complications through appropriate monitoring and intervention. If implemented, the proposed changes for 2007 would reduce the reimbursement for these services roughly 5 to 8 percent.

Although we understand that some of the reductions are due to changes required by the Deficit Reduction Act (DRA) that seek to ensure more appropriate payment for imaging services, we are extremely concerned that this proposal misaligns the goals and incentives established in the Fistula First Program. We support a more thorough review

of the utilization of services in this domain and realize that CMS is severely limited in its ability to pick and choose which physician services the DRA provisions would apply to in the face of the broad brush of legislative direction. Nonetheless, we urge the Agency to recognize the misalignment of these changes and the goals of the Fistula First initiative. If not changed, the proposal will create a disincentive to provide the necessary services related to vascular access. KCP encourages CMS to seek creative methods for administratively addressing this problem.

KCP members appreciate your review of our concerns and look forward to working with the Agency on issues affecting the care provided to the nation's kidney patient population. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have questions regarding these comments.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

4824824
4823636v1

**ATTACHMENT A.**
**COALITION MEMBERS**

**Kidney Care Partners:**

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

**Submitter :** Dr. John Acquaye-Anay **Date:** 08/21/2006

**Organization :** Joint Letter from 47 Physicians

**Category :** Physician

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

See attachment

CMS-1512-PN-2098-Attach-1.DOC

Attach #
2098

August 18, 2006

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

**RE: Practice Expense RVU for CPT 93701 / 93701-TC**

To whom it may concern:

This letter is a joint comment by a total of 47 multi-specialty physicians in response to the five-year review of work relative value units under the physician fee schedule. We are very concerned about how the proposed changes would affect **CPT code 93701-TC**, thoracic electrical bioimpedance. This procedure is most often billed in the outpatient setting and under the global CPT code, 93701. CMS has proposed a fully-implemented RVU value of 0.64 for the practice expense component of CPT 93701-TC. This RVU value would result in a large reduction in payment and significant hardships for CMS providers offering this service and would therefore significantly hurt CMS beneficiaries. Our specific concerns with your proposed changes are noted below:

1. **Direct Expense – Equipment - Utilization Rate Assumption for CPT 93701-TC**
   CMS has stated that the proposed change to a "bottom-up" methodology is to make payments more fair and accurate and based on the actual costs incurred in providing a service. To do this, CMS has used unique cost inputs for equipment, supplies, and labor for each procedure code. This approach appears to be intuitive as each procedure has different costs for these inputs. However, in the calculation of the direct expense for equipment for each procedure, CMS has assumed that each procedure has a similar utilization rate of 50%. This approach is significantly flawed because equipment utilization varies significantly between different types of equipment. Because the utilization rate is the most significant driver of the per-procedure equipment direct expense calculation, using the same 50% utilization rate for all equipment leads to inaccurate and unfair expense calculations for equipment that is used less than 50% of the time.

   CPT code 93701-TC is an excellent example of how this flawed assumption leads to unfair and inaccurate calculations of direct expense for equipment. The actual utilization rate for CPT 93701 and other procedures can calculated by: 1) calculating the average frequency the procedure is performed per year by dividing the frequency that the global code is billed per year by the number of physicians billing the code; 2) calculating the use in minutes per year by multiplying the average frequency per year times 20 minutes (the current CMS input for equipment procedure time); 3) calculating the actual frequency rate by dividing the use in minutes per year by 150,000 (CMS input for total potential minutes of use per year). We believe that the average practice billing CPT 93701 uses it one to three times per day, or an average of two times per day. This represents a range of 20 to 60 minutes of actual use in an ten hour day, or a utilization rate ranging from 3.3% (20 / 600 minutes) to 10% (60/600). At the expected utilization of two times per day, the utilization rate would be 6.6% (40/600). Using all other inputs currently in place, this would equate to a $19.05 unadjusted direct expense for equipment for this procedure. However, with the current equipment cost input of $28,625 and presumed-but-incorrect utilization rate of 50%, the unadjusted direct expense for equipment is $2.51. This means CMS has underestimated the equipment cost by 87% [(19.05 – 2.51)/19.05]! If more accurate utilization rates were used, the direct equipment expense would be much more appropriate and closer to actually being able to pay for the equipment price. A typical lease for this equipment is $900 per month. To illustrate the absurdity of the current $2.51 equipment

component, this means that the test must be performed 358 times in one month to pay the lease payment (900/2.51). **We propose that CMS use variable utilization rates for each procedure that are updated each year. We also propose that for CPT code 93701-TC the utilization rate for 2007 be equivalent to use of two procedures per day, or approximately a 6.6% utilization rate in your equipment calculation.**

2. **Direct Expense – Equipment – Equipment Price Input for CPT 93701-TC**
   The total equipment cost for CPT 93701-TC includes assumptions in cost for two pieces of equipment, an exam table and thoracic electrical bioimpedance equipment. The cost input of $28,625 for thoracic electrical bioimpedance equipment is significantly lower than the actual price for thoracic electrical bioimpedance equipment. The RUC survey value for this equipment must be very old or based on very few misrepresentative examples. One manufacturer, CardioDynamics (www.cdic.com), supplies more than 90% of all thoracic electrical bioimpedance equipment used in the United States. This manufacturer has two commercially available devices, model 5100 (BioZ Dx) and model 4100 (BioZ Monitor). Model 5100 has a price of $43,995 and Model 4100 has a list price of $32,995. These prices do not include tax or shipping, which adds approximately 8% additional cost. Approximately 90% of the new devices CardioDynamics' sells are model 5100 and 10% are model 4100. Using a blended average of the two device prices at the volume they are being purchased yields an average device cost of $42,896 [(90% x $43,995) + (10% x $32,995)]. Assuming that physicians are able to negotiate a discount of 10%, the actual price is roughly $38,606. When tax and shipping are added, the cost totals $41,694. **We propose that for CPT 93701-TC that CMS use a thoracic electrical bioimpedance-equipment cost input of $41,694.**

3. **Direct Expenses – Use of the Adjustor to Reduce RVU Values (applies to all codes)**
   The fundamental premise of a new "bottom-up" methodology is that the actual costs are accounted for and reimbursed by CMS. This is a reasonable approach. However, each direct expense RVU has a direct "adjustor" applied of 0.667. The effect of using the direct adjustor of 0.667 is to reimburse providers 33.3% less than the costs they incur for performing the test. This is neither fair nor accurate, and it has the opposite effect of the intent of the "bottom-up" methodology because it applies a "top-down" reduction factor to the "bottom-up" costs. **We propose that CMS eliminate the use of adjustors in RVU calculations.**

4. **Conversion Factor Reduction (applies to all codes)**
   The proposed reduction in the conversion factor from its 2006 value of $37.90 to $36.16 in 2006 results in a reduction in payment for all services. Each year, the cost of running a medical practice rises. However, each year CMS proposes a reduction in the conversion factor to meet artificial budget goals. **We propose that each year, the previous year conversion factor be used as a basis to calculate the next year conversion factor based on the expected increase in the cost of running a medical practice.**

We are very hopeful that CMS will seriously consider our comments in the publication of the final fee schedule for 2007. **If these changes we propose cannot be made, we request that CMS delay the implementation of any changes in RVU values until a fairer and more accurate system can be proposed.**

Sincerely,

John Acquaye-Anay MD
Chicago, IL 60610

Mike Arsov MD
Kissimmee, FL 34741

Martin Bloom MD
Boca Raton, FL 33486

Richard Blum MD
Wilkes Barre, PA 18702

Harry Brodie MD
Littleton, CO 80123

Lauren Byrd MD
Livingston, NJ 07039

Michael Cafaro MD
Trumbell, CT 06612

James Caluert MD
Grants Pass, OR 97526

Terence Carewe MD
Tulsa, OK 74114

Jessie Cockrell MD
Senatobia, MS *38665*

John Cox MD
Rochester, New York

Michael Crawford MD
Turnbull, CT 66611

Richard Fedderbush MD
Syosset, NY 11791

Jesus Fonesca MD
Willis, TX 77378

Alejandro Garcia MD
Oxnard, CA 93036

Kevin Garner MD
Maryville, IL 62062

Steve Gidde MD
Oak Grove, MO 64075

Yusoof Hamuth MD
Plantation, FL 33324

E. Johnson MD
Worchester, MA 01602

Joe Jones MD
Blytheville, AR 72315

C. Tucker Joustra MD
Lamar, MO 64759

Muthu Krishnan MD
Columbia, MO 65201

Jeremy Laomirance MD
Albuquerque, NM 83102

Tim Laurie MD
Okalahoma City, OK 73102

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Phoenix, Arizona 85024

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George Murillo MD
Tomball, TX 77375

Ross Nochimson MD
Lauderhill, FL 33351

Hayan Orfaly MD
Monroe, LA 71203

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Granada Hills, CA 91344

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Charles Ray MD
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Holtville, CA 92250

Laura Samuel MD
Grand Rapids, MI 49512

Mark Stine MD
Indianapolis, IN 46254

Gordon Wang MD
Punta Gorda, FL 33950

Robert Weiss MD
San Antonio, TX 78202

Robert Woodruff MD
Willburton, OK 74578

Samuel Wu MD
Gilroy, CA 95020

Robert Yuhas MD
Solana Beach, CA 92075

**Submitter :** **Mrs. Leanne Burns** **Date: 08/21/2006**

**Organization :** **The Physical Therapy Clinic, Inc.**

**Category :** **Physical Therapist**

**Issue Areas/Comments**

**Other Issues**

Other Issues

August 21, 2006
**
Leanne Lyon Burns, PT
The Physical Therapy Clinic, Inc.
26 Office Park Drive
Jacksonville, NC 28546
910-577-3355
**
Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014
Baltimore, MD 21244-8014
**
Subject: 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,

I am a physical therapist and owner of an outpatient private-practice physical therapy clinic. I have over 20 years of experience as a PT and have been the owner of my clinic for 12 years. My clinic has been serving the Jacksonville, NC area for the past 18 years and we have helped thousands of patients recover from physically debilitating circumstances, a large number of which have been Medicare patients. I love helping people of all ages and have weathered many healthcare storms during my tenure and plan to stay in practice for many years to come.

With that in mind, I desire to comment on the June 29 notice of proposed revisions to work relative value units which revises the methodology for calculating practice expense RVU s under the Medicare physician fee schedule. Having reviewed the proposed revisions I am most opposed to such measures along with the entirety of physical therapy professionals.

I implore you to review and reconsider this drastic proposition. Please ensure that these severe Medicare payment cuts for physical therapists and other health care professionals do not occur in 2007. The effects of the proposed plan could devastate the field of physical therapy and guarantee that millions of Medicare patients will not receive the care they need because of the cost of doing business.

Right now we cannot afford to treat Medicaid patients and patients covered by selected other insurance companies because we LOSE MONEY if we treat them due to low reimbursement rates. It would be a tragedy for a similar situation to arise for Medicare patients.

A wiser win-win solution for all would be to transition the changes to work relative value units over a four year period to ensure that patients continue to have access to valuable health care services and the providers are able to continue to financially afford to provide the same quality care that we have been committed to.

The writing on the wall projects a 4.6% cut in payments for 2007, but by 2015 those cuts would total 37%! Additionally, physical therapists cannot bill for E/M codes and thus will derive no benefit from increased payment in this area. While increasing payment for E/M services is important the value of all Medicare providers should be acknowledged.

As a physical therapist, I spend a considerable amount of time in face-to-face consultation and treatment with patients (including a one hour initial exam / evaluation and 30-60 min for each visit, which is far more than their primary physician), and yet the professional services that I provide are being diminished by this proposal.

Again, I ask you to reconsider this proposal or at least transition these changes over a several year period. Unfortunately the real loser in this plan will ultimately be the patient.

I would like to thank-you for your time and consideration of my comments. I trust that the final decision will result I a win-win situation for all stakeholders.

Sincerely,

//s//

Leanne Lyon Burns, PT
Owner

The Physical Therapy Clinic, Inc.

CMS-1512-PN-2099-Attach-1.DOC

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

**Organization :** **The Jackson Clinic Professional Association**

**Category :** **Physician**

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

See attachment.

CMS-1512-PN-2100-Attach-1.DOC

Attach ff
2100

August 21, 2006

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

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

Dear Dr. McClellan:

On behalf of The Jackson Clinic Professional Association and our 120 employed physicians, including seven cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

The Jackson Clinic is the oldest multispecialty physician group practice in Tennessee, with 120 physicians practicing in more than 20 specialties and subspecialties. The J ackson Clinic provides comprehensive health care services to patients from a 17-county area of rural West Tennessee, including a large number of Medicare beneficiaries among its patients. For the past 20 months, The Jackson Clinic has operated one outpatient cardiac catheterization laboratory at our central Jackson location. This catheterization laboratory is a physician-practice owned and operated facility. In 2005, a total of 845 diagnostic procedures were performed by Jackson Clinic physicians at this lab.

The proposed approach in the CMS PE Notice 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 that the proposed methodology has 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 reduction in payment of greater than 50% for CPT 93510 TC. Similarly, payment for two related codes -- 93555 TC and 93556 TC -- would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

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

The stated purpose of the proposed change to a bottom up 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 we believe were submitted by the Society for Cardiovascular Angiography and Interventions ("SCAI") through the American College of Cardiology. 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 percent.

Even if the RUC estimates included the additional costs submitted to the RUC, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

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

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

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

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

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. 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 the 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 that do not reflect the cost profile of cardiac catheterization facilities. Instead, cardiac catheterization facilities may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (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 catheterizations 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 organizations, including the American Medical Group Association ("AMGA") and the Cardiovascular Outpatient Center Alliance ("COCA"), to develop more accurate 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 to evaluate the impact of the PE RVU methodology on our practices.

Thank you again for the opportunity to share theses comments concerning the CMS PE Notice. We look forward to working with you to correct the flaws in your proposal and to achieve an accurate revision to the PE methodology.

Very truly yours,

/s/

Kevin P. McMahon
General Counsel
The Jackson Clinic, P.A.
616 West Forest Avenue
Jackson, TN 38301
Tel: (731) 422-0242
Fax: (731) 422-0499
Email: gcounsel@jacksonclinic.com

cc:
Hon. Bill Frist
Hon. Lamar Alexander
Hon. John Tanner
Hon. Harold Ford Jr.

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

**Organization :** **Consumer-Purchaser Disclosure Project**

**Category :** **Other**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Joint Employer, Consumer, and Labor Comments

CMS-1512-PN-2101-Attach-1.PDF

Attach #
2101

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

August 21, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

File Code: 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)

**RE: Comments on Medicare Physician Payments**

Dear Dr. McClellan:

The undersigned organizations believe strongly that the system of payment for services provided or controlled by physicians, for both Medicare and commercial payers, is in need of a major overhaul. Rather than promoting better quality, coordination, greater efficiency and more effective delivery of care, most payments reward quantity, errors, rework and unnecessary care. Medicare can, and should, lead the way in reforming these dysfunctional payment policies.

The proposed rules represent a significant first step in correcting a perverse payment system by addressing the undervaluation of Evaluation and Management (E/M) services by substantially increasing their relative work weight. With this change, physicians providing more E/M services would experience a corresponding increase in Medicare payments. This change represents a redistribution that allocates Medicare payments more appropriately. We applaud and support the proposed rules because they correct the dramatic erosion of the relative weight accorded to E/M services over the past fourteen years.

These proposed changes are of vital importance to millions of Medicare beneficiaries and the physicians who provide complex evaluative and management services. However, Medicare's underlying payment system still lacks sufficient incentives for improving the quality, coordination and efficiency of care. The need to conduct a more complete review and revision of physician payments is urgent and goes beyond these changes. Payment reform must include addressing the flawed Sustainable Growth Rate formula, which is an inequitable and poor mechanism to control volume without any relationship to the quality or efficiency of individual physicians. We urge the Centers for Medicare and Medicaid Services to undertake a comprehensive process to review and revise payments considering factors such as:

- Differentially rewarding physicians who deliver higher quality, evidence-based care more efficiently;

C/O National Partnership for Women & Families
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- Developing payments for care coordination that support the integration and delivery of services for those with chronic illnesses;
- Developing payments that support reengineering of care, such as, but not limited to, reimbursing structured "online-visits," group visits, and telemedicine-mediated care;
- Structuring payments that recognize efficient and effective care may reduce expenditures both within a single sector and between sectors (e.g., physician services may reduce expenditures in emergency rooms and hospital care); and
- Balancing the desire to provide patients with "one-stop shopping" with a critical review of self-referral arrangements, especially those in which a physician stands to financially benefit by providing tests, procedures or imaging that do not require his or her personal time and involvement.

Thank you for the opportunity to comment on these proposed rules and for your leadership in this important area. If you have any questions, please contact either of the Disclosure Project's co-chairs, Peter Lee, CEO of the Pacific Business Group on Health, or Debra Ness, President of the National Partnership for Women & Families.

Sincerely,

AFL-CIO
American Benefits Council
American Hospice Foundation
Associated Industries of Massachusetts
CalPERS
Care Focused Purchasing, Inc.
Carlson Companies
Cisco Systems
Consumers Union
Employer Health Care Alliance Cooperative
Employers' Coalition on Health
ERISA Industry Committee
General Motors
HR Policy Association
Motorola
National Business Coalition on Health
National Business Group on Health
National Consumers League
National Partnership for Women & Families
National Retail Federation
Northeast Pennsylvania Regional Health Care Coalition
Pacific Business Group on Health
PG&E Corporation
Piedmont Health Coalition, Inc.
Service Employees International Union
St. Louis Area Business Health Coalition
Xerox

**Submitter :** **Ms. Ann Parker** **Date: 08/21/2006**

**Organization :** **The Heart Group, Inc.**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**Practice Expense**

Practice Expense

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

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

**Organization :** Thoracic Cardiovascular Institute

**Category :** Health Care Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

**Submitter :** **Dr. William Wickemeyer** **Date: 08/21/2006**

**Organization :** **Iowa Heart Center**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2105-Attach-1.DOC

A Hach 1E
2105-

**IOWA HEART CENTER**

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

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

August 21, 2006

Dear Dr. McClellan:

Iowa Heart Center appreciates the opportunity to submit comments to CMS regarding proposed changes to the practice expense (PE) methodology and the five-year review of work RVUs under the Medicare Physician Fee Schedule.

Iowa Heart represents 58 physicians and 500 employees who serve more than 120,000 patients in the central and southwest Iowa. We, along with more than 220 private practices and 3,700 cardiologists as represented by the Cardiology Advocacy Alliance (CAA), are concerned that the changes currently proposed by CMS to the practice expense portion of the RVU system are based on incomplete data and a flawed methodology. We sincerely request that CMS delay implementation of the rule for one year until data are corrected to accurately reflect the direct and indirect costs of providing care, and the methodology is updated to better reflect the ratio of direct to indirect costs. Our comments on the five-year review of the Work RVUs under the Physician Fee Schedule also are included below.

## Comments regarding Proposed Changes to the Practice Expense Methodology

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

The rule as currently proposed is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component (TC) is a significant part of the overall procedure.

**Iowa Heart Center will use catheterization procedures as an example as outlined below of the impact of the proposed methodology on all procedures with significant TC costs. We also believe that the same solution should be applied to all procedures with significant TC costs.**

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

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

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

**Direct Costs**

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

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

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

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

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

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

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

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

**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 does not reflect the cost profile of cardiac catheterization facilities that may have a cost profile similar to Cardiology in terms of the higher indirect costs that are associated with performing these services.

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

**Summary of Iowa Heart Center comments on the Proposed Rule re: Practice Expense changes**

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

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

1. Insufficient reimbursement would force outpatient cath labs to close. Medicare patients would be directed back to the inpatient setting for cath services. This runs counter to CMS' long-term goal of providing care in the outpatient setting whenever clinically appropriate.

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

The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. We are concerned that the problems with the catheterization codes as outlined above may extend to other CPT codes with significant TC costs as well, since the inadequate funding of catheterization codes illustrates that the data and formula used to calculate practice expense components is incomplete and inaccurate.

**As a result, Iowa Heart Center requests that CMS delay implementation of the practice expense changes for one year.** During this time period, CMS, RUC, SCAI, CAA and other interested parties will be able to complete a thorough assessment of the direct and indirect cost data and the methodology currently under consideration to ensure that they are accurate and complete. CAA will be collaborating with our members and other organizations to develop improved estimates of direct costs and to offer additional comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007.

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

Iowa Heart Center understands that CMS is required by statute to offset costs in excess of $20 million that result from the Agency's mandatory five-year review of Work RVUs under the Physician Fee Schedule. Our practice believes that the $20 million offset threshold set for five-year mandatory reviews in the early 1990s should be adjusted for inflation and the rising costs of providing medical care to our nation's growing Medicare population. We and other CAA members are working with Congressional leaders to address this issue legislatively.

It seems nonsensical that CMS must complete the rigorous task of realigning Work RVU weights every five years only to reduce the fee schedule as a whole to pay for the review, which was mandated to ensure that Work RVUs accurately reflect the amount of time medical professionals devote to procedures and ensure appropriate reimbursement. CAA members will see their total reimbursements slashed by up to $1.65 million in 2007 as a result of the 2006 review, depending upon the method CMS chooses to offset costs. Until such time as the arbitrary $20-million cap is changed, we acknowledge that CMS must continue its actions to offset the 2006 Work RVU review.

Sincerely,

**William Wickemeyer, M.D.**, Board Chair

**Julie Younger**, Chief Executive Officer
jyounger@iowaheart.com

On behalf of Iowa Heart Center
5880 University Avenue
West Des Moines, IA 50266
(515) 633-3600
www.iowaheart.com

**Submitter :** Dr. Joseph Bailes, MD **Date:** 08/21/2006

**Organization :** American Society of Clinical Oncology

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2106-Attach-1.PDF

Attach M
2006

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AMERICAN SOCIETY of CLINICAL ONCOLOGY



August 21, 2006

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

Re: Comments on the 5-Year Review of Work Relative Values and Proposed Changes to the Practice Expense Methodology

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the results of the 5-year review of work relative values and the proposed changes to the practice expense methodology under the Medicare physician fee schedule that were published in the Federal Register on June 29, 2006. ASCO is the national organization representing physicians who specialize in the treatment of patients with cancer.

## EVALUATION AND MANAGEMENT SERVICES

The American Medical Association's Relative Value Update Committee (RUC) reviewed the work relative values for evaluation and management services as part of the 5-year review of work relative values. As CMS states in the Federal Register notice, "the RUC agreed that there was compelling evidence to review the E/M services because of evidence that incorrect assumptions were made in the previous valuation of the services."

ASCO strongly supports the proposed new relative values for the evaluation and management codes as recommended by the RUC and proposed by CMS. We believe that the current work relative values for evaluation and management services do not accurately recognize the amount of work involved. The proposed changes in the relative values would help rectify this shortcoming, and we urge their adoption.

## PRACTICE EXPENSE

### Background

Practice expense relative values in the Medicare physician fee schedule are currently determined through a "top down" methodology. The starting point for this methodology is a survey of the practice expenses of each physician specialty. The practice expenses determined in this manner are allocated to each CPT code through a complex methodology that distinguishes between direct costs (clinical staff, supplies, and certain equipment) and indirect costs (administrative staff and overhead costs).


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Under the June 29 proposal, CMS would no longer use surveys of practice expenses to determine the amount of direct costs attributable to each CPT code. Instead, relative value units would be allocated to each code in proportion to the estimated costs of clinical staff, supplies, and equipment for each code as developed through the RUC process.

The method of allocating relative value units to account for indirect costs would also be revised. Under the current methodology, relative value units are allocated to each CPT code based on the amount of direct costs and the amount of physician work attributable to each code. Because some codes involve little or no physician work, CMS is proposing to revise the method to use the amount of clinical staff time when the practice expense relative value units attributable to that time exceed the number of relative value units attributable to the physician work involved.

**The Medicare Modernization Act**

In the Medicare Modernization Act of 2003 (MMA), Congress addressed the issue of underpayment for oncology drug administration services. Section 1848(c)(2)(H) was added to the Social Security Act to require CMS to use ASCO's supplemental survey of practice expenses "[i]n establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004. . . ." The statute was also amended to provide that subparagraph (H) "shall not be construed as preventing [CMS] from providing adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively." Subparagraph (B) authorizes periodic adjustments in the relative values "to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures."

We question whether the proposed change in determining practice expense relative values is consistent with the MMA's provisions with respect to the drug administration codes. Under the proposal, ASCO's supplemental survey would no longer be used to determine the practice expense relative values with respect to the direct costs of drug administration services even though the statute requires use of the survey in determining payments for services furnished in 2004 and later years. As a result, the relative values assigned to at least some of the drug administration codes would decline. The purpose of the MMA provision was to improve the accuracy of payments for drug administration services by using the results of the ASCO supplemental survey. Applying the ASCO survey data led to increases in the practice expense RVUs for these services. To the extent that the proposed change in methodology would reduce the relative values for many chemotherapy administration services by failing to use the ASCO survey, it is inconsistent with the intent of the MMA."

We acknowledge that the ASCO survey would still be used in part of the proposed methodology – the allocation of relative value units for indirect costs. The proposal not to use the survey in a substantial part of the methodology (direct costs) with the result that payments for drug administration services decline, however, fails to carry out the purpose of the MMA provision. Moreover, while the statute does explicitly allow changes in the MMA-derived relative values, the only changes permitted are those made to "to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures." There is no provision allowing CMS to reduce the relative values of the drug administration services by adopting a methodology that ignores the ASCO supplemental survey in a substantial part of that methodology.

**Direct Costs**

A CMS assumption underlying the proposed use of the RUC estimates of direct costs is that they are accurate. These estimates were developed over a period of years, however, during which the degree of rigor employed by the RUC and its subcommittee in reviewing estimates of clinical staff time varied. Consequently, we believe that there is no assurance that the use of the RUC estimates provides greater accuracy in allocating relative value units for direct costs than the current methodology. The proposed change should not be made until the same standard of rigorous review is applied in analyzing the estimates of clinical staff time for all of the codes.

**Indirect Costs**

The current methodology of allocating relative value units to account for indirect costs is based in significant part on the amount of physician work associated with each code. As a CMS contractor, The Lewin Group, and the Government Accountability Office have concluded, this methodology is biased against services that involve little or no physician work, such as drug administration services. Under the proposal, this deficiency would be addressed by using the relative values associated with non-physician clinical staff time if those values exceed the values associated with physician work.

ASCO applauds CMS's effort to make the indirect cost allocation methodology fairer for services that have little or no associated physician work by substituting the use of clinical staff work when it predominates. This approach should help eliminate the bias in the current methodology. We are uncertain, however, whether this proposed change in the methodology truly places services with little or no physician work on an equal footing with codes that involve significant physician work. We urge CMS to continue to analyze this issue and to be open to consideration of alternative approaches.

Sincerely,

Joseph S. Bailes, MD
Interim Executive Vice President

**Submitter :** **Ms. Kenda Fuller** **Date: 08/21/2006**

**Organization :** **American Physical Therapy Association**

**Category :** **Physical Therapist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2108-Attach-1.DOC

CMS-1512-PN-2108-Attach-2.DOC

Attach #
2108

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August 21, 2006

**To: CMS**

**RE: PROPOSED DECREASE IN PAYMENTS FOR PHYSICAL THERAPY IN 2007**

I work in a practice that treats patients who have suffered a neurological insult, most often with diagnoses of Multiple Sclerosis, Stroke, and balance disorders. These patients have significant impairments and functional limitations that impact their lives. We work very hard with them to allow an increased independence, reduced risk of falling and to move with less effort and pain. In order for this to happen, the patients must have access to our services.

As you know, all of our expenses have increased. Most of what we use to support our business has added costs related to increased fuel prices, this is something we have no control over.

We have no access to the increase in payments under the Evaluation and Management codes as therapists, so this proposal would essentially decrease significantly our ability to treat these patients.

At this time, due to the nature of our practice, almost 50% of our patients are insured under the Medicare system.

Please take this into consideration and do not limit your participant's access to this service that is critical to their lives after injury.

Kenda Fuller, P.T., N.C.S

**Submitter :** Dr. JAMES BISKUP **Date:** 08/21/2006

**Organization :** BELLEVUE FAMILY PRACTICE, P.C.

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1512-PN-2109-Attach-1.DOC

Attach #
2109

August 15, 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: Proposed reimbursement changes for DXA
CMS-1512-PIN

To Whom It May Concern:

I have recently become aware of the proposed reimbursement change for DXA that I would like to address. The CMS is considering a great decrease in reimbursement for bone density DXA scans. This is surprising and unfortunate.

This change would call for a substantial decrease in the professional component (50%) as well as the technical portion of reimbursement (80%). I believe this would cause many people suffering from bone loss or osteoporosis to go undiagnosed and untreated. Osteoporosis is a very treatable condition if detected in the early stages. If untreated, there would be a great increase of health care costs as these same patients are suffering from the advanced affects of the disease. Just two of these devastating and debilitating affects are spine and hip fractures.

DXA has been proven to be very accurate in the diagnosis and treatment for osteoporosis. The accuracy is dependent on several factors; one of these is the proper training of the unit operator. We know education is a worthwhile but expensive investment. In some areas, the use of ionizing radiation warrants the individual states to allow only Registered Radiological Technologists to perform this exam.

The continual upkeep and calibration of the machine are necessary in order that the DXA is accurate and safe for the patient. A service contract on the DXA unit can be over $8000.00 per year.

If these reimbursement changes are implemented, the DXA scan will become less available to patients who need them. The medical facilities and specifically small practices cannot endure such a loss. We will not be able to provide proper medical care and preventive help for our patients; this will translate to astronomical health care costs as the disease progresses.

I trust as you review these facts; you will reconsider and not allow these reimbursement changes at this time.

Thank you for your consideration in this very important matter.

Sincerely,

James T. Biskup, M.D.

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

**Organization :** **American Thoracic Society**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2111-Attach-1.DOC

Attach #
2111

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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, Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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; Notice

American Thoracic Society Comments address: Evaluation and Management Codes, Critical Care Codes, CMS Budget Neutrality, SGR, Practice Expense Survey and Methodology

Dear Dr. McClellan:

On behalf of the members of the American Thoracic Society (ATS), I would like to express our appreciation for the opportunity to comment on the final rule for the 2006 Medicare Physician's Fee Schedule published on June 29, 2006. The ATS represents over 13,000 physicians, researchers, and allied health professionals, who are actively engaged in the diagnosis, treatment and research of respiratory disease and critical care medicine. We are most interested in quality care and access to care for the beneficiaries you represent, and those same patients we serve.

The ATS offers the following comments:

SUSTAINABLE GROWTH RATE (SGR) FORMULA

The American Thoracic Society continues to be disappointed that neither Congress nor CMS has done all within their power to fix the SGR formula. ATS strongly believes that the SGR formula is seriously flawed and needs to be replaced. Both Congress and CMS need to play significant roles in addressing the replacement. We strongly support the removal of the costs of Medicare-covered physician-administered drugs from the SGR calculation. CMS needs to use its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation, which have increased from $1.8 billion in 1996 to $8.6 billion in 2004 and an estimated $8.2 billion in 2005. Nearly all of the medical community has commented on this issue and remain frustrated that the SGR-adjustment to the Medicare physician fee schedule has not been made. CMS continues to underestimate the impact of National and Local Coverage Decisions on increased spending on physician services under Medicare. Additional funds need to be added to the MPFS for all the ancillary costs associated with new preventive benefits being added for beneficiaries.

While ATS recognizes it is beyond the scope of CMS to address this, the American Thoracic Society will continue our effort in Congress to address the flawed SGR formula through legislation.

EVALUATION AND MANAGEMENT (E/M) CODES

ATS was an active participant in the coalition of medical specialty societies and applauds the efforts of all physicians as part of this Five-Year Review process. We appreciate CMS acceptance of 100 percent of the RUC recommended E/M codes and support the physician work values developed through the RUC survey process for the Evaluation and Management codes.

CRITICAL CARE CODES, CPT 99291 and 99292

While the ATS appreciates the increases in the physician work value recommended for critical care (CPT 99291 and 99292) we note that these increases are driven exclusively by the need to prevent rank order anomalies caused by increases in other E/M codes.

The ATS and our sister organizations conducted surveys for the critical care codes and presented what we believe is compelling evidence that the physician work associated with these codes has increased. However, the RUC stated that we had not met the compelling evidence criteria. The ATS and other societies have surveyed the critical care codes in each of the three 5 year RUC reviews and have consistently collected data that supports a physician work value of approximately 5.00 RVW.

While we support the proposed increases for 99291 and 99292 because no increases occurred in the previous two Five-Year Reviews, we believe our surveys more than support the proposed value of 5.10 RVU, and we intend to pursue these codes in the next 5-year RUC review.

CMS BUDGET NEUTRALITY

Resulting from proposed increases to the physician work values of the Evaluation and Management codes in the Five-Year Review, CMS estimates a $4 billion increase in Medical expenditures. As you know, the law requires budget neutrality for both physician work and practice expense changes. ATS strongly disagrees with CMS's proposed negative budget neutrality adjuster of 10 percent being applied to the MPFS physician work relative values. The application of budget neutrality to physician work causes great confusion to non-Medicare payers who use the RBRVS payment system. ATS strongly supports the view that the adjuster should be applied to the conversion factor and notes the strong historical precedent for achieving budget neutrality through the conversion factor.

We are further concerned that achieving budget neutrality through the adjustments to work values will inappropriately change the relative value scale of the RBRVS and will have impact on practice expenses and PLI.

As Pay-for-Performance quality performance measure initiatives move forward, we expect that there will be additional costs to physician practices to implement these new standards, and we want to go on record to say that we do not want physicians to support these additional costs to their practice under a budget neutral system.

MULTI-SPECIALTY PE SURVEY

The ATS supports the CMS decision to accept additional nationally valid survey data on physician practice expense. To this end, the ATS will participate with AMA in the all-physician practice expense survey that will be conducted between April and December 2007 to be used as a basis as the multi-specialty survey to calculate indirect expenses (e.g., heat/air, light, phones, office expenses). This survey will replace the AMA SMS survey for the calculation of pe/hr.

PRACTICE EXPENSE METHODOLOGY

Regarding practice expense, the ATS supports the:

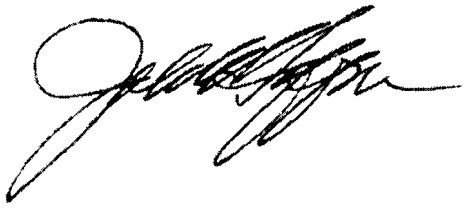
- Proposed methodology of the "bottom-up" approach that uses the best available refined data from the RUC and PERC deliberations for clinical labor, medical supplies and medical equipment in the calculation of direct practice expenses.
- Elimination of the non-physician work-pool as proposed by CMS.
- Four year transition on the changes to the practice expense values, even though the proposed pulmonary impact is projected to be +2 percent.
- Proposed 50 percent equipment utilization rate.
- Adjust the 11 percent cost of equipment capital rate to a market competitive rate.

PRACTICE EXPENSES REDUCED BY TWO-THIRDS (page 37250)

The ATS strongly opposes the unilateral decision by CMS to reduce direct practice expense costs by 2/3 in calculating the practice expense reimbursement. ATS applauds CMS's desire for transparency in the system; however, we were shocked to learn of the across-the-board repricing by a decrease of direct practice expense costs by two-thirds. We understand this policy has been in effect for some years and was previously part of the unknowns associated with the practice expense calculation. However, just because this policy has been in place for several years does not make it appropriate policy. We question what statutory authority CMS uses to justify reducing reimbursement for direct practice expense costs by 2/3.

The ATS appreciates the opportunity to comment on the proposed rule under the Medicare Physician Fee Schedule. Should you or your staff have any questions, please do not hesitate to contact me or Gary Ewart at gewart@thoracic.org or 202-785-3355 x 226.

Sincerely,



John E. Heffner, MD
President, American Thoracic Society

Cc: ATS Clinical Practice Committee

**Submitter :** **Dr. Stuart Jordan** **Date: 08/21/2006**

**Organization :** **Women's Wellness Center, PA**

**Category :** **Physician**

**Issue Areas/Comments**

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

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

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

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

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-1512-PN-2118-Attach-1.DOC

Attach # 2118


# MONTGOMERY CARDIOVASCULAR ASSOCIATES, P.C.

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

Dear Dr. McClellan:

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

Montgomery Cardiovascular Associates, P.C. represents 11 of physicians and 106 employees who serve more than 12,244 patients in Central Alabama. We, along with more than 220 private practices and 3,700 cardiologists as represented by the Cardiology Advocacy Alliance (CAA), are concerned that the changes currently proposed by CMS to the practice expense portion of the Relative Value Unit (RVU) system are based on incomplete data and a flawed methodology. Montgomery Cardiovascular Associates, P.C. requests that CMS delay implementation of the rule for one year until (1) data are corrected to accurately reflect the direct and indirect costs of providing care, and (2) the methodology is updated to better reflect the ratio of direct to indirect costs. Our comments on the five-year review of the Work RVUs under the Physician Fee Schedule also are included below.

## Comments regarding Proposed Changes to the Practice Expense Methodology

Montgomery Cardiovascular Associates, P.C. wants to ensure that the revisions to the practice expense component of Medicare's RBRVS are methodologically sound and are driven by accurate, representative data on physicians' practice costs. Our physicians are particularly concerned about the methodology, data sources and assumptions used

to estimate the direct and indirect practice expense costs associated with cardiovascular CPT codes, including services performed in cardiac catheterization labs.

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

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

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

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

Direct Costs

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

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

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

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

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

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

| *Direct Cost Category* | *Included In RUC-Determined Estimate* | *Excluded From RUC-Determined Estimate* |
|---|---|---|
| Clinical Labor | • Direct Patient Care For Activities Defined by RUC<br>• Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) | • Direct Patient Care For Activities Not Defined by RUC<br>• Actual Staff Allocation Based on Patient Needs |

| | | |
|---|---|---|
| Medical Supplies | • Supplies Used For More Than 51% of Patients | • Supplies Used For Less Than 51% of Patients |
| Medical Equipment | • Equipment Used For More Than 51% of Patients | • Equipment Used For Less Than 51% of Patients |
| All Direct Costs for Cardiac Catheterization | • Approximately 55% of the direct costs are included in the RUC estimate | • Approximately 45% of the direct costs are not included in the RUC estimate |

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

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 does not reflect the cost profile of cardiac catheterization facilities that may have a cost profile similar to Cardiology in terms of the higher indirect costs that are associated with performing these services.

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

Summary of Montgomery Cardiovascular Associates, P.C. comments on the Proposed Rule re: Practice Expense changes

Our practice believes that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization and other TC-heavy procedures, and that CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool has been eliminated. The RUC-

determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

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

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

The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. We are concerned that the problems with the catheterization codes as outlined above may extend to other CPT codes with significant TC costs as well, since the inadequate funding of catheterization codes illustrates that the data and formula used to calculate practice expense components is incomplete and inaccurate. As a result, **Montgomery Cardiovascular Associates, P.C. requests that CMS delay implementation of the practice expense changes for one year. During this time period, CMS, RUC, SCAI, CAA and other interested parties will be able to complete a thorough assessment of the direct and indirect cost data and the methodology currently under consideration to ensure that they are accurate and complete. CAA will be collaborating with our members and other organizations to develop improved estimates of direct costs and to offer additional comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007.**

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

Montgomery Cardiovascular Associates, P.C. understands that CMS is required by statute to offset costs in excess of $20 million that result from the Agency's mandatory five-year review of Work RVUs under the Physician Fee Schedule. Our practice believes that the $20 million offset threshold set for five-year mandatory reviews in the early 1990s should be adjusted for inflation and the rising costs of

providing medical care to our nation's growing Medicare population. We and other CAA members are working with Congressional leaders to address this issue legislatively. It seems nonsensical that CMS must complete the rigorous task of realigning Work RVU weights every five years only to reduce the fee schedule as a whole to pay for the review, which was mandated to ensure that Work RVUs accurately reflect the amount of time medical professionals devote to procedures and ensure appropriate reimbursement. CAA members will see their total reimbursements slashed by up to $1.65 million in 2007 as a result of the 2006 review, depending upon the method CMS chooses to offset costs. Until such time as the arbitrary $20-million cap is changed, we acknowledge that CMS must continue its actions to offset the 2006 Work RVU review.

Sincerely,

Paul B. Moore, M.D., F.A.C.C.
President

Cullen Smith
Chief Operating Officer

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Attach #
2118


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August 21, 2006

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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

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indirect practice expense costs associated with cardiovascular CPT codes, including services performed in cardiac catheterization labs.

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Summary of Montgomery Cardiovascular Associates, P.C. comments on the Proposed Rule re: Practice Expense changes

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

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

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6. Physician practices are small businesses, employing hundreds of thousands of people and providing valuable services to the Medicare population. The physician sector must have stable reimbursement patterns that keep pace with the increasing cost of providing care.

The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. We are concerned that the problems with the catheterization codes as outlined above may extend to other CPT codes with significant TC costs as well, since the inadequate funding of catheterization codes illustrates that the data and formula used to calculate practice expense components is incomplete and inaccurate. As a result, **Montgomery Cardiovascular Associates, P.C. requests that CMS delay implementation of the practice expense changes for one year. During this time period, CMS, RUC, SCAI, CAA and other interested parties will be able to complete a thorough assessment of the direct and indirect cost data and the methodology currently under consideration to ensure that they are accurate and complete. CAA will be collaborating with our members and other organizations to develop improved estimates of direct costs and to offer additional comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007.**

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

Montgomery Cardiovascular Associates, P.C. understands that CMS is required by statute to offset costs in excess of $20 million that result from the Agency's mandatory five-year review of Work RVUs under the Physician Fee Schedule. Our practice believes that the $20 million offset threshold set for five-year mandatory reviews in the early 1990s should be adjusted for inflation and the rising costs of providing medical care to our nation's growing Medicare population. We and other CAA members are working with Congressional leaders to address this issue legislatively. It seems nonsensical that CMS must complete the rigorous task of realigning Work RVU weights every five years only to reduce the fee schedule as a whole to pay for the review, which was mandated to ensure that Work RVUs accurately reflect the amount of time medical

professionals devote to procedures and ensure appropriate reimbursement. CAA members will see their total reimbursements slashed by up to $1.65 million in 2007 as a result of the 2006 review, depending upon the method CMS chooses to offset costs. Until such time as the arbitrary $20-million cap is changed, we acknowledge that CMS must continue its actions to offset the 2006 Work RVU review.

Sincerely,

Paul B. Moore, M.D., F.A.C.C.
President

Cullen Smith
Chief Operating Officer

Montgomery Cardiovascular Associates, P.C.
2119 East South Blvd
Montgomery, AL 36116
Phone: (334) 280-1520
Email: bamaheart@mindspring.com

**Submitter :** Mrs. Gayle Lee **Date:** 08/21/2006

**Organization :** American Physical Therapy Association

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2126-Attach-1.PDF

Attach # 2126

APTA
American Physical Therapy Association

August 21, 2006

Centers for Medicare and 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

**Re: Comments of the American Physical Therapy Association on 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. 37170)**

Dear Administrator McClellan:

On behalf of our 66,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the notice that sets forth proposed revisions to work relative value units and revises the methodology for calculating practice expense RVUs under the Medicare physician fee schedule. Outpatient physical therapy services are billed under the physician fee schedule in private practices, outpatient rehabilitation facilities (ORFs), skilled nursing facilities (Part B), home health (Part B), comprehensive outpatient rehabilitation facilities (CORFs), and outpatient hospitals. Thus, this rule has a significant impact on physical therapists.

As our comments will reflect, APTA is deeply concerned about the severe payment cuts that are projected in 2007 and subsequent years as a result of the budget neutrality adjustor and the reduction in the conversion factor due to the SGR formula. Such payment cuts could put Seniors' access to care at risk.

***Work RVU changes and budget neutrality***

In the notice, the Centers for Medicare and Medicaid Services (CMS) explains that Medicare statute requires CMS to review the work relative value units (RVUs) at least every 5 years. CMS includes information on the Current Procedural Terminology (CPT) codes that were considered during the current 5-year review, the assessment by the Relative Value Update Committee (RUC) of those codes and its recommendations, and CMS's decision as to whether it accepts the recommendation. This year significant changes to the work RVUs occurred with respect to the "evaluation and management" CPT codes. As a result of these changes, the work component for RVUs

associated with an intermediate office visit, the most commonly billed physician's service, will increase by 37 percent and the work component for RVUs for an office visit requiring moderately complex decision-making and for a hospital visit also requiring moderately complex decision-making will increase by 29 percent and 31 percent, respectively.

The proposed changes in work values resulting from the third five-year review would produce an estimated increase in Medicare payments of $4 billion, about $400 million more than the combined impact of the first and second five-year reviews. CMS states that this necessitates an offsetting budget neutrality adjustment of 10 percent if applied to work values or 5 percent if applied to the conversion factor. Either way, **APTA feels very strongly that the magnitude of such an adjustment is too great to be made in a single year.** This is especially true given the expected reduction in the conversion factor under the "Sustainable Growth Rate" (SGR) methodology, payment reallocations that would flow from the proposed change in practice expense relative values, and the effect of other policy changes.

Specifically, under current law, the SGR formula is projected to trigger a 5.1 percent cut in payments in 2007. These cuts are forecasted to continue, totaling about 37 percent (or perhaps even more) by 2015. **The SGR cuts combined with the proposed budget neutrality adjustment would result in a cut in payments of around 10% for physical therapists and many other health care professionals in 2007.** Health care professionals, such as physical therapists in particular, are negatively impacted by the budget neutrality adjuster because they do not bill evaluation and management services and thus are not able to offset the reduction in payment from the budget neutrality adjustment by the increase in payment for the evaluation and management (E/M) services. The impact of these payment cuts will be further exacerbated by the expiration on January 1, 2007 of the exceptions process to the financial limitation on outpatient therapy services.

CMS emphasizes the importance of increasing payment for E/M services to allow physicians to manage illnesses more effectively and therefore result in better outcomes. Increasing payment for E/M services is important – but the value of services provided by all Medicare providers should be acknowledged under this payment policy. Physical therapists spend a considerable amount of time in face-to-face consultation and treatment with patients, yet their services are being reduced in value.

These proposed cuts undermine the goal of Congress to create a Medicare payment system that preserves patient access and achieves greater quality of care. If health care professionals experience significant and compounding cuts in payment, access to care for millions of elderly and disabled will be jeopardized.

CMS is obviously sensitive to the implications of significant reallocations of relative values as witnessed by its proposed four-year transition period for the new practice expense methodology. Likewise, **APTA strongly recommends that the changes in work values from the most recent five-year review of work values be similarly**

**phased in over a multi-year period.** We see nothing in the statutory requirements for a periodic review and adjustments in relative values found at section 1848(c)(2)(B) that would preclude such a transition period, especially under the unusual circumstances described above.

However, APTA believes that CMS should reconsider its plan to make the budget neutrality adjustment only on the work values, producing an estimated reduction of 10 percent (if done in a single year). Instead, **we urge CMS to apply the budget neutrality adjustment to the conversion factor in a phased manner** as suggested above. Budget neutrality adjustments have been more commonly applied to the conversion factor. In fact, in the final rule implementing the first five-year review of relative values, CMS specifically noted 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). The magnitude of the proposed adjustment on the work values is very large (even if spread out over several years as we suggest), and we believe it would be more appropriate to spread the adjustment across all relative values by applying it to the conversion factor.

This approach would also be much simpler and more transparent. As it stands today, the work values published in Addendum B of the proposed notice are not the real work values, implying a reduction in the actual work component of the service provided, and an unwary user of the table might easily overlook the fact that a "behind the scenes" adjuster will be applied to these published values prior to payment being made by a Medicare contractor. Applying the budget neutrality adjustment to the conversion factor would mean that all the CMS-published values, both RVUs and conversion factor, would be true and accurate and not subject to misunderstanding or misuse. Finally, we believe that a budget neutrality factor applied to the conversion factor would be more equitable than one applied only to the work values, in that it would affect all specialties equally. In contrast, a large budget neutrality factor applied only to work values has the effect of penalizing specialties for whom work values are a large proportion of total values. In sum, **we believe that the budget neutrality adjustment required as a result of the third five-year review should be applied to the conversion factor, not the work values themselves.**

***Practice Expense Relative Values Units: use of Bottom-Up Methodology (p.45776)***

In the rule, CMS proposes to adopt a "bottom-up" methodology to calculate the direct practice expense RVUs instead of the "top-down" approach currently used. Under this methodology direct costs would be determined by summing the cost of the resources (clinical staff, equipment and supplies) required to provide the services. The cost of the resources would be calculated from the refined CPEP/RUC inputs in the database.

**APTA supports the use of the "bottom-up" approach.** We agree with CMS's assessment that using this methodology appears to create a system that would be more stable from year to year than the current "top-down" approach. We also support this methodology because revisions to the direct inputs appear to have more predictable results and reflect the actual relative resources required for each service. As CMS states in the rule, the costs of clinical staff, supplies and equipment should be the same for a given service regardless of the specialty performing that service.

APTA participated in the refinement of the direct practice expense data for physical medicine and rehabilitation CPT codes (97000 series) at the PEAC. Through this process, we believe the PEAC has been able to provide CMS accurate data regarding the practice expense inputs for these codes. Because accurate data is now available, we agree with CMS that it makes sense to use the bottom-up methodology.

**APTA strongly recommends that CMS continue to enable the RUC and HCPAC to review practice expense data for new and revised codes on an annual basis.** We look forward to continuing to work with CMS and the RUC as you work to achieve your goals regarding stability of practice expense payments, predictability of impact of changes, and accurately reflecting the resources requirement for each service under the payment schedule.

***Practice Expense—Indirect Practice Cost Index***

One of the final steps in calculating PE RVUs under the new methodology involves the application of specialty-specific indirect scaling factors (using an Indirect Practice Cost Index). APTA believes this step is unnecessary under the new "bottom up" approach. While the proposed rule carefully describes how the Indirect Practice Cost Index is created and how the scaling factors are applied, it only vaguely justifies this particular step by asserting that it helps "ensure the capture of all indirect costs." However, the proposed methodology already makes use of specialty-specific relationships between direct and indirect costs (using the refined CPEP/PEAC direct cost inputs, the central element of the new "bottom up" methodology, and specialty-specific practice expense survey data) in allocating indirect practice expenses. And the methodology makes a budget neutrality adjustment before applying the Indirect Practice Cost Index, thereby assuring that indirect practice expense values match the available indirect practice expense values in the aggregate. **In our view, indirect scaling factors simply have no place under the new "bottom up" methodology, and arbitrarily re-allocate indirect relative values, thereby penalizing specialties, such as physical therapy, family practice, internal medicine, general surgery, optometry, pediatrics, and podiatry, with lower Indirect Practice Cost Index values. We urge CMS to reconsider this particular step in the proposed methodology.**

***Regulatory Impact Analysis***

In the regulatory impact section of the rule, CMS includes Table 56, which shows a net impact of -$40 million resulting from an increase in FY 2007 payments for mammography and a decrease in FY 2007 payments for physical therapy. CMS has clarified to APTA that this decrease represents the savings that the Medicare program will incur as a result of decreases in payment for outpatient therapy services in outpatient hospitals, home health (Part B), skilled nursing facilities (Part B), comprehensive outpatient therapy services, and rehabilitation agencies. We urge CMS to separate mammography from physical therapy in this calculation so that the impact of the fee schedule changes will be more transparent. As shown in the table, it is impossible to determine how much the actual reduction is payment for outpatient physical therapy services would be.

Thank you for consideration of these comments. Please do not hesitate to contact Gayle Lee at gaylelee@apta.org or at 703/706-8549 with any questions you may have.

Sincerely,

Dave Mason
Vice President, Government Affairs

**Submitter :** **Dr. Timothy Newton** **Date: 08/21/2006**

**Organization :** **Pulaski Physical Therapy**

**Category :** **Physical Therapist**

**Issue Areas/Comments**

**Other Issues**

Other Issues

see attached

CMS-1512-PN-2128-Attach-1.DOC

Attach #
2128

203 Village Sq
Pulaski, TN 38478
August 15, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dear Mr. McClellan:
I am a Doctor of Physical Therapy practicing in Pulaski, Tennessee. I am writing in regards to the June 29 proposal that would reduce the relative work values for services provided by physical therapists and other health care providers who bill Medicare under the Physician fee schedule. I strongly urge that you cease action on this proposal. If these proposed Medicare payment cuts go into effect, it would severely threaten physical therapists and other health care provider's ability to provide quality healthcare to Medicare patients. These cuts contradict the goal that Medicare has; a payment system that preserves patient's access to achieve quality healthcare. If these cuts are made, the access to this care will be jeopardized for many Medicare patients. Also, with the fact that physical therapist's cannot bill for E/M codes, we will not benefit from the increasing of these payments. I do understand that increasing payments for E/M codes is important, however, the quality of service provided by all Medicare providers should be taken into consideration. Physical therapists spend a vast amount of time in face- to- face consults and in the treatment of patients yet, the value of our services are being reduced. I, as a physical therapist, recommend that Medicare try and transition these changes to the relative value units over a four-year period to ensure that Medicare patients may continue to have accessibility to and receive the quality healthcare that they deserve. Thank you for your time, and I hope that you will take this into consideration when you make your final decision.

Sincerely,

Scott Newton PT, DPT, OCS, CWS

**Submitter :** **Mrs. Denise Merlino** **Date: 08/21/2006**

**Organization :** **Society of Nuclear Medicine**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1512-PN-2133-Attach-1.PDF

Attach #
2133

snm
advancing molecular imaging & therapy

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Fax: 703.708.9015
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**August 21, 2006**

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecoments

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

ATTN: FILE CODE CMS-1512-PN

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

Dear Administrator McClellan:

The Society of Nuclear Medicine (SNM) representing more than 16,000 physicians, physicists, scientists, pharmacists and nuclear medicine technologists, appreciates the opportunity to comment on the June 29, 2006, (Vol. 71 No. 125 Fed. Reg. 37170) proposed notice on the "5-year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology."

The SNM offers comments and recommendations on the following topics addressed in this proposed notice:

1. Discussion of Comments- Radiology, Pathology, and Other Misc. Services;
2. Budget Neutrality;
3. Transition of Five-Year Review; and
4. Practice Expense

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

As part of the 5-year review process, CMS referred five nuclear medicine CPT codes to the RUC, specifically CPT 78306, 78315, 78465, 78478 and 78480. These codes are listed in Table 27 of the proposed notice. ***The SNM appreciates the CMS decision to accept the RUC recommendations for all five of these nuclear medicine codes.***

## Budget Neutrality

Budget Neutrality requirements mandate that any increases in payments for some physicians' services must be counteracted by reductions elsewhere in the Medicare payment system. In this proposed notice, CMS describes two options to achieve the requirement for budget neutrality. 1) Reduce all work RVUs with a "work adjustor." CMS estimates that all work RVUs would have to be reduced by 10 percent to maintain budget neutrality under this 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.

CMS states they are proposing option 1, noted above, as they believe it is more equitable to apply the budget neutrality adjustor across services that have work RVUs. We are concerned with CMS' proposed decision to apply this adjustor to the work relative values as opposed to the historically accepted method of applying monitory adjustors to the conversion factors. The ***SNM supports maintaining the stability of the work RVUs*** as these are often used by a variety of payers as well as the basis for physician productivity, and we are opposed to CMS' choice of option 1.

Additionally, we are concerned that our membership will have difficulty with the concept of scaling the work RVUs and support CMS' goal to achieve transparency. CMS stated this in previous rules as follows: "*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). Therefore, ***the SNM recommends Option 2, for CMS to apply the budget neutrality adjustment for the 5-year review to the conversion factor rather than physician work.***

## Transition for 5-Year Review

Similar to CMS' proposed notice regarding the Practice Expense methodology transition, 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.*" ***The SNM recommends CMS apply this same logic and transition the work RVUs over a four-year phase in process.*** This would maintain consistency with the implementation processes.

**Practice Expense**

In this proposed notice, CMS states three major goals with respect to the practice expense (PE) methodology changes: 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 SNM supports these goals and, in general, we believe CMS is getting closer and on track for achieving these with the June 29th proposed notice. However, we do have some concerns, comments and refinements as listed below for your consideration.

CMS proposes a blend between a "bottom up" approach and a "top down" approach for this new practice expense methodology. CMS proposes to calculate direct practice expense RVUs using data refined by the RUC and its Practice Expense Review Committee (PERC) (and formerly the Practice Expense Advisory Committee). The application of this ***direct practice expense data appears more straightforward,*** and, therefore, more transparent than the current system. However, after review of the nuclear medicine codes, we find some variations that we are not able to explain or understand. This could require the modification of PE inputs to some of the nuclear medicine codes. The SNM will bring these to the PERC and request the agency consider correcting the inputs ahead of any scheduled review of practice expense data. ***We support the CMS proposal for a four-year phase in to allow for these types of refinements.***

CMS also acknowledges that only 2/3 of the direct expenses are recognized due to budget constraints. ***The SNM is concerned that Medicare payments are not currently covering physicians' practice costs.*** The indirect practice expenses, often a significant portion of the formula, are still based on a "top down" approach. The continence of a "top down blend" is inconsistent with the goal of achieving transparency. The SNM believes that any new practice expense methodology used should provide more consistent RVU assignment across like nuclear medicine procedures. We continue to notice wide ranges in these values and seek CMS's continued assistance for explanation of these variations for our members.

Supplemental Survey and Multi-Specialty Physician Practice Expense Survey

CMS currently utilizes practice expense data and physician hours from 1995-1999 AMA Socioeconomic Monitoring System (SMS) survey to calculate a "practice expense per hour" estimation for most specialties. In this proposed rule, CMS plans to use the supplemental surveys and crosswalk nuclear medicine physicians to the radiology adjusted survey data. In general, we support use of the supplemental surveys, as we believe the data is more accurate and up to date. However, our membership is made up of several specialties and we believe that a direct crosswalk to radiology could be undervaluing the specialty of nuclear medicine. At present our physician membership includes a mix of nuclear medicine physicians, radiologists and cardiologists who

specialize in nuclear medicine. ***We suggest that CMS consider a blend of the supplemental survey from both the radiology and cardiology supplemental surveys to set the nuclear medicine rate in 2007 as opposed to a direct crosswalk to only the radiology survey.***

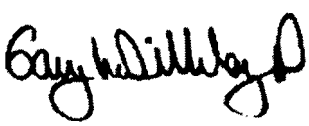
The SNM is pleased with and has agreed to participate in the AMA coordinated multispecialty survey effort. In the future, **we urge CMS to work with the AMA and other physician and health professional organizations to fund this multi-specialty survey effort and to ensure that the resulting data may be utilized in 2009.**

Equipment Assumptions – Equipment Utilization Data

Currently, CMS uses a 50% utilization rate for all equipment. In the proposed rule, no proposals are made to revise the formula. ***The SNM supports continued use of this 50% utilization rate*** until a time that CMS has the data to substantiate alternatives, as well as ensure that these alternate utilization rates have been vetted through the general public and specialty societies for validation. We believe there may be factors such as equipment service contracts, required quality maintence and geographic variations, which are not accounted for in the current calculations. We would be willing to work with CMS to collect and or review the necessary data. ***The SNM strongly urges CMS to allow the public the opportunity to comment on any proposed changes to the formula in a future Federal Register notice or proposed rule prior to implementation.***

The SNM appreciates the opportunity to comment on this proposed notice to the CMS. Should you find it appropriate to do so, the SNM is ready to discuss any of its comments on the above issues. Please contact the Society of Nuclear Medicine coding and reimbursement advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124.

Respectfully Submitted,



Gary Dillehay, M.D.
Chairman, Coding and Reimbursement Committee

Cc: Herb Kuhn, CMS
Carolyn Mullen, CMS
Pam West, CMS
SNM Coding and Reimbursement Committee
SNM Board of Directors
Emily Gardner, SNM
Edith Hambrick, MD, CMS
Kenneth Simon, MD, CMS
Kenneth McKusick, MD, SNM