

Submitter : Mr. John Moore
Organization : Hiawatha Community Hospital
Category : Critical Access Hospital

Date: 08/18/2006

Issue Areas/Comments

GENERAL

GENERAL
see attachment

CMS-1512-PN-1834-Attach-1.DOC

08/18/06

Hiawatha Community Hospital
300 Utah
Hiawatha, KS 46643

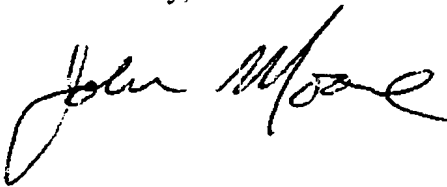
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014
Baltimore, MD 21244-8014

76082 and 76083

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

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

Sincerely,



Administrator
Hiawatha Community Hospital

Submitter : Mr. Scott Wolven

Date: 08/18/2006

Organization : Ethicon

Category : Drug Industry

Issue Areas/Comments

Practice Expense

Practice Expense

CMS should not move to full implementation of the bottom-up methodology until it has updated indirect practice expense data for all specialties. Additionally, if a delay is not possible, then we would also support the phase-in transition of the practice expense methodology with a dampening rule to limit decreases to 5% to 10% in any given year.

CMS-1512-PN-1835-Attach-1.DOC

August 17, 2006

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

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

Dear Dr. McClellan:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Five-Year Review of Work Relative Value Units and Changes to the Practice Expense Methodology for the 2007 Physician Fee Schedule. ETHICON, INC, a Johnson & Johnson Company, is a medical device company working in the areas of wound management, women's health, cardiovascular surgery, and surgical wound closure.

Based on the proposed changes in the practice expense methodology, we are concerned about the possible impact on Medicare beneficiaries' access to certain gynecologic and urology procedures. For many of these procedures, we are concerned that the reduction in direct practice expense in the non-facility setting will result in physicians making clinical site of service decisions based solely on reimbursement, instead of considering the best interest of the Medicare beneficiary, which in many cases, is the convenience of the physician office.

We therefore have the following recommendations:

Recommendation 1:

CMS should limit decreases in physician reimbursement to 5% to 10% in any given year, compared to the prior year base in order to allow physicians time to make appropriate adjustments to their practices to maintain the same level of service and continued access for Medicare patients.

Less than two years ago, CMS recognized the value of performing certain gynecologic and urology procedures within physician offices, which resulted in an increase in the practice expense for these surgical interventions. For example, Current Procedural Terminology (CPT) codes 58353 *Endometrial ablation, thermal* and 58563 *Hysteroscopy, ablation* are currently paid under the 2006 Medicare physician fee schedule at \$1,506 and \$2,397, respectively. Under the 2007 proposed transitional phase-in methodology, these rates would decrease to \$1,384 and \$2,216,

percentage changes of 8.10% and 7.53%. These changes do not include the 5.1% decrease due to the sustainable growth rate (SGR). By combining these two proposed changes together the decrease in the 2007 physician fee schedule would be on average of 12% to 13%. These changes would have a dramatic negative impact on beneficiary access to these procedures across the country.

The American Medical Association (AMA) has major concerns over the recently announced 5.1% decrease in the physician fee schedule. According to the AMA website, the "results of a recent AMA member connect survey indicate that Medicare payment cuts to physicians will hurt access to care for America's seniors. The results show that 45 percent of physicians will either stop accepting or decrease the number of new Medicare patients they accept if Medicare payments are cut in 2007."¹

Considering that the proposed 5.1% cut in the Medicare physician fee schedule is causing major concern within the physician community, the additional decrease of 7-8% in practice expense for these two gynecologic procedures will limit or even eliminate access to these necessary medical treatments. If access to these treatment modalities is denied, then beneficiaries' only option will be a more radical surgery alternative, such as a hysterectomy.

Therefore, our first recommendation is that CMS apply a "dampening rule" to limit decreases of 5% to 10% in any given year, compared to the prior year base, during the transition contemplated in the proposed rule. This would allow physicians time to make appropriate adjustments to their practices in order to maintain the same level of service and continued access for Medicare patients.

Recommendation 2:

CMS should delay the implementation of the bottom-up methodology until it has up-to-date and consistent indirect practice expense data for all specialties. At a minimum, the implementation of the proposed methodology should be limited to no more than a blend of 50 percent of practice expense Relative Value Unit (RVUs) calculated using the current methodology and 50 percent of RVUs calculated using the bottom-up methodology until the indirect practice expense data are updated.

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

To achieve CMS' goal to make the practice expense RVUs calculation fair and predictable, it is critical to update the indirect expenses for all specialties in a consistent manner. This should be a top priority, given the high percentage of overall practice expenses attributable to indirect costs. We recommend that CMS delay the implementation of the bottom-up methodology until it has up-to-date and consistent indirect practice expense data for all specialties. At a minimum, the implementation of the proposed methodology should be limited to no more than a blend of 50 percent of practice expense RVUs calculated using

¹ <http://www.ama-assn.org/ama/pub/category/6583.html>

the current methodology and 50 percent of RVUs calculated using the bottom-up methodology until the indirect practice expense data are updated.

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

In conclusion, CMS should not move to full implementation of the bottom-up methodology until it has updated indirect practice expense data for all specialties. Additionally, if a delay is not possible, then we would also support the phase-in transition of the practice expense methodology with a "dampening rule" to limit decreases to 5% to 10% in any given year. This will allow Medicare beneficiaries' access to these important gynecologic and urology procedures, without negatively impacting patient care.

We look forward to the published comments before the final rule is implemented on January 1, 2007.

Thank you for your review and consideration of these comments. If you have any questions, please feel free to contact me at 908-218-2358.

Sincerely,

Scott Wolven
Reimbursement Director
ETHICON, Inc.
Route 22 West
PO Box 151
Somerville, NJ 08876
908-218-2358

Submitter : Dr. Boyd Helm
Organization : Dr. Boyd Helm
Category : Physician

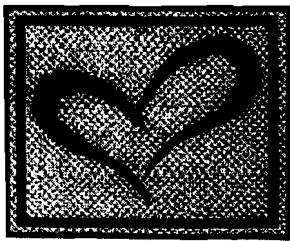
Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense
see attachment

CMS-1512-PN-1836-Attach-1.DOC



**BATON
ROUGE
CARDIOLOGY
CENTER**

*HFR 11
1836*

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
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James R. Calvin, M.D., F.A.C.C., Emeritus

- By Appointment
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- Arrhythmia Management
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- Diagnostic Heart Catheterization
- Post Heart Surgery Cardiac Management
- Balloon & Laser Coronary Angioplasty
- Coronary Atherectomy & Stents
- Cardiac Rehabilitation
- Pacemaker Implantation & Follow-up
- Lipid Management
- Syncope Evaluation
- Electrophysiologic Studies
- Radiofrequency Catheter Ablation
- Defibrillation Implantation & Follow-up

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

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

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

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments 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.

222

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 were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 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***

<i>Direct Cost Category</i>	<i>Included In RUC-Determined Estimate</i>	<i>Excluded From RUC-Determined Estimate</i>
Clinical Labor	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • Approximately 45% of the direct costs are 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 practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities (“IDTFs”), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 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.

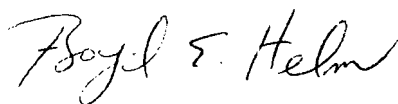
Solutions

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

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

Sincerely,



Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.

Submitter : Dr. Jeffrey Leach
Organization : East Texas Medical Center
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

GENERAL

GENERAL

I have recently become aware of proposed changes in the Medicare reimbursement for dual energy x-ray absorptiometry(DXA). If adopted, this could have a significant negative impact on patient access to osteoporosis screening and may negatively impact women's access to this important test. I am not in favor of the proposed reduction in the reimbursement for bone density.

Submitter : Dr. Joseph Cefalu
Organization : Dr. Joseph Cefalu
Category : Physician

Date: 08/18/2006

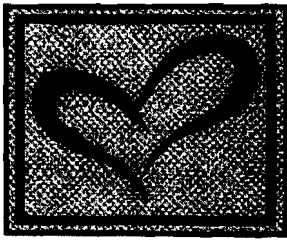
Issue Areas/Comments

Practice Expense

Practice Expense

see attachment

CMS-1512-PN-1838-Attach-1.DOC



**BATON
ROUGE
CARDIOLOGY
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Office # 1838

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James R. Calvin, M.D., F.A.C.C., Emeritus

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- Nuclear Testing
- Echocardiology
- Transesophageal
Echocardiography
- Tilt Table Testing
- Holter Monitors
- Event Recorders
- Diagnostic Heart
Catheterization
- Post Heart Surgery
Cardiac Management
- Balloon & Laser
Coronary Angioplasty
- Coronary Atherectomy
& Stents
- Cardiac Rehabilitation
- Pacemaker Implantation
& Follow-up
- Lipid Management
- Syncope Evaluation
- Electrophysiologic Studies
- Radiofrequency Catheter
Ablation
- Defibrillation Implantation
& Follow-up

Mark McClellan, M.D., Ph.D.
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U.S. Department of Health and Human Services
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7500 Security Boulevard
Baltimore, Maryland 21244-1850

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☺☺

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***Categories of Cardiac Catheterization Direct Costs Included or Excluded
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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.

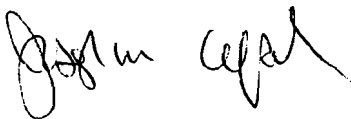
Solutions

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

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

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph Cefalu". The signature is fluid and cursive, with the first name "Joseph" and last name "Cefalu" clearly distinguishable.

Joseph Cefalu, M.D., F.A.C.C.

Submitter : Ms. Laurel Sweeney
Organization : Philips Medical Systems
Category : Health Care Industry

Date: 08/18/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1512-PN-1839-Attach-1.PDF

#7160114

1839



PHILIPS

LAUREL SWEENEY
Philips Medical Systems
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August 18, 2006

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

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:

On behalf of Philips Medical ("Philips" or "Philips Medical"), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on June 29, 2006 in the Federal Register (the "Proposed Notice"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET), radiation therapy planning, patient monitoring and resuscitation, as well as information technology solutions.

Philips very much appreciates the time and effort that CMS has devoted to the sweeping changes set forth in the Proposed Notice. We understand and appreciate that the tasks involved are especially difficult in light of the lack of clear cost finding and allocation rules in this area, alternative budget neutrality methodologies, evolving data issues, and the need to ensure that the various medical specialties involved view the changes as fair and equitable.

Preliminarily, we recognize that because there are no clear rules for determining and allocating practice costs at the service level, many of the decisions that must be made are essentially arbitrary. However, some decisions are clearly more arbitrary than others and, in choosing among the various more-or-less arbitrary choices that are available, it is crucial to establish decision-making criteria. In this regard, we respectfully suggest that CMS determine the methodology to be used on the basis of stability, equity, access to high quality services and transparency.

Promote Stability

We cannot overestimate the importance of stability and predictability of Medicare payment for technical component services, which are the services generally provided by Philips Medical's customers. Technical component services are by definition capital intensive--the acquisition and maintenance of the medical equipment necessary to provide these services requires significant forethought and financial planning. If payment allowances fluctuate significantly on a year to year basis, providers of these services simply cannot budget reasonable and necessary expenditures for costly medical equipment and highly skilled personnel with confidence.

In light of the need to ensure that allowances are stable from year to year to the maximum degree practicable, we strongly support CMS's proposal to provide a four-year transition for practice expense changes. We also suggest that CMS provide a similar transition period for the changes resulting from the five-year review. While we understand that five-year review changes are generally incorporated into the PFS without a transition period, the changes resulting from prior five-year reviews have not been of the magnitude set forth in the Proposed Notice. This year's five-year review changes significantly increase payment allowances for internists, family practitioners, and others who provide extensive evaluation and management services, as well as surgeons (who will experience RVU increases for post-operative services). As proposed, the cost of these changes will be borne disproportionately by radiology, cardiology, and other professional component services, resulting in one-year reductions in the range of 6-7% for some professional component services. We believe that reductions of such magnitude are better absorbed over several years.

We are also concerned about CMS's proposal to revise practice expense allowances on an annual basis, based on the most recent year's utilization data. We note that utilization of services may experience unpredicted variation, which may have significant impact on TC allowances. For example, because of single year variations in utilization, the TC allowances paid under the current Non-Physician Work Pool methodology experienced an unanticipated drop, and, as a result, the methodology was modified to take into account several years of utilization. We urge CMS to test the sensitivity of the system to changes in utilization and, if the revised methodology appears to be extremely sensitive to such changes, appropriate methodological changes should be made to assure stability.

In fact, we urge CMS to consider adopting a review cycle that does not necessitate significant changes on an annual basis. It is our understanding that work relative value units (W-RVUs) are not changed significantly except as the result of the five-year review, and a similar process could be established for practice expense (PE-RVUs). In this regard, the need for stability is at least as great--if not greater--for physicians' practice expenses than for physician work, since large fluctuations in payment for practice expenses fundamentally preclude physician practices from effective financial planning, staff recruitment, and facility construction and maintenance.

Ensure Equity

Budget Neutrality

The Proposed Notice proposes to make budget neutrality adjustments necessitated by the five-year review by adjusting the W-RVUs and to make budget neutrality adjustments necessitated by changes in the practice expense values by adjusting PE-RVUs. However, the practice expense budget neutrality reduction lowers payments for practice expenses overall by approximately 58% while the work budget neutrality adjustment lowers payments for physician work by approximately 10%. Thus, under the Proposed Notice, services that are heavily comprised of PE-RVUs (such as TC services) absorb a disproportionate share of the budget neutrality adjustments. For this reason, while the CMS Proposal is reasonable, it does not appear to be ideal.

A more equitable alternative would be to make all budget neutrality adjustments on a fee-schedule-wide basis, and to phase in both the PE-RVU changes and the W-RVU changes over a period of four years. Of the alternatives available, we believe that this is likely the best, since it phases in the extraordinary increase in payment for evaluation and management services over a period of time, treats five-year review and practice expense changes similarly, and advantages neither services that are primarily comprised of W-RVUs nor those comprised primarily of PE-RVUs.

We understand that there is considerable opposition to CMS's proposal among certain specialties that want CMS to use different methodologies to make budget neutrality adjustments resulting from the five-year review and those resulting from changes in PE data and methodology. Specifically, some have suggested that the budget neutrality adjustment for W-RVUs be made on a fee-schedule-wide basis while the budget neutrality adjustment for PE-RVUs be absorbed exclusively by the PE-RVUs.

This proposal is clearly inequitable for technical component services, which are already absorbing a 58% budget neutrality adjustment. These services should not also have to absorb budget neutrality adjustments resulting from the five-year review process. This is especially true since the extraordinarily large practice expense budget neutrality adjustment is primarily the result of the creation of the significant number of additional PE-RVUs that are then allocated based on W-RVUs. While technical component services are not eligible for indirect cost allocations based on W-RVUs, but must bear their proportionate share of the resulting budget neutrality adjustments. Thus, technical component services already bear a disproportionate share of the practice budget neutrality adjustment. The proposal to make work budget neutrality adjustments on a fee-schedule-wide basis, while making PE budget neutrality adjustments solely by reducing PE-RVUs would exacerbate a clear and substantial inequity that already exists in the Proposed Notice. This proposal clearly should not be accepted.

Indirect Cost Allocation

Philips strenuously objects to the continued use of W-RVUs as an allocator for indirect costs, which substantially disadvantages technical component services. Since indirect costs constitute approximately 60% of all practice expenses and approximately two thirds of indirect costs appear to be allocated on the basis of W-RVUs, approximately 40% of all dollars available to pay providers for their practice expenses are allocated based on W-RVUs. Technical component services have no W-RVUs and are thus ineligible to receive any of this Medicare payment.

A service's W-RVUs are entirely unrelated to the indirect practice costs (e.g., overhead and administrative costs) involved in providing that service. While an argument can be made that a physician incurs overhead costs for his office even when he is performing services outside of the office, is there any reason to believe that the amount of overhead incurred is related to the value of the physician's professional services? Does a family practitioner incur lower indirect costs per hour than a neurosurgeon? Where an estimated 40% of the available funds available to pay for physician practice expenses are distributed among various services on a basis that is not at all related to relative costs, is the methodology truly resource-based?

CMS has indicated that because technical component services have very high direct costs, the allocation of some portion of indirect costs on the basis of W-RVUs does not unduly disadvantage technical component services, even though technical component services have no W-RVUs. But what if CMS or Congress modifies the direct cost calculations—by, for example, significantly changing the equipment utilization or interest rate assumptions or the equipment acquisition cost data?

We urge CMS to at the very least limit the use of physician work to no more than a designated percentage of indirect costs. For example, CMS could limit the proportion of indirect costs allocable on the basis of physician work based on the proportion of out-of-office services (as opposed to in-office services) provided under the PFS. We also note that limiting the number of PE-RVUs created in order to accommodate the indirect costs of physicians in out-of-office settings, would significantly reduce the practice budget neutrality adjustment that is necessary.

At the very least we request CMS to commit to re-examine its allocation methodology for indirect costs when and if it changes any of the major assumptions or data used to determine technical component services and, in the interim, to make a number of adjustments to pay technical component services more equitably for indirect costs. In this regard, we support CMS's proposal to use non-physician staff time as an allocator for services with no physician work. We also suggest that CMS consider refraining from adjusting direct costs for budget neutrality before using direct costs as an allocator of indirect costs. This change should modestly benefit TC services and other services with relatively high direct costs.

Access and Quality

We have identified a number of services that would incur such substantial payment reductions under the Proposed Notice that the proposed changes may jeopardize access and quality. For example, under the Proposed Notice, Medicare payment for cardiac monitoring services would be reduced in the range of 40% -70%, depending on the service involved. Reductions of this magnitude will jeopardize the financial viability of the affected providers and could limit access to these services by Medicare beneficiaries.

Moreover, it is our understanding that TC providers of cardiac monitoring services are not directly represented through the RUC process and that the direct cost data upon which the proposed allowances are based are incomplete for these kinds of TC services. We urge CMS to maintain current allowances at least until complete and accurate data can be obtained from the providers involved.

We also note that certain in-office cardiac services, such as in-office echocardiography and nuclear medicine services will incur substantial reductions under the Proposed Rule. We urge CMS to consider imposing a cap on the amount of any reduction, as it did most recently in conjunction with the hospital inpatient prospective payment system final rule.

Transparency

We understand that one of CMS's primary priorities in the Proposed Notice was to increase the transparency of the methodology. Regretfully, it is unclear to us that CMS has achieved this objective. While the proposed methodology is more transparent in some respects (e.g., the elimination of certain scaling factors), it is equally if not more obtuse in others (e.g., the practice expense budget neutrality methodology). We urge CMS to continue to work with all affected groups, including manufacturers of major medical equipment, to further improve the transparency of the process.

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

Sincerely yours,

PHILIPS MEDICAL SYSTEMS



Laurel Sweeney
Sr. Director, Reimbursement & Legislative Affairs

Submitter : Mrs. Kerensa Wenzlick
Organization : Covenant Healthcare
Category : Health Care Professional or Association

Date: 08/18/2006

Issue Areas/Comments

GENERAL

GENERAL

A reduction in Medicare reimbursement for dual energy x-ray absorption (dexa) will only have a negative effect for the nearly 10 million people who have been diagnosed with osteoporosis, and the millions of people yet to be diagnosed.

I have been involved with health care since 1991 working as a radiographer. I have seen so many unnecessary fractures due to osteoporosis. I have watched patients suffer for months and even years due to osteoporotic fractures. The fractures cause great pain and lead to million and millions of dollars in our health care bills each year. They have a significant economic impact on our nations health care. The majority of these patients are elderly and need our help.

If medicare and medicaid reduce the reimbursement for the Bone Density test many Dr.'s and facilities will do away with the testing all together. I see people every day who can't take medication they need, or have tests done to help them because they cannot afford to. It is our responsibility to do everything we can to prevent this from happening. A bone density test is a simple screening/diagnostic tool that has already proven how cost effective it is time and time again. The adverse effects of osteoporosis could be significantly minimized on a nationwide basis with strong compliance to screening and treatment guide lines.

In the three year time peroid form 1999-2001 only 22.9% of females over the age of 65 had bone density tests, according to a study based on medicare claims (1) There are four times as many mammography claims as bone densitometry claims (2).

further efforts are needed to increase utilization of Bone

Density testing to promote the early detection and treatment of osteoporosis. This would lead to an improvement in the quality of life of many elderly Americans and a significant decrease in health care cost incurred due to osteoporotic related fractures.

Kerensa L. Wenzlick
Covenant Healthcare

- (1) Us markets for Womens Health imaging Systems 2005. Millenium research group
- (2) Disease Management Advisor. National Health Information LLC, Vol 9, 2003 pgs 1-16

Kerensa L. Wenzlick RT(R)(M)

Submitter : Dr. Kevin Kilpatrick
Organization : Dr. Kevin Kilpatrick
Category : Physician

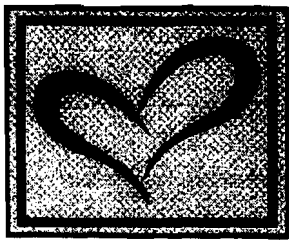
Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense
see attachment

CMS-1512-PN-1841-Attach-1.DOC



BATON ROUGE CARDIOLOGY CENTER

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Evens Rodney, M.D., F.A.C.C.
Darrin M. Breaux, M.D., F.A.C.C.
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James R. Calvin, M.D., F.A.C.C., Emeritus

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By Appointment

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Cardiac Evaluation & Counseling

Arrhythmia Management

Stress Testing

Nuclear Testing

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Transesophageal Echocardiography

Tilt Table Testing

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Event Recorders

Diagnostic Heart Catheterization

Post Heart Surgery Cardiac Management

Balloon & Laser Coronary Angioplasty

Coronary Atherectomy & Stents

Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

Syncope Evaluation

Electrophysiology Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up

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

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

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

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments 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 were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 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	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • Approximately 45% of the direct costs are 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 practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities (“IDTFs”), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 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 catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Kilpatrick". The signature is stylized with a large, looped initial "K" and a trailing flourish.

Kevin Kilpatrick, M.D., F.A.C.C.

Submitter : Dr. Terry Zellmer
Organization : Dr. Terry Zellmer
Category : Physician

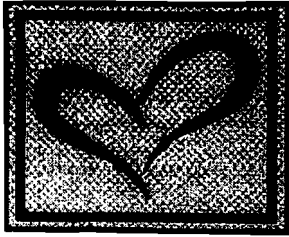
Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense
see attachment

CMS-1512-PN-1843-Attach-1.DOC



BATON ROUGE CARDIOLOGY CENTER

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By Appointment

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Nuclear Testing

Echocardiology

Transesophageal Echocardiography

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Coronary Atherectomy & Stents

Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up



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Administrator
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Mail Stop C4-26-05
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Baltimore, Maryland 21244-1850

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

Direct Costs

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

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 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***

<i>Direct Cost Category</i>	<i>Included In RUC-Determined Estimate</i>	<i>Excluded From RUC-Determined Estimate</i>
Clinical Labor	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • Approximately 45% of the direct costs are 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 practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities (“IDTFs”), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 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 catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Terry Zellmer', with a long horizontal flourish extending to the right.

Terry Zellmer, M.D., F.A.C.C.

Submitter : Mr. Steven Oscherwitz

Date: 08/18/2006

Organization : Infectious Disease

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Regarding 2007 PFS Final Rule in November 2006:

Sir or Madam,

The E/M service code wRVU recommendations submitted by the Relative Value Update Committee will help to guarantee patient access to cognitive specialties, such as infectious diseases, that have long been undervalued compared to their surgical colleagues.

Budget neutrality should be maintained through a change to the conversion factor rather than the 10 percent decrease in work Relative Value Units (wRVU's) proposed by CMS.

A wRVU adjustment will disproportionately impact those services with low practice expenses, such as the E/M service codes used by infectious diseases specialists.

Adjusting the conversion factor is a more appropriate way to address budget neutrality issues.

A conversion factor budget neutrality adjustment is preferable because it recognizes that budget neutrality is a fiscal issue, not an issue of relativity. The issue of relativity is also important because many private payers use the RVUs included in Medicare's physician fee schedule to determine their payment rates.

Current physician payment rates for E/M codes make it increasingly difficult for me to provide high quality care to Medicare beneficiaries with serious infections.

Thank you,

Steven L. Oscherwitz MD
Infectious Disease
Tempe, Arizona

Submitter : Ms. Dawn Briskey
Organization : American Society for Surgery of the Hand
Category : Health Care Professional or Association

Date: 08/18/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-1844-Attach-1.PDF

ATTACHMENT TO # 1844



ASSH

American Society
for Surgery of the Hand

Excellence in hand and upper extremity care since 1946.

August 18, 2006

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

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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

Submitted electronically at <http://www.cms.hhs.gov/eRulemaking>

Dear Dr. McClellan:

On behalf of the members of the American Society for Surgery of the Hand, the following comments are submitted in response to the Proposed Rule published in the *Federal Register* on August 29, 2006. We appreciate the participation of CMS staff during the review of physician work and for accepting many of the RUC recommendations, including the few codes that we offered for review. We will be commenting on both general issues and code specific issues relating to other codes where CMS disagreed with some basic RUC approved principles that we believe are extremely important. We are also offering comments on some proposed changes to the methodologies for practice expense calculations and for budget neutrality. We have organized our comments into sections as requested in the Proposed Rule.

General Comments

We join the American College of Surgeons, the American Medical Association, the Society of Thoracic Surgeons, the American Academy of Orthopaedic Surgery, and essentially all of medicine in being disappointed by CMS' treatment of data collected from the National Surgical Quality Improvement Program (NSQIP) database, the Society of Thoracic Surgeons (STS) National Database, and the CMS national DRG database. Unless CMS can provide objective comments and rationale as to why CMS has decided that a survey of 30 (or fewer) respondents is more representative, accurate, and meaningful than independently collected and audited data sources, we would

urge CMS to reconsider its decision to ignore the value of information collected from the above listed databases. In general, we believe CMS' treatment of massive data collection efforts is arbitrary and does not support the regulatory requirements to maintain a resource-based relative value scale that is an accurate representation of the work performed by physicians. Clearly, the average (or median) of hundreds or thousands of cases will approach a national distribution better than 30 willing survey volunteers. We continue to make the point that these databases are more representative than is data obtained from a 30-person survey.

We strongly encourage CMS to join all of medicine in adopting a policy to use the best data possible when valuing the work of physicians. Despite the AMA/Specialty Society RVS Update Committee's (RUC) efforts, the decisions presented in the Notice of Proposed Rulemaking do not reflect this principle of searching for the most accurate and objective data. In addition, many of CMS' decisions have produced a plethora of rank order anomalies that create inaccurate and bizarre situations that will have to be corrected during the next five-year review period. If left uncorrected, these anomalies will also cause havoc in the selection of reference codes over the next five years. For these reasons, we urge CMS to reconsider the peer-reviewed recommendations of the RUC that utilize these large databases in various ways (often in conjunction with surveys) and accept the RUC recommendations in the final rule. Alternatively, the Agency should provide a clinical rationale, as required in all other reviews by the Agency and the RUC for the past 15 years, for why a specific work RVU chosen by the Agency is more correct or appropriate than one derived from large numbers of objectively collected encounters and extensive deliberation by all of medicine. Simply stating that the Agency "believes" that repair of a fractured hip is similar to an arterial bypass graft without supporting objective statistically valid data, is unacceptable.

Discussion of Comments – Orthopaedic Surgery

In its proposed rule, CMS rejected the RUC's recommendations for three orthopaedic codes – 27130 (total hip arthroplasty); 27236 (open treatment for femoral fracture); and 27447 (total knee arthroplasty). We are concerned about the methodology CMS used to develop its proposed work RVUs and urge CMS to reconsider and review all relative information. First, the RUC recommendations for these three codes were based on survey data, which was supplemented by NSQIP data and data from the CMS DRG database. As we have stated above, we strongly believe databases are the most valid, accurate method for measuring time available. The RUC carefully scrutinized these codes and after much discussion, the RUC decided to add the NSQIP intra-time to the RUC database, as more accurate. In disagreeing with the RUC's recommendations, CMS indicated that these codes had never been reviewed by the RUC, but this is incorrect. The RUC based its recommendations for these codes on RUC survey data and comparison to reference codes, and recommended to maintain the current work RVUs, which were lower than the survey medians for all three codes.

To develop proposed work RVUs, CMS selected several codes that "it believes" are similar and made a recommendation based on these supposedly similar codes. CMS decided that a total knee

The Honorable Mark B. McClellan, MD, PhD
August 20, 2006

replacement is similar to a vagotomy and a thyroidectomy; an open treatment to a thigh fracture is similar to a thrombectomy; and a total knee replacement is similar to an artery bypass graft. As surgeons, we are perplexed by CMS' comparisons. We do not understand the clinical rationale for comparing such dissimilar procedures. It appears CMS simply scanned the Medicare Fee Schedule for codes that have similar times, but lower work RVUs, and applied those values to these three orthopaedic codes. This is not a standard RUC methodology for valuing codes; it is not an accepted RUC method for changing the work RVU of a code; and it certainly is not "compelling evidence" that the time or intensity of a code has changed and the work RVU should, therefore, be altered. If a specialty society used this methodology to argue for an increased work RVU, it would surely be rejected by the RUC and CMS.

We also note that the valuations proposed by CMS will create rank order anomalies within the family of orthopaedic codes and with other codes that were part of the five-year review. For example, codes 27465 (shortening of the thigh) and 27470 (repair of thigh) were valued considerably lower than code 27130 in 2005 and CMS accepted a higher value for those codes during the five-year review. However, the almost 25 percent decrease to code 27130 now makes that code lower in value than codes 27470 and 27465. In addition, the difference in the RVWs of code 27130 (total hip) and code 27447 (total knee) is now exaggerated. While in 2005, code 27447 was valued seven percent more than code 27130, CMS' proposed rule values code 27447 at almost 20 percent more than code 27130. We do not believe these discrepancies are an accurate reflection of work difference. We urge CMS to review the information that we have provided, along with additional information that the RUC and the orthopaedic societies are sending in their own comment letters, and we urge CMS to maintain the current work RVUs for 27130, 27447, and 27236.

Discussion of Comments – Evaluation and Management Services

We join other specialties in being concerned about the dramatic increase in several Evaluation and Management (E/M) codes, in particular 99213. We do not believe that compelling evidence was presented to increase the work RVU of this code by more than 37 percent. Furthermore, this spectacular increase creates a host of rank order anomalies for codes with a global period that includes E/M services that will create an avalanche of requests for increases during the next five years and in the next five-year review. We urge CMS to correct the anomalies within and between the E/M code families before the final rule is published in November.

CMS acknowledges that the RUC's recommendations were based on the principle that incorrect assumptions were made when these E/M codes were originally valued. While this may be true, these false assumptions were corrected in the first five-year review and 35 E/M codes, including 99213, were increased by upwards of 16 percent to compensate for these issues. It is not equitable to allow these codes to be brought forward again for revaluation based upon incorrect assumptions that were already corrected over ten years ago. The primary compelling evidence that was discussed and accepted by the RUC was that "all codes within a family should not have the same intensity." Therefore, we believe that the adjustments should have been made within

and between families to correct this and not to increase almost all E/M codes to a higher level.

More importantly than the intensity issue, we strongly believe physicians have already been compensated for the increased work of providing E/M services by billing longer and more intense visits (ie, higher levels). CMS and the RUC have been shown concrete data that since 1994, despite an increased number of total beneficiaries, the number of 99212 office visits has decreased from 31,656,490 to 26,354,871. At the same time, the number of 99213 office visits has increased from 83,527,221 to 112,649,520 and the number of 99214 office visits has increased from 30,561,026 to 55,837,512. These changes have cost the Medicare program more than \$3 billion. In total, there has been an 85 percent increase in allowed charges for 99213 alone between 1997 (the last review of E/M codes) and 2004. In 2003, E/M services accounted for more than 30 percent of the growth in Medicare physician spending, a trend that continued into 2004. This has been a concern expressed by the Agency in all of its reports, yet the Agency has ignored this in its decision to increase even further the work RVUs for these codes despite this clear and unprecedented shift to longer and more intense office visits

While we agree the demographics of Medicare patients are changing and the average beneficiary is older with more co-morbidities, this trend is not unique to E/M services. When these same patients have surgery, their increased co-morbidities and risk factors do not disappear. The characteristics that justify a 37 percent increase for 99213 can be used to argue for a 37 percent increase to many procedural codes on the Medicare Fee Schedule. We do not believe the Medicare program can sustain such an increase, no matter how justified, and do not believe it is equitable to grant an increase to one code based on factors that apply to all specialties when that increase cannot be applied across the board. While it is correct that the E/M increases were applied to global surgical services, for many codes the total work RVU was not calculated using the full value for E/M services, so adding only a differential means that these codes are still not "whole." Additionally, in many instances the actual pre-, intra-, and immediate post-services are also made more difficult by a patient's advanced age or co-morbidity, yet there was no consideration for changes in the work in these time periods.

We are concerned that the true cost of the E/M increases will be much more than CMS' current \$4 billion estimate as more and more physicians bill code 99213 or 99214 instead of a lower level code. We note that the difference in these codes is often only the number of organ systems examined, something that is in the control of the physician, and which the physicians today are trained to pay attention to in correct coding. We already are concerned about the unexplainable increase in billing of code 99213 instead of lower level codes and fear this trend will increase exponentially with the 37 percent increase in this code.

Discussion of Comments – Cardiothoracic Surgery

We have concerns regarding the rejection of the RUC recommended work RVUs for the cardiothoracic codes. The RUC (which represents all of medicine) and the Society of Thoracic Surgeons (STS) worked diligently over several years of discussion to ensure these codes were

placed in the correct relative rank order. The ASSH joins all of medicine in being concerned that the recommendations put forward by CMS in the proposed rule destroy this work relativity and leave these codes in a state of disarray. For example, a three-vein CABG procedure is now valued higher than a four-vein CABG procedure. In addition, there are now many codes with higher values than a heart transplant, clearly the most difficult and work intensive of the cardiothoracic procedures.

We are also disappointed by CMS' comments regarding the STS Database. As we indicated in our General Comments above, we feel this information is invaluable, accurate, and objective and should be considered the gold standard. While there will always be a certain amount of estimation and opinion, especially when attempting to determine intensity, we feel audited actual time measurements should be used whenever possible. We emphasize that many of the concerns raised by CMS in the proposed rule were vetted during the RUC Research Subcommittee meetings in February and April of 2005, at the Workgroup meeting in August 2005, and again at the RUC meetings in October 2005 and February 2006. CMS was in attendance at all of these meetings. Additionally, we do not understand CMS' concerns over representativeness of this data. The STS database includes over 3 million patient records, with more than 70 percent of hospitals reporting. How can this even be compared to a survey of 30 surgeons *willing* to complete a RUC survey instrument?

Further, it is important to acknowledge that certain procedures, including heart transplants and other advanced cardiothoracic procedures, do, in fact, occur much more often in an academic center than in a community hospital. No data collection since the inception of the MFS, including the Harvard study, ever required that the geographic and practice distribution of data (by survey or database) match the geographic and practice distribution of procedures on a code-by-code basis. Clearly, the average (or median) of millions of cases will approach a national distribution better than the median of 30 survey volunteers.

We also agree with STS that the mean times are appropriate in this instance. While the RUC normally uses median times, this is because there is such little data to work with that the median is considered a statistically more reasonable "estimate" in those instances. This is not the case for data derived from the STS database, with millions of records. When a significant number of actual measurements are being used and not estimations, such as the case with the STS database, we believe mean times are appropriate, and we note that the RUC (and all of medicine) is in agreement with this. On the other hand, in determining which figures to use when analyzing NSQIP data, the RUC believed that the median times were more appropriate because the volume per code is much less than the STS database. Had NSQIP had the same percentage volume of cases, the mean data would have been more reflective of the true median. Statistically, this can be demonstrated. Statistically, this is why the RUC correctly uses the median for 30 surveys and Harvard used the geometric mean of 100-200 surveys. When the number of records approaches the level of the STS database, it was significantly clear to the RUC that the statistic that is most appropriate is the true mean (and not the median or the geometric mean). Also significantly, it should be noted that for procedures tracked by the STS database that have low volume, in

particular several of the general thoracic codes, the median times were used for work RVU recommendations. While the RUC and STS attempted to review codes using the correct statistic (mean or median), CMS has chosen to not consider that statistics is a science with many variables that require unique consideration.

Regarding the Agency's discussion of intensity, we do not agree with the intensity values recommended by CMS for the cardiothoracic codes. The RUC spent considerable time over the past five years reviewing various methods for determining intraservice work per unit of time (IWPUT) and the methods used by STS were approved by the RUC after thorough vetting. First, STS utilized a magnitude estimation survey of more than 19 percent of practicing cardiothoracic surgeons. This method was approved by the RUC, with CMS in attendance; the surveys and instructions were reviewed by the RUC, with CMS in attendance; the reference codes utilized were RUC reviewed, with CMS in attendance; and CMS has accepted this methodology in the past as a reliable method for developing IWPUTs (eg, neurosurgery and vascular surgery). In addition, a 32-member expert panel (with RUC oversight) was utilized to review the results code-by-code to ensure proper rank order of total work (ie, magnitude estimation) – and not work RVUs. Finally, the Rasch survey method was utilized to validate the survey results. This method has been used to validate work magnitude and intensity in the past. The Rasch analysis is simply standard regression analysis for surveys with subjective variables and not some black magic formula. In its final recommendation, the RUC used the average of the IWPUTs generated from the magnitude estimation survey and Rasch methods, recognizing that they were maintaining a relativity between procedures, as determined by the "experts" using two valid approaches. However, in rejecting the RUC's recommendations, CMS states that it believes the IWPUTs created in the second five-year review are more accurate and should be used. We note that STS did use the IWPUTs from the second five year review as anchors for the IWPUT magnitude estimation and Rasch surveys, and, we believe that CMS did not use the correct IWPUT numbers in the proposed rule because we cannot replicate CMS' math.

Again, we urge CMS to review all of the information provided by STS and the RUC regarding the cardiothoracic codes and reconsider the RUC recommendations as most correct to set these codes relatively and accurately within the Medicare fee schedule.

OTHER ISSUES

Postoperative Visits Included in Global Surgical Packages

In the Proposed Rule, CMS indicated that it would apply the RUC-recommended new values for the E/M services to all surgical services with 010 and 090 day global periods. The RUC indicated that E/M work is equivalent and a crosswalk of 100% of the E/M valuation should be added to the codes with global periods of 010 and 090 days. In the Proposed Rule, it appears that CMS has incorrectly implemented this recommendation. CMS, when calculating the increment to be added to all of the services with post-operative visits in the 010 and 090 global periods, used the non-discounted work RVUs instead of the discounted work RVUs. We ask CMS

review their calculations and implement the correct work RVUs for all procedures that have a 010 and 090 global period to reflect the RUC recommendation.

Budget Neutrality

We disagree with CMS's decision to utilize a separate work adjuster for the work RVUs. We believe that this additional calculation is cumbersome for billing purposes. We note that CMS has previously tried this methodology after the first five year review but abandoned it after two years because "...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." Additionally, after the second five year review, CMS adjusted the conversion factor to adjust for changes in physician work. In the proposed rule, CMS states it is implementing the work adjuster as opposed to a conversion factor reduction because it believes it is more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the five-year review. However, we note that the work RVUs are also used to determine the practice expense RVUs and it appears CMS has proposed to use the adjusted work RVUs to determine the indirect practice expenses. This in essence allows CMS to cut physicians twice – once by reducing the work RVUs and again when determining the indirect practice expenses. So this adjuster is NOT only applicable to the work RVUs.

Use of Supplemental Survey Data

We have concerns regarding CMS' acceptance of supplemental survey data. We do not understand how surveys originally rejected and marked as unacceptable are now considered acceptable even though the surveys have not been redone or modified in anyway. We do not see how a survey deemed unacceptable can be used. For example, CMS originally expressed concerns regarding a survey conducted by the American Society for Therapeutic and Radiation Oncology (ASTRO) and stated the survey did not meet the agency's criteria. However, in the current proposed rule, CMS has accepted the survey data and proposes to blend it with a survey from another society. We do not believe blending a survey with another one corrects the initial concerns with the original survey, but instead just dilutes the questionable data. In addition, we have concerns about the survey submitted by the National Coalition of Quality Diagnostic Imaging Services (NSQDIS). We do not believe deleting records from the data set in order to obtain an acceptable precision range is an accepted statistical principle.

We also question the validity of all of the supplemental surveys given the fantastic increases many specialties claim have occurred in just a five year period. Either most or all specialties would have this same increase or these surveys are not comparable to the SMS survey data.

First, we note that the accounting method for writing off capital equipment is key in calculating the "cost" of the equipment. CMS itself changed the life expectancy for many pieces of equipment recently. It may be that specialties are now "accounting" for it differently, and this

The Honorable Mark B. McClellan, MD, PhD
August 20, 2006

would apply to all specialties. Second, we note that labor is the most significant component of practice expense and every practice has seen labor cost increase. We believe this data either seriously brings into question the validity of the original survey data, or brings into question the credibility of the supplemental surveys. In either event, we do not believe it is plausible to use supplemental survey data for some specialties and use original data for others adjusted for inflation because we believe the numbers themselves show the two surveys are not comparing apples to apples. If the supplemental surveys are correct, then costs have outpaced inflation and this would apply to all specialties, so adding only a minor inflation adjuster to some specialties is unfair.

Additionally, there has been no investigation regarding the funding, validity, or reproducibility of the supplemental survey data, so we find it extremely interesting that CMS has chosen to use supplemental survey data that CMS itself has questioned for practice expense purposes, while in the same Rule CMS indicates that the NSQIP, STS, and CMS DRG databases are unacceptable, even though the former are society and possibly company financed and driven and the later are CMS and/or national audited databases. Again, how can the original data be almost 200 percent underestimated, unless this is true for all specialties? For CMS to "adjust" for inflation a minor percentage for some specialties and at an inflated percent for others is not equitable. This should be extremely clear to the Agency. We are concerned that such a policy compromises the relativity of the entire fee schedule. We believe the fair solution is to determine the practice expense per hour for these seven specialties by a formula that blends the specialties original survey rates with those in the supplemental data. This solution allows these specialties to receive some benefit from the supplemental survey process, but recognizes that the practice expense per hour figures for these specialties have to bear some relation to the remainder of the physician specialties. As with physician work, just because the survey median is 100 work RVUs does not mean that 100 work RVUs will be accepted - there needs to be relativity to all other procedures.

We thank CMS for considering our recommendations for these two codes. If you have any questions, please contact Ms. Dawn Briskey at 847-384-8300 or Dr. Daniel Nagle at 312-337-6960.

Sincerely yours,



David M. Lichtman, MD
President, American Society for Surgery of the Hand
Retired Rear Admiral, United States Navy

Submitter : Mr. Keith Prince

Date: 08/18/2006

Organization : San Diego Imaging - Chula Vista

Category : Health Care Provider/Association

Issue Areas/Comments

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

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

Please accept this attachment regarding the proposed reduction in the Technical component of CAD for digital mammography.

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

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

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

Submitter : Dr. Robert Havey
Organization : Chicago Lake Shore Medical Associates Ltd
Category : Health Care Professional or Association

Date: 08/18/2006

Issue Areas/Comments

Other Issues

Other Issues
see attachment

CMS-1512-PN-1846-Attach-1.DOC

ATTACHMENT TO # 1846

**Chicago Lake Shore Medical Associates, Ltd.
676 North St. Clair Suite 2300 Chicago, IL 60611**

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
Baltimore, MD 21244-1850

To whom it may concern:

This letter is in response to your request for comments related to the proposed changes in reimbursement for dual energy x-ray absorptiometry (DXA). It is our understanding that under the proposed change DXA reimbursement would decrease by 73%. This new reimbursed amount would not cover even the direct costs of providing this important service.

Studies indicate that nearly 50% of all women will get an osteoporosis related fracture in their lifetime. DXA is an important tool in the prevention of these fractures and the resulting extensive and expensive care and cost to the Medicare program for their recovery. Additionally, the majority of patients over 65 years of age who incur an osteoporosis related fracture will not live independently again in their lifetime.

In the case of DXA, an ounce of prevention is clearly worth a pound of cure. If the new rates are implemented, a large number of DXA providers will be forced to eliminate this service and access will be significantly reduced. The resulting effects of the proposed change will be more costly to CMS on a whole and highly detrimental to women's health nationwide.

Sincerely,

Robert J. Havey, M.D.

Submitter : Dr. David Rice
Organization : Association of Freestanding Radiation Oncology Cen
Category : Health Plan or Association

Date: 08/18/2006

Issue Areas/Comments

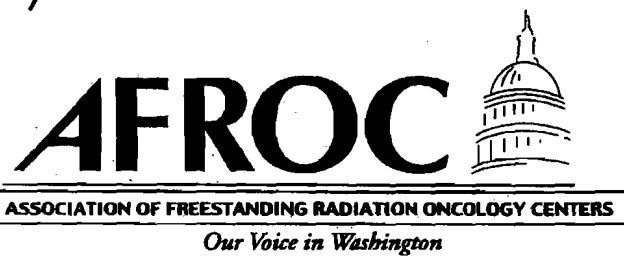
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CMS-1512-PN-1847-Attach-1.PDF

ATTACHMENT TO # 1847



August 18, 2006

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

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:

On behalf of the Association for Freestanding Radiation Oncology Centers (AFROC), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on June 29, 2006 in the Federal Register (the "Proposed Rule"). AFROC is an association representing non-hospital providers of radiation oncology services throughout the country. Accordingly, these comments focus primarily on the practice expense (PE) methodology described in the Proposed Rule.

These comments address a number of issues arising from the proposed PE data and methodology. For the reasons set forth below, AFROC respectfully requests that CMS:

- Substitute the PE/hr of \$213/hr for the current PE/hr for radiation oncology, for the reasons set forth in the attached report.
- Limit the application of physician work as an allocator of indirect PE-RVUs.
- Maintain the proposed methodology for including non-physician staff time as an indirect cost allocator, and consider eliminating or adjusting the direct and indirect adjustments to maximize the proportion of indirect costs distributed on the basis of direct costs.
- Modify the Indirect Practice Cost Index ("IPCI") methodology, as described below.
- Make the changes recommended by the American Association of Physicists in Medicine (AAPM).

- Either (a) require work RVUs to bear the budget neutrality adjustment resulting from the five-year review and the PE-RVUs to bear the budget neutrality adjustment resulting from the proposed PE changes; OR (b) maintain budget neutrality solely through the conversion factor. In any event, however, budget neutrality adjustments should be done in the same way for both W-RVU and PE-RVU changes.

Each of these issues is described below:

Radiation Oncology PE/Hr.

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

AFROC engaged the services of an independent claims analyst, Christopher Hogan of Direct Research, to determine whether or not the 75/25 “blend” ratio is correct. Direct Research’s report is attached. That report demonstrates that the Lewin Group’s analysis is flawed, and that the more accurate methodology for blending the AFROC and ASTRO survey results yields a PE/hr for radiation oncology of \$213/hr. We respectfully request that CMS substitute this figure for the PE/hr for radiation oncology used in the Proposed Rule.

Indirect Expense Allocation

AFROC strenuously objects to the continued use of work-RVUs as an allocator for indirect costs. It is clear that the intensity of physician work bears no relationship whatsoever to the practice expenses incurred by that physician: While there may be an argument that some portion of indirect costs should be apportioned to services performed outside of the office, there is no basis for determining that the intensity of physician work should be taken into account. For example, is there any reason to believe that more indirect costs (e.g., overhead, administrative costs, billing costs) are associated with the services of an internist who performs a hospital consultation for a half hour than for a surgeon who performs surgery for the same half hour?

The use of physician work RVUs as an allocator for indirect costs is quite simply a political accommodation to those specialties with relatively high W-RVUs. The impact of this political accommodation is extraordinary: We estimate that, if indirect expenses allocated on the basis of staff time are not taken into account, approximately 40% of total practice expense payments are distributed on the basis of W-RVUs. Because technical component services are not associated

with work RVUs, these codes are essentially ineligible for 40% of the total amounts paid under the PFS for practice expenses.

CMS has indicated that because technical component services have very high direct costs, the allocation of some portion of indirect costs on the basis of physician work does not unduly disadvantage technical component services. But what if CMS modifies the direct cost calculations--by, for example, significantly changing the equipment utilization or interest rate assumptions or the equipment acquisition cost data?

We respectfully urge CMS to limit the use of physician work to no more than a designated percentage of indirect costs. (One possible approach might be to limit allocation of indirect costs based on physician work to the percentage of time spent by physicians out of the office to the amount of time spent on in-office services, calculated as an average over some period of years.) Alternatively, the percentage could be established arbitrarily, recognizing that the reason for allocating any indirect costs on the basis of W-RVUs is a political accommodation in the first place.

At the very least, we request CMS to commit to re-examine its allocation methodology for indirect costs when and if it changes any of the major assumptions or data used to determine technical component services, such as the equipment utilization or interest rate assumptions, which may substantially affect payment for technical component services. In the past, CMS has indicated that the proposed indirect cost allocations methodology does not significantly disadvantage these services because of their high direct costs. However, if the direct cost allocations are reduced substantially, this rationale no longer can be used to justify using W-RVUs to allocate indirect costs, and the indirect cost allocation methodology must be revisited.

Non-Physician Staff Time as Indirect PE Allocator

AFROC supports the use of non-physician staff time as an indirect PE allocator, as set forth in the Proposed Rule. As set forth below, we believe that the use of physician work RVUs as an allocator is quite simply a political accommodation to the surgical community. To the extent that the use of non-physician staff time at least moderates some of the impact of this decision, we believe that it is more than justified in the context of the overall methodology.

We also note that direct costs are reduced by about 33% through application of the direct adjuster before they are used as an allocator for indirect costs. In light of the arguments set forth above, we believe that the portion of indirect costs allocated on the basis of direct costs should be increased, and one option might be to eliminate this adjustment for the purposes of indirect cost allocation.

Indirect Practice Cost Index ("IPCI") Methodology

We believe that CMS should closely examine and consider modifying the methodology used to determine the Indirect Practice Cost Index ("IPCI") with respect to radiation oncology. It appears that the IPCI, as presently configured, serves a number of different purposes:

- (1) The IPCI adjusts the indirect PE-RVUs of each service to reflect the relative indirect costs of the specialists who provide that service.
- (2) The IPCI "ties" each specialty's survey data to the PFS. Since the surveys provide practice expense data per physician hour, a specialty with more physician hours should have more indirect practice expenses.
- (3) The IPCI is the mechanism by which CMS maintains the "top down" aspects of its methodology, which serves a budget neutrality function by limiting indirect expense payments made to each specialty to amounts in that specialty's "pool."

It is unclear to us whether the current methodology for determining the IPCI is the best way to achieve any of these objectives.

It is our understanding that one of the primary functions of the IPCI is to ensure that the indirect PE-RVUs are adjusted to reflect each specialty's relative indirect PE/HR, as reflected in each specialty's survey. As we understand it, by the time the IPCI is applied, the direct PE-RVUs for each code have been determined based on the PEAC data and indirect PE-RVUs have been obtained based on direct costs, physician work and (in some cases) non-physician staff time. All that remains at that point is to adjust the indirect RVUs based on the various specialties' relative indirect costs, as reflected in the survey data.

Conceptually, a specialty with indirect expenses substantially higher than the average, such as radiation oncology (with indirect expenses of \$73.50/hr (not taking into account the adjustments supported by the attached Direct Research report) compared with the all physician average of \$46.30/hr) should have an index factor significantly greater than 1. Yet, the radiation oncology index factor resulting from the CMS methodology is .70. Thus, the current methodology is not a pure measure of the relative indirect costs of the various specialties.

We understand that this result is attributable to the fact that, while radiation oncology's indirect PE/hr is high, the number of radiation oncology physician hours is low--what is unclear is why the number of physician hours should be a factor. It could be argued that the inclusion of physician time in the formula is necessary because each specialty's PE survey reports practice expenses **per physician hour**; therefore, a specialty with twice the number of physician hours should have twice the indirect PE-RVUs. However, it seems to us that the amount of physician time is implicitly included in the calculation of indirect PE-RVUs on a CPT code-by-CPT code

Mark McClellan, MD, Ph.D.

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basis before the IPCI is applied, through the inclusion of W-RVUs as an indirect PE allocator. Thus, all other things being equal, a specialty that has twice the number of physician hours might be expected to have substantially higher indirect PE-RVUs, **without regard to the IPCI.**

One alternative is to derive the IPCI by taking the ratio of each specialty's indirect costs (as reflected in that specialty's survey) to the all-physician average indirect PE/hr. Once this IPCI is applied, the "pool" of indirect PE-RVUs for all services can be made budget neutral by an across-the-board adjustment, comparable to the budget neutrality adjustment methodology used for direct costs. This methodology has the advantage of transparency, which CMS has indicated is a major priority. Essentially, the suggested methodology makes it clear what percentage adjustment is necessary to make indirect PE-RVUs budget neutral. Under the current methodology, it is our understanding that some part of the budget neutrality adjustment is essentially built into the IPCI, and is difficult to determine.

Other alternatives might include eliminating the IPSI with respect to radiation oncology, in light of the fact that radiation oncology includes an extraordinary proportion of services with no physician time that do not contribute to the radiation oncology "pool." In addition, adjusting the PE/hr data as set forth in the Direct Research report may help address the IPSI problem by ensuring that, at the very least, the radiation oncology "pool" takes into account an appropriate proportion of technical component providers. Finally, CMS should also consider using staff time in lieu of physician time to determine the contribution of TC services to the radiation oncology "pool" for the purposes of determining the IPSI.

Physics Codes.

We note that the Proposed Notice would result in extraordinary reductions in Medicare payment for physics codes, which are addressed in detail in the comments submitted by the AAPM. We strongly support the recommendations made by AAPM with regard to the physics codes and urge CMS to include these modifications in the final rule.

Budget Neutrality Adjustment for PE-RVU Changes

We support CMS's proposal to make budget neutrality adjustments for W-RVUs and PE-RVUs separately. In the alternative, we believe that it may be appropriate to make all budget neutrality adjustments to the conversion factor. However, we believe that it would be manifestly unfair to make W-RVU adjustments to the conversion factor while continuing to make PE-RVU adjustments to PE-RVUs only, especially in light of the fact that the proposed methodology already imposes a significantly larger budget neutrality adjustment on PE-RVUs than on W-RVUs.


Mark McClellan, MD, Ph.D.

August 18, 2006

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We hope that this letter is helpful and look forward to working with CMS to address these important methodological and data issues.

Sincerely yours,

A handwritten signature in cursive script that reads "David Rice M.D." followed by a stylized flourish that looks like "1/02".

David Rice, M.D.

President

Association of Freestanding Radiation Oncology Centers

Enclosure

cc: AFROC Board
Sheila Gell

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

**Final Report
May 4, 2006**

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

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

1) The Lewin Study.

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

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

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

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

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

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

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

Data Year	Count of UPINs			Percent of UPINs		
	Not hospital based	Hospital based	Total	Not hospital based	Hospital based	Total
2002	948	1808	2756	34%	66%	100%
2003	1003	1843	2846	35%	65%	100%
2004	1046	1897	2943	36%	64%	100%
Source: Analysis of Medicare 5 percent sample standard analytic file physician supplier file, LDS version, claims lines with CMS specialty code "92", radiation oncology.						

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

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

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

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

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

1.2 A better methodology: time-weighted average.

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

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

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

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

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

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

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

1.3 Re-weighting the practice expense data.

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

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

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

Source: Lewin study (cited in text), analysis of 2004 5 percent sample SAF data (Table 1, physician counts), and 2004 100% summary file data (Table 2, physician time).

Notes: The Lewin weighted average is as-published in the Lewin report, and appears to reflect slightly less than 75.0% in hospital-based settings.

Executive Summary

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

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

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

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

Submitter : Dr. Daniel Fontenot

Date: 08/18/2006

Organization : Dr. Daniel Fontenot

Category : Physician

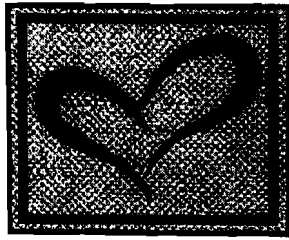
Issue Areas/Comments

Practice Expense

Practice Expense

see attachment

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BATON ROUGE CARDIOLOGY CENTER

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Syncope Evaluation
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Radiofrequency Catheter Ablation
Defibrillation Implantation & Follow-up

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

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

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments 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 were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 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	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • Approximately 45% of the direct costs are 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 practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities (“IDTFs”), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 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 catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Fontenot', with a stylized flourish at the end.

Daniel Fontenot, M.D., F.A.C.C.

Submitter : Mr. Walter Garbarczyk
Organization : Chicago Lake Shore Medical Associates, Ltd
Category : Individual

Date: 08/18/2006

Issue Areas/Comments

Other Issues

Other Issues

Dexa - see attached

CMS-1512-PN-1850-Attach-1.DOC

ATTACHMENT TO # 1850

**Chicago Lake Shore Medical Associates, Ltd.
676 North St. Clair Suite 2300 Chicago, IL 60611**

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
Baltimore, MD 21244-1850

To whom it may concern:

This letter is in response to your request for comments related to the proposed changes in reimbursement for dual energy x-ray absorptiometry (DXA). It is our understanding that under the proposed change DXA reimbursement would decrease by 73%. This new reimbursed amount would not cover even the direct costs of providing this important service.

Studies indicate that nearly 50% of all women will get an osteoporosis related fracture in their lifetime. DXA is an important tool in the prevention of these fractures and the resulting extensive and expensive care and cost to the Medicare program for their recovery. Additionally, the majority of patients over 65 years of age who incur an osteoporosis related fracture will not live independently again in their lifetime.

In the case of DXA, an ounce of prevention is clearly worth a pound of cure. If the new rates are implemented, a large number of DXA providers will be forced to eliminate this service and access will be significantly reduced. The resulting effects of the proposed change will be more costly to CMS on a whole and highly detrimental to women's health nationwide.

Sincerely,

Robert J. Havey, M.D.

Submitter : Dr. Harold Clausen
Organization : Dr. Harold Clausen
Category : Physician

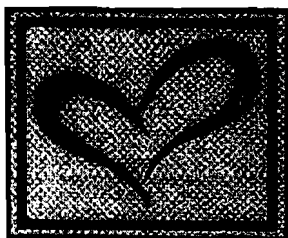
Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense
see attachment

CMS-1512-PN-1851-Attach-1.DOC



BATON ROUGE CARDIOLOGY CENTER

ATTACHMENT TO # 1851

- Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
Kevin L. Kilpatrick, M.D., F.A.C.C.
Terry L. Zellmer, M.D., F.A.C.C.
Daniel T. Fontenot, M.D., F.A.C.C.
Harold G. Clausen, Jr., M.D., F.A.C.C., F.S.C.A.I.
Fred H. Petty, M.D., F.A.C.C., F.S.C.A.I.
Henry C. Patrick, M.D., F.A.C.C.
Venkat R. Surakanti, M.D., F.A.C.C.
Evens Rodney, M.D., F.A.C.C.
Darrin M. Breaux, M.D., F.A.C.C.
Boyd M. Helm, M.D.
James R. Calvin, M.D., F.A.C.C., Emeritus

5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

- By Appointment
Practice Limited to Cardiology
A Professional Medical Corporation
Cardiac Evaluation & Counseling
Arrhythmia Management
Stress Testing
Nuclear Testing
Echocardiology
Transesophageal Echocardiography
Tilt Table Testing
Holter Monitors
Event Recorders
Diagnostic Heart Catheterization
Post Heart Surgery Cardiac Management
Balloon & Laser Coronary Angioplasty
Coronary Atherectomy & Stents
Cardiac Rehabilitation
Pacemaker Implantation & Follow-up
Lipid Management
Syncope Evaluation
Electrophysiologic Studies
Radiofrequency Catheter Ablation
Defibrillation Implantation & Follow-up

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

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

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

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments 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 were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 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	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
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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.

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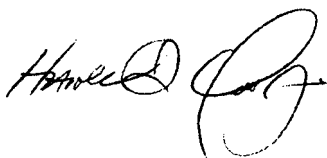
Solutions

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

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Sincerely,



Harold Clausen, Jr., M.D., F.A.C.C.