Submitter : Mr. John A Lutz

Organization : Prime Care Physicians

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2244-Attach-1.DOC

Date: 08/21/2006

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

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

2244

August 21, 2006

Dear Dr. McClellan:

On behalf our physicians, Prime Care Physicians appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the June 29, 2006 Proposed Notice re: Proposed Changes to the Practice Expense (PE) Methodology and the Five-Year Review of Work RVUs under the Physician Fee Schedule.

Prime Care Physicians represents 102 physicians and 400+ employees who service more than 60,000 patients in the greater Albany, New York area. Prime Care Physicians is concerned that the changes currently proposed by CMS to the practice expense portion of the Relative Value Unit (RVU) system are based on incomplete data and a flawed methodology. <u>Prime Care Physicians' requests that CMS delay implementation of the rule for one year until (1) data are corrected to accurately reflect the direct and indirect costs of providing care, and (2) the methodology is updated to better reflect the ratio of direct to indirect costs. Prime Care Physicians' comments on the five-year review of the Work RVUs under the Physician Fee Schedule also are included below.</u>

Comments Regarding Proposed Changes to the Practice Expense (PE) Methodology:

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

The rule as currently proposed is biased against procedures, such as outpatient cardiac catheterizations, for which the Technical Component (TC) is a significant part of the overall procedure. Prime Care Physicians will use catheterization procedures as an example as outlined below of the impact of the proposed methodology on all procedures with significant TC costs. We also believe that the same solution should be applied to all procedures with significant TC costs. Prime Care Physicians has requested via letter and e-mail correspondence to Mr. Herb Kuhn

on July 31, 2006 that CMS delay the comment period for the proposed rule on practice expense changes to allow concerned parties additional time to analyze additional CPT codes to determine if the indirect and direct costs have been adequately addressed in the proposed rule. Mr. Kuhn has not yet indicated whether the request to extend the comment period will be granted.

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

CPT Code	Description
93510 TC	Left Heart Catheterization
93555 TC	Imaging Cardiac Catheterization
93556 TC	Imaging Cardiac Catheterization
93526 TC	Right & Left Heart Catheterizations

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

Direct Costs

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

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

For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients.

Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

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

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

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

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate				
Clinical Labor	Direct Patient Care For Activities Defined by RUC	 Direct Patient Care For Activities Not Defined by RUC 				
	• Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery)	 Actual Staff Allocation Based on Patient Needs 				
Medical Supplies	• Supplies Used For More Than 51% of Patients	 Supplies Used For Less Than 51% of Patients 				
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients				
All Direct Costs for Cardiac Catheterization	• Approximately 55% of the direct costs are included in the RUC estimate	• Approximately 45% of the direct costs are 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 <u>two</u> times the proposed amount, and would begin to approximate the actual costs of providing the service. In addition, there are further improvements that can be made in the manner by which the indirect costs are estimated.

Indirect Costs

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In

addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties -Independent Diagnostic Treatment Facilities (IDTFs), which account for about two-thirds of the utilization estimate for 93510 TC, and Cardiology. The IDTF survey includes a wide range of facilities, but does not reflect the cost profile of cardiac catheterization facilities that may have a cost profile similar to Cardiology in terms of the higher indirect costs that are associated with performing these services.

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

Summary of Prime Care Physicians' Comments on the Proposed Rule Regarding Practice Expense Changes:

- 1. Prime Care Physicians believes the proposed "bottom up" methodology is flawed with respect to cardiac catheterization and other TC-heavy procedures, and that CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.
- 2. The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterizations. Should CMS adopt its proposed rule on practice expenses as it is currently written, the unintended consequences would be significant:
 - a. Insufficient reimbursement would force outpatient cath labs to close. Medicare patients would be directed back to the inpatient setting for cath services. This runs counter to CMS' long-term goal of providing care in the outpatient setting whenever clinically appropriate.
 - b. Hospitals are not prepared to handle a large influx of catheterization cases, and the resulting wait times may very well endanger Medicare beneficiaries who need these diagnostic cardiac catheterization services.
 - c. Medicare beneficiaries' out-of-pocket costs would increase, as hospital co-pays are up to 40 percent higher than those in the outpatient setting.
 - d. Medicare patients also would be inconvenienced by longer drive times and increased waiting periods for test results.
 - e. Driving Medicare patients back into the hospital setting for imaging tests also would include increased costs to the Medicare program as a whole.
 - f. Private physician practices are small businesses, which employ hundreds of thousands of professional staff members and provide valuable services to the Medicare population. The physician sector must have stable reimbursement patterns that keep pace with the increasing cost of providing care. The current reimbursement environment is non-sustainable, inhibits cost effective business growth in the ambulatory setting and fosters more costly hospital-based diagnostic invasive services.

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. Prime Care Physicians is concerned that the problems with the catheterization codes as outlined above may extend to other CPT codes with significant TC costs as well, since the inadequate funding of catheterization codes

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

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

Prime Care Physicians understands that CMS is required by statute to offset costs in excess of \$20 million that result from the Agency's mandatory five-year review of Work RVUs under the Physician Fee Schedule. Prime Care Physicians believes that the \$20 million offset threshold set for five-year mandatory reviews in the early 1990s should be adjusted for inflation and the rising costs of providing medical care to our nation's growing Medicare population. Prime Care Physicians is working with Congressional leaders to address this issue legislatively. It seems nonsensical that CMS must complete the rigorous task of realigning Work RVU weights every five years only to reduce the fee schedule as a whole to pay for the review, which was mandated to ensure that Work RVUs accurately reflect the amount of time medical professionals devote to procedures and ensure appropriate reimbursement. Prime Care Physicians will see their total reimbursements slashed by up to \$1.65 million in 2007 as a result of the 2006 review, depending upon the method CMS chooses to offset costs.

Until such time as the arbitrary \$20-million cap is changed, Prime Care Physicians acknowledges that CMS must continue its actions to offset the 2006 Work RVU review. It is the Prime Care Physicians understanding that CMS is considering two offset strategies: an across-the-board cut of 10 percent to Work RVUs, or a 5-percent reduction in the conversion factor used to determine physician fee payments. As both strategies appear to provide sufficient funds for the offset, <u>Prime Care</u> <u>Physicians recommends CMS to utilize the 10-percent cut to offset the costs of the five-year review</u> since it slightly decreases the impact of the mandated offset for the majority of our members.

Please refer all correspondence related to the above comments to myself, at <u>john.lutz@primecarepc.com</u> (4 Atrium Drive, Albany, New York 12205, phone (518) 435-2704).

Sincerely,

John A. Lutz, Chief Executive Officer Prime Care Physicians, PLLC

Submitter : Mr. Andy Williamson

Organization : Medical Center LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2245-Attach-1.DOC

Date: 08/21/2006

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2245

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

08/18/2006

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

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

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

Thank you in advance for your reconsideration in this matter.

Sincerely,

and elim

Andy F. Williamson, MD

Submitter : Ms. Linda Niles

Organization : Adams County Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2247-Attach-1.DOC

CMS-1512-PN-2247-Attach-2.DOC

Date: 08/21/2006

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ATTACHMENTITO # 2247



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* ex officio

Interim Chief Staff Officer and General Coursel Thomas L. Aretul Jr. August 21, 2006

Submitted Electronically: http://www.cms.hhs.gov/erulemaking/

Mark McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS 1512-PN Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-8018

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 30,000 member nonprofit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled Medicare Program: Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (CMS 1512-PN) published in the *Federal Register* on June 29, 2005. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

Practice Expense

The ACC is pleased that CMS modified the informal proposals for revising the practice expense methodology presented at the February 15 Town Hall meeting. In our response to the Town Hall information, the ACC and other cardiovascular organizations expressed grave concerns about the magnitude of the impacts on some specialties, as well as the inadequacy of the methods of allocating indirect practice expenses to codes with no physician work RVUs.

Heart House 9111 Old Georgetown Rd. Bethesda, MD 20814-1699 USA

(301) 897-5400 (800) 253-4636 Fax: (301) 897-9745 www.acc.org Mark McClellan, MD, PhD August 21, 2006 Page -2-

We appreciate that CMS has made some efforts to moderate the effect of the practice expense revisions. Nevertheless, we remain concerned about the impact of large payment decreases for key cardiovascular services at a time when physicians already face increasing economic pressures. Our comments on several aspects of the proposed methodology follow.

Supplemental surveys

The ACC is pleased that CMS proposed implementation of the supplemental survey data submitted by seven specialties. We believe that CMS should make use of the best available data in determining the practice expense RVUs. The ACC dedicated considerable staff and physician volunteer time and significant financial resources to submitting supplemental survey data, as provided by the Balanced Budget Refinement Act of 1999 (BBRA) and requested by CMS. Incorporating this data into the CY 2007 fee schedule will increase the accuracy in determining the PE RVUs for the services our members provide, as well as improving the overall accuracy of the practice expense component of the fee schedule.

Multi-specialty survey

The American Medical Association (AMA) is sponsoring a multi-specialty supplemental study of practice expense costs. A multi-specialty survey equal in rigor and quality to the supplemental surveys already submitted to and accepted by CMS is a worthwhile endeavor. It is important that the design and structure of the new survey be in compliance with all of the criteria established for the specialty specific practice expense supplemental surveys accepted by CMS. Such a survey will require a significant investment of time and funding. The ACC will continue to work with CMS, the AMA and the physician community to develop plans for updating the practice expense per hour data for all specialties.

Transition

The ACC supports CMS's proposal to transition the proposed Practice Expense changes in over a 4-year period. This provides specialty societies and the RUC an opportunity to identify any issues with the current PE data, to make any further appropriate revisions, and to collect additional data as needed prior to the full implementation of the proposed changes.

Clinical labor in indirect cost allocation formula

The ACC strongly supports CMS's proposal to use clinical labor costs in the indirect allocation for a service when the clinical labor costs are greater than the physician work RVUs. This proposal represents an important improvement in the indirect cost allocation methodology and is essential to an equitable approach to elimination of the nonphysician work pool. The existing indirect cost allocation formula is wholly inadequate for fairly assigning practice expense relative values to codes with little or no physician work. Mark McClellan, MD, PhD August 21, 2006 Page -3-

Cardiac catheterization services - non facility

Under CMS's proposed new practice expense methodology, non-facility payment rates for many cardiac catheterization procedures face drastic reductions by 2010. For example, the national average payment for CPT 93510 (Left heart catheterization) would fall from \$1750 in 2006 to \$964 in 2010, not accounting for any changes in the Medicare conversion factor. We note that in the Notice of Proposed Rulemaking released on August 8, CMS proposes carrier pricing for codes in this family when performed in the nonfacility setting. We understand that CMS has proposed this approach for 2007 because of concerns about the accuracy of the direct cost inputs. The ACC will provide more extensive comments about the direct cost inputs for the cardiac catheterization codes in our response to the August rule and will work though the PERC process to ensure the availability of accurate direct cost data for these codes.

We believe also that CMS's data on indirect practice costs may not be appropriate for cardiology practices that operate free standing cardiac catheterization labs. Nonfacility billing of the technical component of cardiac catheterization procedures is dominated by the Independent Diagnostic Testing Facility (IDTF) specialty classification because many non-hospital based cardiac catheterization facilities enroll in Medicare as IDTFs. Thus, the supplemental survey data for IDTFs are influential in determining the IPCI for cardiac catheterization procedures. The IDTF supplemental survey, however, was conducted in free standing imaging centers. Consequently, it may not reflect the costs of cardiology practices that operate outpatient cardiac catheterization labs.

Cardiac Monitoring Services

Under the proposed new practice expense methodology, payment rates for many cardiac event monitoring services drop dramatically, some even to zero in 2010. For example, the national average payment for CPT 93236 (ECG monitor/report 24 hrs) would fall from \$104.98 in 2006 to \$0 in 2010. We note that in the Notice of Proposed Rulemaking released on August 8, CMS acknowledges the lack of inputs for many of the codes in this family and encourages data submission. The ACC will continue to work CMS and the providers through the PERC process to ensure the availability of accurate direct cost data for these codes.

As with cardiac catheterization services – non facility, ACC believes that CMS's data on IDTF indirect practice costs do not reflect the costs of remote cardiac monitoring. Issues such as hours of operation, intense staffing needs and equipment variances are not taken into account. We encourage CMS to work with the cardiac monitoring provider community to determine accurate indirect cost data.

Five Year Review

CPT code 93325 - Doppler Color Flow Add-On

At the September 2005 meeting of the AMA RUC, the RUC could not recommend a change in the value of the code without CPT review of the code. The RUC recommended that code 93325 be referred to the CPT Editorial Panel for consideration for inclusion of the work of 93325 in the

Mark McClellan, MD, PhD August 21, 2006 Page -4-

work of 93307. The NPRM, however, stated that (93325 was) referred to the CPT Editorial Panel by the RUC with the recommendation that this service be bundled with CPT code 93307(Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete). We believe that the NPRM statement mischaracterizes the RUC recommendation in a subtle, but important manner.

The ACC has sent correspondence to both AMA and CMS outlining the rationale for maintaining the current echocardiography nomenclature structure. The current structure allows for the most accurate reporting of the echocardiography procedures that are actually performed by cardiologists and other physicians.

Cardiothoracic Surgery

The ACC opposes CMS's proposal for revising the work RVUs for cardiothoracic surgical procedures. We urge CMS to instead adopt the RUC's recommendations for these codes for several reasons. First, the RUC developed and approved its recommendations for the cardiothoracic surgical procedures through the process developed for all specialties for the five year review. Although there were some differences between the Society of Thoracic Surgeons' data and methods and the RUC's standard methodology, most of the elements supporting the recommendations – for example, intensity surveys, building block methodology, expert panels – are approaches the RUC has used before to develop either recommendations or the rationale to support a recommendation. Moreover, both the five year review workgroup and the full RUC subjected the STS recommendations and data to a rigorous review and thorough debate before approving the recommendations.

We are concerned that CMS's proposed work RVUs for cardiothoracic surgery threaten to distort relative work intensity both within cardiothoracic code families and across specialties. The RUC recommended intensity for cardiothoracic surgery is on average 2 to 3 times higher than the RUC recommended intensity for office and hospital based non-critical care evaluation and management codes. This relationship is well within historical studies of surgical intensity as it relates to evaluation and management intensity. In addition, the CMS proposal creates rank order anomalies within cardiothoracic surgery . The ACC believes these flaws in the CMS-proposed RVUs will hinder future efforts to assign appropriate work RVUs to cardiothoracic surgery and cardiology procedures.

Finally, the ACC believes that the inappropriately low work RVUs CMS proposes could limit access to important lifesaving care. We are concerned about possible future shortages of qualified cardiothoracic surgeons. Medicare's physician payment system must support the full continuum of treatment options for Medicare beneficiaries with cardiovascular disease. Cardiothoracic surgeons are critical to that continuum of care.

Mark McClellan, MD, PhD August 21, 2006 Page –5-

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 301-498-2398 or <u>rkelly@acc.org</u> with any questions.

Sincerely,

Star Umers

Steven E. Nissen, MD, FACC American College of Cardiology President

ATTACHMENT 2 TO #2247



American College of Surgeous

Washington Office: 1640 Wisconsin Avenue, NW • Washington, DC 20007 • 202/337-2701 • FAX 202/337-4271 e-mail: postmaster@facs.org ACS Web site: http://www.facs.org

August 21, 2006

The Honorable Mark McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

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

Dear Dr. McClellan:

On behalf of the 71,000 Fellows of the American College of Surgeons, I am pleased to submit the following comments on the Proposed Rule published in the *Federal Register* on June 29, 2006. We will address general comments and decisions, the work RVUs for certain codes, global surgery packages, the budget neutrality adjustment for the five-year review of work, and practice expense methodology. We strongly believe the Centers for Medicare and Medicaid Services' (CMS) decision to reject the work RVUs of codes that were based on high quality data is arbitrary and inconsistent with other CMS policies; the proposed rule creates severe rank order anomalies in several areas that must be addressed; and the proposed method for handling the budget neutrality requirement is unworkable and inequitable in the long-term. We also note that the rule proposes to pay physicians for 90 percent of the work they perform; 66 percent of the direct expenses incurred for treating beneficiaries; and 35 percent of indirect expenses. We believe these facts demonstrate that comprehensive reform of the Medicare Part B physician reimbursement system is desperately needed.

General Comments

We are 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 CMS' own DRG database. We urge CMS to reconsider its decision to discount the value of information collected from these databases. In general, we believe CMS' treatment of massive data collection efforts is arbitrary and capricious and does not

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support the mission of developing a resource-based relative value scale that is an accurate representation of the work performed by physicians.

We strongly encourage CMS to adopt a policy to use the best data available 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. 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. It will also cause havoc in the selection of reference codes over the next five years. For these reasons, we urge CMS to correct these problems in the final rule, or to provide commentary on why the agency feels that a specific work RVU it has chosen is more correct or appropriate than one derived from large numbers of objectively collected encounters.

1. NSQIP Data

While CMS states it supports the use of databases such as NSQIP, the hard fact of the matter is that it rejected NSQIP data in all incidences where the RUC considered NSQIP data to recommend a work RVU higher than the median survey data. Under CMS' directive, NSQIP data can only be used in conjunction with a survey and it can only be used to support a work RVU that is at or below the median survey work RVU. This makes NSQIP data irrelevant and unnecessary and sends the message that in CMS' eyes the only valid data source is the 30-person survey.

NSQIP is a comprehensive quality improvement program that has been in existence since 1991. Through NSQIP, highly trained surgical clinical nurse reviewers enter more than 130 data points about surgeries conducted in a variety of healthcare settings. To date, the ACS NSQIP can document a 97 percent success rate in capturing 30-day outcomes on all cases in the program database. All data are continuously submitted and monitored via the acsnsqip.org website and annual on-site audits of all participating sites' data are performed. The data input into NSQIP is accurate, thorough and standardized and this is supported by the fact that since inception of the program participating facilities have seen a 28 percent reduction in 30-day postoperative mortality and a 45 percent reduction in 30-day postoperative morbidity. Dozens of peerreviewed journal articles have been generated from the data included in NSQIP.

NSQIP also includes information on actual intraservice skin-to-skin times. This information is collected in the regular process of entering data into NSQIP and is verified through operating room logs. The College strongly believes this information is the absolute gold



standard for estimating surgeon intraservice times. It is a well-known statistical principle that data collected for purposes other than the current use is viewed as more objective and unbiased.

Unlike the RUC survey process where a minimum of 30 physicians are selected by their specialty society to provide an estimate of work time for purposes of determining payment, the individuals inputting data into the NSQIP database have no incentive to misvalue the time. Furthermore, the times are based on actual operative times, not an <u>estimate</u> of time based on one hypothetical case. We do not think there could be a better measure of time unless CMS sent surveyors out with stop watches to monitor operations across the country. The RUC agreed with the College and accepted NSQIP as an alternative method in August, 2005.

We strongly disagree with CMS' position that data from sources like NSQIP cannot be used until it is available for all procedures listed on the fee schedule. The sheer volume of procedures documented and measured would argue against this policy and prejudice. We believe CMS' principle should be to use the best possible data, rather than rely on the lowest common denominator. Furthermore, only by using databases in this way will societies be encouraged to develop additional data sources that can be used for both time measurement and quality improvement.

Currently, a variety of different methodologies have been used to evaluate physician services and create work RVUs. For example, some codes are still valued using Harvard data. Others have been surveyed using the 30-person survey. Still others are based on the building block methods or have been crosswalked based on reference codes or other data. For example, when the original Harvard data was developed, some codes, including the entire field of vascular surgery, were not included. As the process has evolved, the RUC Research Subcommittee has approved different methodologies and these methodologies have been applied at varying levels. At no time, until now, has CMS required that one methodology be used for all codes.

We also are concerned with CMS statement that NSQIP might not be "representative." CMS provides no basis for this statement, and it is completely unfounded. NSQIP includes data from a variety of different hospitals, including community hospitals, academic medical centers and the Veterans Health System. For example, while the Cleveland Clinic Foundation and the University of Michigan submit data to NSQIP, so do the Alaska Native Medical Center, a tribally owned and operated hospital that provides services to Alaska Natives and American Indians; Danbury Hospital, a community teaching center in western Connecticut; North Michigan Hospital, a 247-bed community hospital serving a large rural area in Michigan's northern lower peninsula; and Central DuPage Hospital, a community hospital in suburban Chicago. While the number of VA hospitals currently reporting is greater than the number of



community and academic hospitals, the participating non-VA hospitals have significantly greater volume and, therefore, the balance of the data is improved. Furthermore, in using the NSQIP data, the College only used records from 1999 to the present in order correlate its data with the time when more community and academic health centers began reporting. In addition, the notion that the information from the VA centers is skewed is completely unfounded. 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 hundreds or thousands of cases will approach a national distribution better than 30 willing survey volunteers. We continue to make the point that NSQIP data is more representative than data that is obtained from a 30-person survey.

Discussion of Comments - Otolaryngology

The American Head and Neck Surgeons (AHNS) presented recommendations to the RUC for many of the major head and neck cancer operations. We would like to comment on eight of these codes 31360, 31365, 31367, 31368, 31390, 31395, 41155 and 42845 where CMS disagreed with the RUC recommendation. For all of these codes, the rationale in the Proposed Rule states: "The median values for intraservice times were accepted by the RUC for these services, which is an indication that a value other than the 75th percentile for work also may be appropriate." No rationale for comparison services at the proposed work RVUs was provided.

Although these procedures are performed at a low frequency, the CMS proposed work RVUs will create rank order anomalies. These head and neck codes represent complex, lengthy, and demanding cancer operations performed by a limited number of surgical subspecialists with focused expertise.

In sending a multitude of information to CMS from the five year review, the RUC summary of its recommendations may not have been clear in reflecting the rationale for recommending the 75th percentile of the survey data for these services. A standard RUC survey was conducted for each of these codes. In the specialty society's rationale for recommendations for these codes, comparisons to codes on the multispecialty points of comparison (MPC) table were presented. In the specialty society's recommendations and in its discussions at the RUC, these procedures were compared to other major oncologic resections that have similar length, complexity, and impact of decision making, such as 58210 *Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s); 47120 Hepatectomy, resection of liver; partial lobectomy; and 48153 Pancreatectomy, proximal subtotal with near-*



total duodenectomy, choledochoenterostomy and duodenojejunostomy (pylorus-sparing, Whipple-type procedure); with pancreatojejunostomy. In comparison to the cited major oncologic operations, the RUC agreed that the head and neck resections typically require more postoperative care that included management of wound problems in radiated and contaminated fields, and in the recovery of speech, swallowing, airway function and upper extremity usage.

The outcome of discussions at the RUC was that the survey median work RVUs for these eight low volume codes underestimated the work involved and would create rank order anomalies. For these eight codes, the RUC recommended work RVUs would be a better relative value in comparison to other head and neck codes and other major operations. We urge CMS to reconsider and review the information that the RUC and the AHNS are sending in their own comment letters and to implement the RUC recommendations for these codes.

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 the information that we are providing below, along with additional information that the RUC and the orthopaedic societies are sending in their own comment letters.

The RUC recommendations for these three codes were based on survey data, which were supplemented by data from NSQIP and the CMS DRG database. As we have stated above, we strongly believe databases are the most valid, accurate method available for measuring time.

The RUC carefully scrutinized these codes and compared data from a variety of sources. For example, for code 27130 the original Harvard data showed an intraservice time of 128 minutes. NSQIP data, based on almost 6,000 records, demonstrated a median intraservice time of 135 minutes and CMS DRG data, based on more than 3,000 records, demonstrated a total intraservice time of 143.7 minutes. The survey showed an intraservice time of 110. After much discussion, the RUC determined the NSQIP intra-time was the most accurate. Further, because the survey median work RVUs were similar to the current RVUs, the RUC did not find there was compelling evidence that the work of the procedures has changed and recommended that the work RVUs for the codes remain the same.



CMS did not agree with the RUC's recommendation. To develop proposed work RVUs, CMS selected several codes that "it believes" are similar and made recommendations based on these supposedly similar codes. CMS decided that a total hip replacement is similar to a vagotomy and a thyroidectomy; an open treatment of 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 cannot perceive the clinical rationale for making these overt comparisons for such disassociated 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 the three orthopaedic codes. This is not a standard RUC methodology for valuing codes; is not an accepted RUC method for changing the work RVU of a code; and certainly is not "compelling evidence" that the time or intensity of a code has changed and, therefore, that the work RVU should be altered. If a specialty society used that methodology to argue for an increased work RVU, it would surely be rejected by the RUC and CMS.

As standard practice, the RUC reviewed the survey data and other available data and chose to reduce the number of post-operative visits in the RUC database to reflect the length of stay (LOS) that the both the NSQIP data and CMS DRG data revealed for these codes. However, while the number of visits was reduced, the intensity of several of the visits was increased. The College agrees with these changes because: 1) we believe the NSQIP data is reliable; and 2) the current number and level of visits is based on Harvard data, which is notoriously inaccurate with respect to post-operative visits. Harvard based post-operative visits for a majority of codes on an algorithm based on intra-operative time and random families of codes, rather than survey or data collection. Further, the level and number of post-operative visits have been corrected from the original Harvard recommendations for thousands of surgical codes over the last 15 years, and the RUC recommended changes to the visits for these Harvard-based codes are consistent with these past changes. The RUC found that while the number of visits decreased, the intensity increased, and, therefore, did not find compelling evidence that the total work involved had changed. We agree. Again, we find it difficult to accept the fact that CMS cannot accept the NSQIP intraservice time, but does not question the NSQIP LOS time.

Finally, we note that the valuations proposed by CMS 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 (total hip) 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 dispersion between code 27130 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 codes 27130, 27447, and 27236..

Discussion of Comments - Evaluation and Management Services

As we have expressed before in meetings with CMS, we have great concerns about the dramatic increase in several Evaluation and Management (E/M) codes, in particular code 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 that will spawn an avalanche of requests for increases during the next five years and in the next five-year review. We urge CMS to correct these anomalies before the final rule is published in November.

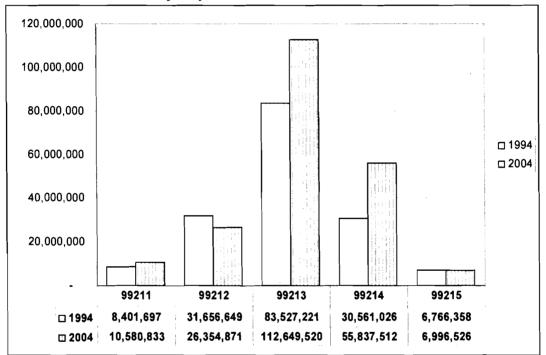
1. Compelling Evidence Standard Not Met/Standard RUC Procedure Not Followed

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 10 years ago and for which a second five-year review was undertaken with no comment from the specialties that primarily use these codes. We also find it questionable that apparently only high volume E/M codes are riddled with these faulty assumptions while low volume E/M codes are not.

Most importantly, we strongly believe physicians have already been compensated for the increased work of providing E/M services by billing longer and more intense office visits. For example, 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 \$3.28 billion. In total, there was an 85 percent increase in allowed



charges for 99213 alone between 1997 and 2004. In 2003, E/M services accounted for more than 30 percent of the growth in Medicare physician spending.

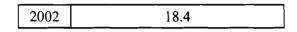


1994 and 2004 Frequency for CPT 99211-99215, Office Visits, Establish Patients

Despite this clear and unprecedented shift to longer and more intense office visits, a National Ambulatory Medical Care Survey (NAMCS) study shows that the duration of the average office visit has decreased, not increased.

Year	NAMCS Mean Visit Duration (minutes)
1997	18.8
1998	18.3
1999	19.3
2000	18.9
2001	18.6





While we agree the demographics of Medicare patients are changing and the average beneficiary is older and has 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 operations are more difficult and require increasingly more intensive work. For example, performing abdominal surgery on an obese patient is more difficult because the surgeon must retract layers of fat and maneuver to extra depth; once exposed, the structures themselves are often covered in fat, making dexterity, visibility and agility difficult; and fatty tissue also bleeds a great deal and hides blood vessels, making hemostasis more difficult to achieve. In short, the characteristics that justify a 37 percent increase to an E/M code 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 some specialties based on factors that apply to all specialties when that increase cannot be applied across-the-board. While the E/M increases were correctly applied to global surgical services, in many instances the actual preintra-, and immediate post-services are also made more difficult by a patient's advanced age or co-morbidity, yet there was no consideration for these time periods.

Finally, while CMS praises the RUC for coming to agreement on its recommendations for these codes, we note that standard RUC procedure was not followed and the RUC's rationale is still unclear today.

We fear that the true cost of the E/M increases will be much more than CMS' \$4 billion estimate as more and more physicians bill code 99213 instead of a lower level code. We note that the difference in these codes is often the number of organ systems examined, something that is completely under the physician's control. 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 work RVUs.

2. Rank Order Anomalies

We are also concerned that CMS has recommended a 37 percent increase to code 99213 without any discussion of how this dramatic change will affect other similar codes. While we are concerned that the increase to code 99213 will lead to increases for codes from other areas, we are specifically troubled by the disproportionate distribution of values within the E/M family. If CMS determines it will stand behind its decision to increase the E/M codes, we ask the agency to consider spreading out the increases more proportionately between codes in a family. For



example, we suggest that instead of increasing code 99213 by 37 percent, CMS instead increase codes 99211, 99212, 99213, 99214 and 99215 in a more proportionate manner. For example, the difference between codes 99212 and 99213 was .22 work RVUs, or about 30 percent. With the increases proposed to code 99213, the difference is now .47 work RVUs, or more than 50 percent. We believe a more proportionate progression within families is a more accurate, consistent reflection of everyday practice and will reduce the incentive to upcode. We do not feel that any of the reasons used to justify the increases to the upper level E/M codes are inapplicable to the lower level E/M codes, and we agree with CMS that codes should not return to the five-year review repeatedly. To be clear, we are suggesting that if CMS is not willing to reduce the overall E/M increases, then the agency should, at the very least, spread those increases more proportionately over the E/M codes by increasing the values of lower E/M codes while decreasing the proposed increases to codes 99213 and 99214 while keeping the budget impact the same.

3. Application of Increased E/M work RVUs to 10- and 90-Day Global Codes

We fully agree with the RUC's recommendation and CMS' proposal to apply the increased E/M work RVUs to E/M services included in the 10- and 90-day global period codes. These E/M services are the same as those that are performed distinctly and they have been recognized as such by both the RUC and CMS. However, it appears that CMS may have inadvertently applied a discounted or different work RVU to the 10 and 90 day global codes. The RUC recommended applying the full work RVU of the E/M codes to global procedures and because CMS did not disagree in its discussion of this issue, we urge CMS to correct this is math oversight in the final rule.

Discussion of Comments - Cardiothoracic Surgery

We have concerns regarding the rejection of RUC recommended work RVUs for the cardiothoracic codes. First, it should be noted that these codes were brought forth because of rank order anomaly issues. The RUC and the Society of Thoracic Surgeons (STS) worked diligently over several years to ensure these codes were placed in the correct order, with the longer, more difficult procedures valued higher than their less work intensive counterparts. 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-artery coronary artery bypass graft (CABG) procedure is now valued higher than a four-artery CABG procedure. In addition, there are now seven codes with higher total work values than a heart transplant, clearly the most total labor intensive of the cardiothoracic procedures, for all work within the 90-day global period.



We also feel it is important to understand that the field of cardiothoracic surgery has changed drastically in the past five years. The data clearly shows that beneficiaries are older, significantly obese, and have a 9.1 percent greater incidence of diabetes and a 20.1 percent greater incidence of peripheral vascular disease. More importantly, when comparing data between 1995-1999 and 2000-2003, the percent of beneficiaries who have undergone a previous cardiac procedure increased by more than 135 percent. Many of these cases include failed medical management, failed stents, and failed less invasive procedures. The marked increase in patients with previous cardiac procedures is significantly unique to cardiothoracic surgery and has a direct impact on the work involved in performing cardiothoracic procedures.

We urge CMS to reevaluate all prior information submitted by STS and the RUC and the comments submitted by STS and the RUC regarding these codes before issuance of the final rule.

1. STS Database

We are extremely discouraged and disappointed by CMS' comments regarding the STS Database. As we have already expressed in our comments regarding NSQIP, we feel this information is tremendously valuable, accurate, and objective, and it should be considered as a gold standard. While there will always be a certain amount of estimation and opinion involved in establishing RVUs, especially when attempting to determine intensity, we feel that solid, actual time measurements should be used whenever possible. We are baffled by CMS' concerns over representativeness. The STS database includes over 3 <u>million</u> patient records, with more than <u>70 percent</u> of hospitals reporting. We do not see how this can even be compared to data collected from 30 surgeons who are willing to complete a RUC survey.

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 and again at the Workgroup meeting in August 2005 and again at the RUC meetings in October 2005 and February 2006, and CMS was in attendance at all these meetings. In 2002, approximately 24 percent of U.S. hospitals were considered academic. In 2002 and 2003, 21 percent of hospitals participating in the STS database were academic centers and 27.5 percent of the procedures reported occurred at academic centers. We believe this demonstrates that the records in the STS database are representative. In addition, it is important to acknowledge that certain procedures, including heart transplants and other advanced cardiothoracic procedures, do, in fact, occur much more often in academic centers than in community hospitals. Additionally, as we indicated above, 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 mean) of millions of cases will approach a national distribution better than 30 willing 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 more accurate "estimate" in those instances. This is not the case for data derived from the STS database. When a significant number of actual measurements is being used rather than estimations, as is the case with the STS database, we believe mean times are appropriate. We also note that the RUC agreed. In determining which figures to use when analyzing NSQIP data, the College felt median times were more appropriate because the volume per code is much less than the STS database. Had the College had the same volume of cases in NSQIP, we also would have used the mean times because it is more reflective of the true average. Statistically, this can be demonstrated, which is why the RUC correctly uses the median for 30 surveys and Harvard used the geometric mean. 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 mean (and not the median or geometric mean). Also significantly, it should be noted that for low volume procedures tracked by the database, in particular several of the general thoracic codes, the median times were used for work RVU recommendation. While the RUC and STS attempted to review codes statistically (mean or median), CMS has failed to consider that statistics is a science with many variables that require unique consideration.

2. IWPUT

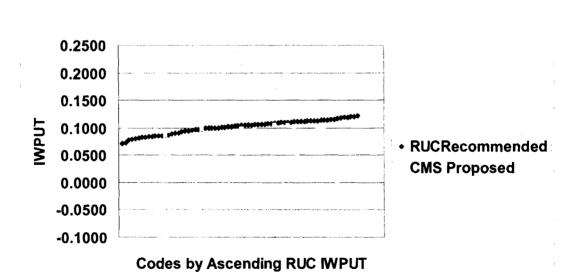
The College does not agree with the intensity values recommended by CMS for the cardiothoracic codes. The RUC has spent considerable time over the past five years reviewing various methods of determining intraservice work per unit of time (IWPUT) and the methods used by STS were approved by the RUC after thorough vetting. First, STS used a magnitude estimation survey of more than 19 percent of practicing cardiothoracic surgeons. This method was approved by the RUC; the surveys and instructions were reviewed by the RUC; the reference codes used were RUC reviewed; 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 used to review the results code-by-code to ensure proper rank order of work – 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. In its final recommendation, the RUC used the average of



the IWPUTs generated from a magnitude estimation survey and Rasch methods, recognizing that they were maintaining a relativity between procedures, as determined by the "experts."

In rejecting the RUC's recommendations, CMS stated it believes the IWPUTs created in the second five-year review are more accurate and should be used. However, it does not appear these numbers were in fact used in the proposed rule, and we cannot replicate CMS' math for numerous codes. In addition, we again note that the purpose of reviewing the cardiothoracic codes at this five-year review was to correct existing rank order anomalies, many of which were created in the last five-year review.

Below is a chart that compares the cardiac IWPUTs as recommended by the RUC versus those recommended by CMS.



IWPUT for Adult Cardiac and General Thoracic Surgery RUC Recommended vs CMS Proposed

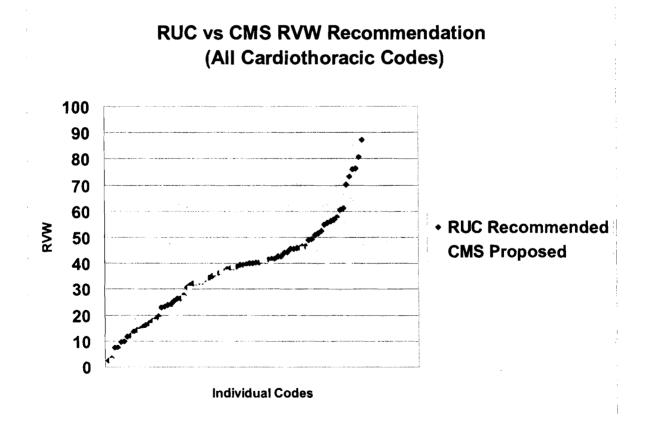
In addition to the rank order anomalies described below, under CMS' proposal, more than 15 cardiothoracic codes have IWPUTs that are less than E/M code 99213. The College strongly believes that the intensity of a cardiothoracic operation is greater than that of an E/M visit. Codes that we have identified as having an extraordinary low or negative IWPUTs include:



33305, 33300, 33460, 32141, 33945, 32815, 33465, 39400, 43113, 32540, 32445, 33474, 33464, 33542, 33463, 35820, and 33140. We feel certain that CMS will agree that a cardiothoracic operation is still more intense and demanding than a mid-level follow-up office visit.

3. Rank Order Anomalies

As a result of CMS' rejection of the IWPUTs for the cardiothoracic codes, there are a plethora of rank order anomalies that are illogical and should be fixed before the final rule is released.



Again, the chart above demonstrates the thoughtful progression of work RVUs that the RUC strived to achieve.

Examples of the rank order anomalies created in the proposed rule are as follows:



Esophagectomy codes	CMS Proposed work RVU
43112 McKeown w/stomach	43.43
43113 McKeown w/colon	40.41
43118 Ivor Lewis w/colon	46.37

In our surgical opinion, within this family, 43113 requires the most <u>total</u> work and should be valued the highest (based on data or magnitude estimation) and code 43118 should have the second highest work RVU. Codes 43113 and 43118 were submitted for review because there was a rank order anomaly. The RUC corrected this anomaly by placing the codes in the correct order – 43113, 43118 and 43112. CMS has reinstated the anomaly in its proposal.

CABG codes	CMS Proposed work RVU
33535 CABG, 3 arterial grafts	38.73
33536 CABG, 4 arterial grafts	38.04

It is clear that a CABG procedure with 4 arterial grafts involves more total work than a CABG procedure with 3 arterial grafts. The RUC recommend work RVUs for these codes at 41.85 and 45.53, respectively, recognizing not only that 33536 entails more work, but that the amount of work is significant, including addition post-operative work. However, the CMS proposed recommendations clearly demonstrate that a review of work both within and between service families was not considered.

Thoracoscopy codes	<u>CMS Proposed work RVU</u>						
32653 VATS removal fibrin	18.05						
32651 VATS partial decort	14.26						

For these two codes, 32651 is the more difficult surgical case with greater total work than 32653 and should be valued higher. Again, it appears that CMS did not review within family work and between family work – creating an anomaly.

Cardiac Wound codes	CMS Proposed work RVU
33300 Rpr cardiac wound	25.09
33305 Rpr cardiac wound w/bypass	27.05

While CMS correctly ranked 33305 higher than 33300 to recognize the extra work that occurs when a patient undergoes cardiopulmonary bypass, these codes are out of order when compared to the larger cardiothoracic family. These patients often have penetrating trauma



wounds (eg, gunshot or knife wounds). The work RVUs proposed by CMS are only slightly higher than for an elective single vessel CABG, even though codes 33300 and 33305 on average have an additional 2.5 hours of intraservice time, an additional two days of mechanical ventilation, and an additional three days of intensive care stay. Again, it appears that CMS did not review within family work and between family work – creating an anomaly.

Heart transplant codes

CMS Proposed work RVU 42.04

33945 orthotopic heart transplant

This code is also significantly out of order when compared with the larger cardiothoracic family and other significant operations requiring significant total work. Orthotopic heart transplant is the most difficult, lengthy and intense procedure in the cardiothoracic family. However, under CMS' proposal, there are now seven codes reviewed during this five year review with higher work RVUs. In addition, the proposed work RVUs for this code are less than would result from just the total pre and post E/M services, resulting in a negative intraservice work RVU for performing a heart transplant.

In order to fix these rank order anomaly issues as well as the low intensity issues, we urge CMS to use the RUC recommended IWPUT values as determined by the average of the surveybased magnitude estimation and the Rasch values as merely validating the rank order and dispersions within the family.

4. ZZZ Add-on Codes

In the proposed rule, it appears that CMS has stripped out all of the post-operative work in the add-on ZZZ codes. At the suggestion of the RUC, CMS changed the definition of ZZZ codes in 2003 by taking out the reference to "intraservice" time. This change was made to recognize the fact that some add-on codes do in themselves generate pre or post-operative work that would not be captured in the 90-day global code associated with the add-on code. While these circumstances are rare, the RUC thoroughly vetted the ZZZ cardiothoracic codes in question to ensure that the post-operative work was not accounted for elsewhere. This issue is the exact reason the definitional change was made in 2003 by CMS and we urge the agency to put the post-operative values back into these codes in the final rule.

Discussion of Comments - General, Colorectal and Vascular Surgery

1. General Surgery Codes



In total, the College submitted 32 codes for review and CMS accepted the RUC recommended work RVUs for 29 of those codes. Although we did not receive our recommended work RVUs for some of these 29 codes, we believe the RUC process was fair and thorough and we thank CMS for accepting the RUC recommendations for the 29 codes. We limit our comments to the three codes that were rejected by CMS and, in particular, are concerned with the questioning of NSOIP data. We note that the three rejected codes -44120, 44130 and 47600 – were rejected because their work RVUs were based upon the survey's 75th percentile, which was considered by the RUC as a better reflection of total work in conjunction with a review of median NSQIP data. CMS instead proposes using the median survey work RVUs. We note that several codes used 25th percentile data, which was lower than the NSQIP values, and CMS did not recommend increasing the values of these codes. This leads us to believe that the proposed work RVUs are arbitrary and without statistical or clinical rationale. In general, it seems clear that CMS was not open to valuing a code higher than the median survey work RVU if the higher value was supported by NSQIP data. For the reasons we stated above, we believe NSOIP provides accurate, highly valuable information and CMS should use the best possible data available.

A. 47600 - Removal of Gallbladder

The RUC recommended 15.88 work RVUs for 47600 and CMS has proposed 14.00 work RVUs. The RUC's recommendation was based on a belief that the median RUC survey work RVU underestimated the total work for this procedure. The RUC review of survey data was supplemented by a review of NSQIP data for 3,026 cases. As with other procedures that have multiple modes of medical and surgical treatment, technology is advancing so that the patient undergoing an open procedure for cholecystectomy more commonly represents a sicker patient who has failed medical management, a patient who has had prior surgery, or an older patient with co-morbidities who is not a candidate for laparoscopy. The RUC and the College felt strongly that the surveyed physicians discounted the intraservice time and IWPUT because they were not considering the correct patient demographics in this case and were instead visualizing a more typical gallbladder patient in their estimates. NSQIP data for 3,026 patients support this conclusion and, in conjunction with a comparison to anchor codes in other general surgery families, the RUC recommended a work RVU greater than the survey median,. We urge CMS to review their attendance notes from all of the RUC proceedings and accept the RUC recommended work RVU for 47600.

It should be noted that the RUC carefully scrutinized each and every general surgery code and, in most cases, both the survey and NSQIP data. On multiple occasions, the RUC recommended a work RVU lower than the proposed work RVU based on NSQIP data and even



lower than the median survey data .and CMS accepted these work RVUs. For example, code 47562 -- laparoscopic cholecystectomy, had a NSQIP-based median work RVU of 11.55 and a median survey work RVU of 13.00. The RUC recommended a work RVU of 12.00, considerably lower than the median survey data. In addition, code 49202 had a NSQIP-based median work RVU of 27.35 and a median survey work RVU of 17.50, but the RUC recommended a work RVU of 15.75. Code 19180 had a NSQIP-based median work RVU of 15.25 and a median survey work RVU of 17.00, but the RUC recommended a work RVU of 14.67. We believe this demonstrates that the RUC carefully considered the work RVU of each code, weighing each argument separately. We believe this strengthens the RUC's recommendation for code 47600 - it is only one of the very few codes where the RUC recommended a work RVU greater than the survey median. If CMS rejects this rare use of a work RVU greater than the median survey level, then we ask CMS to consider the median survey data - using the same rationale - for codes 47562, 49202 and 19180, instead of the RUC recommended work RVUs that are less than the median. If median survey data is the default standard and the RUC's deliberations are ignored, then we believe the median survey work RVU should be applied to these codes as well.

B. 44120 Enterectomy and 44130 Enteroenterostomy

For CPT codes 44120 and 44130, CMS expressed concerns with the RUC methodology to use the NSQIP data to increase the work RVUs above the median from the survey. In disagreeing, CMS proposes to use the median survey work RVUs of 18.00 and 20.00 as the work RVUs for CPT codes 44120 and 44130, respectively.

First, we note that the RUC rationale to CMS did not completely capture all of the discussion for these two codes, which included comparison to the survey reference services and to other codes. When the RUC does not believe that the survey median is the correct work RVU (either too high or too low) for a code, a new work RVU is facilitated – but only after considerable discussion. CMS has also used a facilitative approach in developing alternative proposed work RVUs.

Second, we note that the work RVUs cited by CMS as median survey work RVUs are incorrect. The RUC Summary of Recommendation forms sent to CMS indicate the following work RVU statistics:

СРТ	Min	25th	Median	75th	Max
44120	16.00	17.51	20.00	21.00	30.00
44130	16.00	18.00	19.00	21.00	35.00



Unfortunately, in facilitating new work RVUs, the RUC was using an Excel data summary table that transposed the survey median work RVUs between 44120 and 44130 (the time and visit data on the summary table were correct for each code).

The table below presents the RUC facilitated time and visit data for 44120 and 44130, along with data for three references. We believe that 44120 is more total work than 44130. The 2006 work RVUs confirm this, our survey median data (above) confirms this, and our recommendation to the RUC confirms this. However, through the process of facilitation and a transcription error, the RUC recommendations reversed this rank order. Further, CMS cited incorrect data and also reversed the rank order for 44120 and 44130, creating an anomaly.

A	B	C	D	E	F	F G						H	1	J	K
	TOTAL				IM-	VISITS 992-						2006 WORK	SPEC REC	RUC REC	CMS
CPT	TIME	LOS	PRE	INTRA	POST	33	32	31	38	13	12	RVU	RVW	RVW	RVW
44120	497	8	60	134	30	2	2	3	1	1	1	16.97	23.43	20.11	18.00
44130	484	8	60	131	30	1	1	5	1	2	1	14.47	21.27	20.87	20.00
44140	462	7	60	150	30		1	5	1	2	1	20.97	REF	REF	20.97
43631	507	8	75	150	30		2	5	1	2	1	22.56	REF	REF	22.56
44626	524	8	60	150	30	2	3	2	1	1	1	25.32	REF	REF	25.32

In looking at columns B and K in the table above, and considering the data presented in columns C through G, it is clear that a rank order would be created by using the CMS proposed work RVUs for 44120 and 44130.

For codes 44120 Enterectomy, resection of small intestine; single resection and anastomosis and 44130 Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy (separate procedure), 44626 Closure of enterostomy, large or small intestine; with resection and colorectal anastomosis (eg, closure of Hartmann type procedure) (work RVU = 25.32) was cited as a key reference code. For all three operations, there are similarities in the actual conduct of surgery, such as an intestinal anastomosis. However, CPT 44626 is a complex and difficult pelvic operation with challenges that exceed 44120 and 44130. A second reference code discussed was 43631 Gastrectomy, partial, distal; with gastroduodenostomy. Codes 44120, 44130 and 43631 refer to patients who have urgent and emergent needs for surgery. Intraoperatively, the procedures focus on foregut and midgut surgery. Codes 44120 and 44130 typically involve extremely compromised bowel, reactive ascites and patients potentially suffering from bacterial translocation. This is a significant distinction of 44120 and 44130 compared with the gastrectomy. Pre-service and immediate post-service work is very similar for



all patients. The LOS is the same for all three codes, however, 44120 and 44130 would require higher level of hospital visits because of issues related to the insult from the underlying intestinal conditions, fluid management, a higher risk of wound problems and the risk of fistula formation. The RUC also considered code 44140 (work RVU = 20.97) as a reference for rank order purposes only, because this code was also under review.

After discussion of all reference codes, the RUC agreed that the survey medians underestimated total work compared with several other reference codes that are actually anchors for other families of codes. The RUC agreed that the survey medians would create rank order anomalies. The RUC facilitated a recommendation for 44120 that was 1.11 work RVUs greater than the survey median. For 44130, the RUC facilitated a recommendation that was 0.87 work RVUs greater than the survey median. These facilitated work RVUs, however, were added to survey median work RVUs that were transposed on the data summary table. If added to the correct survey medians, the resulting facilitated work RVUs would be 21.11 for 44120 (20.00 +1.11) and 19.87 for 44130 (19.00 + 0.87), as shown in column K below. The ranking between the codes is consistent with 2006 work RVUs and the specialty recommended RVUs. 44120 is clearly more work than 44130 and 44140, similar to 43631, and less than 44626, as discussed above.

A	В	С	D	E	F	G						Н	I	J	K
	TOTAL				IM-	VISITS 992-						2006 WORK	SPEC REC	CMS	corrected
СРТ	TIME	LOS	PRE	INTRA	POST	33	32	31		13	12	RVU	RVW	RVW	RVW
44130	484	8	60	131	30	1	1	5	20.00	2	1	14.47	21.27	20.00	19.87
44120	497	8	60	134	30	2	2	3	18.00	1	1	16.97	23.43	18.00	21.11
43631	507	8	75	150	30		2	5	22.56	2	1	22.56	REF	REF	22.56
44626	524	8	60	150	30	2	3	2	25.32	1	1	25.32	REF	REF	25.32

We urge CMS to accept the RUC recommended work RVUs for 44120 (21.11) and 44130 (19.87).

C. Colorectal Codes 45300-45327 and 46600-46615

For the proctoscopy-anoscopy families of codes 45300-45327 and 46600-46615, CMS is proposing to maintain the current work RVUs because the method used by the RUC to obtain work RVUs for these services was flawed. CMS indicates that the calculation of the recommended work RVUs depended solely on applying a workgroup-derived IWPUT to the surveyed physician time from surveys that were considered otherwise unusable and that the RUC has established rules stating that IWPUT cannot be the sole rationale for valuation. Further, as



an example of a better methodology, CMS indicates that there were acceptable surveys that were used as anchors to create the correct rank order for dermatology codes without adequate surveys and if the specialty society wishes to resurvey these codes and the RUC submits work RVU recommendations to CMS, the agency would be willing to consider them. The College will be working with the American Society of Colon and Rectal Surgeons to facilitate this process

2. Vascular Surgery Codes

The RUC also used survey and NSQIP data when evaluating several vascular surgery codes. Again, the RUC recommendations for these codes were rejected if they were over the median survey work RVU. In the rule, there is little discussion of the reasons for rejecting the codes, and instead CMS appears to have issued a blanket rejection of any NSQIP-valued codes. We believe each code should be evaluated on its own merits and a blanket rejection of NSQIP data and installation of median survey times without any evaluation or discussion is inconsistent with RUC or CMS procedure. We note that when NSQIP data reduced the work RVU of a code, it was accepted; but when a work RVU was increased, the data was rejected. As with the cardiothoracic codes, CMS' recommendations have created a host of rank order anomalies. We urge CMS to accept the original RUC recommendations and fix the rank order anomalies.

A. 33877 Repair of thoracoabdominal aortic aneurysm

It appears CMS rejected the RUC recommendation of 64.04 for the mere fact that it is based on NSOIP data. CMS has instead proposed a work RVU of 53. The RUC recommendations were based on the building block methodology. There is no discussion of what data - pre service, intraservice, length of stay or intensity - CMS disagrees with and feels justifies the nine RVU reduction. Unlike CMS, the RUC workgroup scrutinized each component of the service when developing its recommendation. It should be noted that the actual median survey data for intraservice time was 360 minutes (based on 39 surveys), substantially more than the NSQIP value of 323 minutes (based on 156 operations) and the STS database value of 326 minutes (based on 108 minutes). Because they believe NSOIP and STS database are the gold standard and because of the astonishing correlation of the data between the two databases, the Society of Vascular Surgeons and the RUC recommended using the mean time from the two databases. After much discussion, the RUC recommended an IWPUT of 0.114, which is consistent with numerous other complex general surgery, cardiothoracic surgery and neurosurgery codes. Under CMS' proposal, there is no discussion of IWPUT. We must assume that CMS has rejected the NSQIP and STS database time and instead is proposing the median survey time of 360 minutes. At 53 RVUs, this would make the IWPUT for this procedure 0.072, which is substantially less than most surgical codes and only .002 more than a level 2 emergency



visit (code 99282). Even if CMS accepts the NSQIP time of 323 minutes, the IWPUT is only .080 if the code is valued at 53. In contrast, in the past six years the RUC has reviewed 16 new or revised vascular surgery codes that relate to aneurysm repairs of the aorta or peripheral arteries or other aortic surgery. An IWPUT of between .082 and .109 has been accepted for all of these codes. As surgeons, we feel strongly that code 33877 is one of the most difficult and complex open surgical operations performed today and should have the highest IWPUT in this family.

In addition, CMS also created a rank order anomaly. Code 43118 has essentially the same intraservice time, length of stay, and post-service times, but has eight more work RVUs. In addition, code 33877 is a more intense procedure than 43118. We urge CMS to accept the work RVU of 64.04 for code 33877.

B. 34201 Embolectomy or thrombectomy

The RUC used NSQIP data to justify a slight increase to this code as well. It should be noted that NSQIP time also reduced the number of post-operative visits. CMS has proposed to reject the NSQIP-derived increase, but has accepted the NSQIP-derived reduction in length of stay. Again, we disagree with this decision. We urge CMS to accept the RUC recommendation of 18.31.

C. 35102 Direct repair of aneurysm

The RUC recommended a value of 36.28 work RVUs for this code. After reviewing both survey data and NSQIP data, the RUC determined the NSQIP data was more accurate of the actual intraservice time. The accepted IWPUT for this procedure is .097. CMS has recommended a work RVU of 34, which would drop the IWPUT down to .075. This is inconsistent with other similar surgical procedures. We urge CMS to accept the RUC work RVU of 36.28 for this code.

D. 35556, 33566, 35583, 33583, 33585 - Lower extremity bypass codes

We believe CMS has undervalued each of these codes. These services are commonly performed on patients with significant co-morbidities in an attempt to save life and limb. For each of these codes, NSQIP data demonstrated that survey respondents consistently underestimated their intraservice time as well as the intensity of the post-operative visits. In each instance, the number of cases available in the NSQIP database outweighed the number of survey respondents by tenfold. CMS' recommendations for each of these codes will lead to IWPUTs



that are considerably less than similar surgical procedures and, in some cases, even less than a standard office visit. We urge CMS to accept the RUC recommendations for these codes.

Other Issues

1. Discussion of Post-Operative Visits Included in the Global Surgical Package

The College does not advocate changing the national definition of the global surgical packages at this time. We note that 42 USC § 1395sw-4 requires a global period for surgical services and we believe the current definition used by CMS is logical, useable and has become ingrained in the surgical culture. It also reflects the profession's definition of a surgical service, as described in the College's own Statements on Principles: "Surgical care includes preoperative diagnosis and care; educating the patient about the risks and benefits of operation and obtaining informed consent; selection and performance of the operation; and postoperative surgical care." It should be noted that prior to the inception of the Medicare fee schedule in 1992, all carriers had a global surgical package in place (although the exact definitions were not always consistent). While it may be true that there are instances where a surgeon provides more or fewer post-operative services, we believe the continued fine-tuning of both the Current Procedural Terminology (CPT©) and RUC processes will help alleviate these issues. In addition, we believe the advent of higher quality data, including that found in NSQIP and the STS database, will further help better define these services.

We also strongly believe that the surgical global period has saved the Medicare program a significant amount of money. For example, the number and intensity of E/M codes included in the global period has remained fairly constant, or decreased since 1997. However, in the overall Medicare program there has been a large shift from the lower level E/M codes to the higher level E/M codes, which has cost the program more than \$4 billion. If post-surgical E/M codes were not built into the global periods, we do not see any reason why this trend would not also apply to independently billed post-surgical E/M services. In fact, we encourage CMS to consider global payments for more services, including the management of medical diseases. We believe this will lead to more efficient and well-managed healthcare and address some of the large volume increases currently plaguing the Medicare program.

2. Budget Neutrality Adjustment for Physician Work

We strongly disagree with CMS' decision to make the necessary budget neutrality adjustments by using a separate adjuster for the work RVUs instead of reducing the conversion



factor. The work adjuster approach was attempted after the first five-year review and was abandoned two years later. When explaining the change, CMS stated:

"We did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare." (Federal Register, Vol. 68, No. 216, Pg. 63246)

Future administrative issues for valuing new and revised codes aside, we believe applying a separate work adjuster to the work RVUs during this five-year review process will lead to the same fate and, therefore, we strongly encourage CMS to learn from its own experience and make the necessary adjustments to the conversion factor instead. We also believe adding the working adjustor will make it difficult for both providers and other payers to use the Medicare fee schedule.

Additionally, the work RVUs are used to determine the practice expense RVUs. As we discuss in the practice expense section of our comments, it appears CMS has proposed to use the discounted work RVUs to determine the indirect practice expenses. This penalizes specialties with high work RVUs and in essence allows CMS to cut physicians twice – once by reducing the work RVUs and again when determining the indirect practice expenses. However, the other option is to use two different work RVU figures – the reduced work RVU for determining work and the full-value RVUs for determining indirect practice expenses. A method that uses a discounted work RVU for all calculations is unfair and using two different work RVUs is confusing, therefore, we believe the only solution is to make the budget neutrality adjustment to the conversion factor.

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. We disagree with this position. First, this theory assumes that all work RVUs were involved in the five-year review and had an equal opportunity to defend or adjust their values. However, only 422 of the more than 7500 physician codes were involved in the five-year review. Yet, many codes are being penalized for the mere fact that they have work RVUs, regardless of whether those work RVUs were even considered in this five-year review process.

Second, CMS' proposal disproportionately affects codes that have high work RVUs, but little practice expense or malpractice RVUs, including many surgery and primary care codes.



While CMS successfully protects those codes without work RVUs in its proposed rule, other areas of the fee schedule are disproportionately affected. For example, the anesthesia codes take the full brunt of the work RVU adjustment without any benefit from the five-year review. Other Medicare practitioners, including pathologists, chiropractors and nurse anesthetists, are in the same position. The work adjuster also has an adverse affect on E/M codes, with 33 of the 35 E/M codes reviewed in the five-year review receiving increases if the budget neutrality adjustment is made to the conversion factor and only 23 of 35 receiving increases under the work adjustment proposal. This is because any work RVU gain from the five-year review is lost when the 10 percent reduction is made. Ironically, the work adjuster benefits some of the fastest-growing services, including imaging and minor procedures. For these reasons, we do not believe the work adjuster is more equitable, and, to the contrary, believe making the budget neutrality adjustment to the conversion factor is the more equitable option.

Finally, while we understand CMS' desire to protect the codes that do not contain work RVUs, the majority of these codes are technical radiology codes. Payment for many of these codes will be cut on January 1, 2007, as a result of the Deficit Reduction Act of 2006. If the five-year review budget neutrality adjustment is made to the conversion factor, payments for these codes will be reduced accordingly, prior to their additional DRA-related cuts. Consequently, the reductions relating to the budget neutrality cut will remain in the Medicare physician payment system, while the cuts relating to DRA will not. Either way, many of these codes will experience drastic cuts on January 1, 2007. Given the current state of the Medicare physician payment system, we advocate maintaining as much money in the system as possible and believe this is the correct approach, given that the five-year review is suppose to be a redistribution of payments within the system and not a method for reducing total Part B expenditures.

3. Perception and Quality Improvement

We also believe the work adjuster is contrary to CMS' current pay-for-reporting and value-based purchasing activities. By using the work adjuster, it is clear CMS is only paying for 90 percent of physician work. However, we certainly do not think CMS is encouraging physicians to do only 90 percent of the job. On the contrary, many of the quality measures proposed by CMS require physicians to do more direct patient work and more administrative work. We believe implementing a policy that pays physicians to take on more work is contrary and incompatible.



The work adjuster reduction also implies that the actual work involved in providing care has decreased. This is not the case. The reduction is being made because CMS does not have the funds to pay for the increase in physician work and unfunded added benefits. The reason is purely monetary and the conversion factor is the appropriate place to make monetary reductions to physician payment.

Practice Expense

We greatly appreciate CMS' thorough and detailed explanation of the proposed methodology and note this is a significant improvement over last year's proposed rule. While we generally agree with methodology and believe it is an improvement over the the one used currently, we have several concerns and suggestions for improvement.

1. Use of Supplemental Survey Data

We have concerns regarding CMS' acceptance of supplemental survey data. First, we note that several of the surveys originally rejected and marked as unacceptable are now considered acceptable, even though the surveys have not been redone or modified in any way. We do not see how a survey deemed incredible 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.

Second, we question the validity of all of the supplemental surveys given the fantastic cost increases many specialties claim have occurred in just a five year period. We do not believe values over \$200 per hour are credible. We do not think radiologists have seen a 199 percent increase in their practice expense in the past five years and we do not think it is reasonable to believe cardiologists have seen a 184 percent increase. We do not believe these specialties have any unique characteristics that would produce such spectacular increases for just those specialties. We believe this data raise serious questions about either the validity of the original survey data or 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 because we believe the numbers themselves show the two data surveys are not comparing apples



to apples. If the original survey data is flawed, it is most likely flawed for other specialties as well.

Specialty	Initial PE/HR (1999)	Proposed PE/HR	Percent Change
Radiology	\$58.2	\$174.20	199%
Cardiology	\$82.9	\$235.10	184%
Radiation Oncology	\$58.2	\$175.90	202%
Urology	\$94.6	\$173	83%
Dermatology	\$115.0	\$225	96%
Allergy/Immunology	\$126.4	\$248	96%
Gastroenterology	\$56.6	\$145.60	157%

There has been no investigation regarding the funding, validity, or reproducibility of this data. It is interesting the CMS has chosen to use supplemental survey data that the agency itself has questioned for practice expense purposes, while in the same Proposed Rule CMS indicates that the NSQIP, STS, and CMS DRG databases are unacceptable, even though the former were drived by society financial concerns and the later are CMS and/or national audited databases.

We understand CMS' desire to use the supplemental survey data. Because of budget neutrality, we do not believe it is fair to base practice expense payments for these specialties on supplemental data while basing the practice expense payments of other specialties on the original survey data. While some may argue that all specialties could have provided supplemental data, that is simply not the case. Such an argument assumes all specialties are on the same financial footing and have the same resources. It discriminates against smaller, less prosperous specialties in favor of large specialties, or those that receive significant support from outside device companies. We believe such a policy is wrong and 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. We also note that many of the specialties supplying supplemental data have seen unprecedented and significant volume increases in the past several years and we question the wisdom of implementing policies that have the affect of increasing payments to high-growth areas.

2. Indirect Practice Cost Index (PCI)



We do not support the use of the PCI or its predecessor, the indirect scaling factor. We believe the determination of indirect practice expenses would be more accurate and fair if this last final adjustment is not made and CMS instead ends its practice expense formula at step 24. We note that in step 23, CMS proposes to reduce indirect practice expenses to 35 percent of their value for budget neutrality purposes. For general surgery, the application of the PCI would further reduce this already reduced figure. In addition, we also note that the majority of the specialties with the highest PCIs are those with supplemental survey data. Again, we question the validity of this supplemental survey data and believe it is unfair for CMS to use 1997 data to determine the PCI for some specialties and unaudited supplemental information to determine the PCI for other specialties. We urge CMS to eliminate this step in the calculation of indirect practice expenses at least until a time when all specialties are using comparable survey data.

3. Use of Clinical Labor Costs for Codes with Low or No Physician Work

CMS has proposed to eliminate the non-physician work pool. We agree with this decision. However, CMS has proposed using clinical labor costs in the indirect allocation for a service when the clinical labor costs are greater than the physician work RVU. We disagree with this proposal. If there is no physician work related to a specific code, then there is no physician work and we do not believe it is necessary to try to make up a figure for something that does not exist. Clinical labor costs are already accounted for in the direct practice expenses. It is not correct to count them again just because a code is lacking, or has only a small amount of, physician work. Double counting clinical labor costs will overvalue the practice expense for these codes. The provider is not paying the clinical labor personnel twice and neither should CMS. In addition, services with low clinical labor costs are not allowed to substitute physician time and we do not believe it is fair to allow the reverse. We urge CMS to use only physician work during this step of the calculation, and if there is no physician work then the figure zero should be used. We strongly disagree that this policy will disadvantage services with no physician work, and believe it will instead more accurately reimburse providers for costs that are actually incurred.

4. Work RVUs and Indirect Practice Expense Calculations

Work RVUs are used in determining indirect practice expenses. We do not believe CMS has used the correct figures when making these determinations. The full value of the work RVUs should be used when determining indirect practice expenses. It appears CMS has instead



used the value of the work RVUs after the five-year review budget neutrality adjustment has been made. We urge CMS to make this correction in the final rule.

5. Other Adjustments

We support two additional modifications to the practice expense methodology. First, the current interest rate assumption used to determine practice expense is 11 percent. We believe this rate is higher than the average rate paid by providers and should be lowered to a competitive market rate, and that it should be updated regularly. Second, the current equipment utilization rate is 50 percent. We believe many pieces of medical equipment have a much higher utilization rate. A recent study performed by the Medicare Payment Advisory Commission showed several high-volume, high-value imaging modalities, including CT scanners and MRIs, have utilization rates near 95 percent. We believe CMS should raise the default utilization rate. We also believe an exemption policy should be established for those services that do not have common utilization rates.

6. Practice Expense Budget Neutrality Adjustment

We again applaud CMS for providing a detailed explanation of the practice expense formula. However, we note that under the proposed rule, CMS states it is paying only 66 percent of direct practice expense and only 35 percent of indirect practice expense. The physician community has long felt that practice costs were not being covered and we appreciate CMS' acknowledgment that this is indeed the case.

We also agree with how the budget neutrality adjustments for practice expense are being made. We believe the direct and indirect budget neutrality adjustments should be made separately, as CMS has done. This policy recognizes that direct and indirect practice expenses are two separate components with separate methodologies and data sources.

We also do not believe the practice expense budget neutrality adjustment should be made to the conversion factor, regardless of how the work budget neutrality adjustment is made. The practice expense formula and data have not been nearly as scrutinized and are not as accepted as those used to determine work. In fact, the proposed rule includes an entirely different methodology for determining practice expense and we have suggested several modifications to this ever-changing formula in our comments. In addition, the issue of unaudited supplemental survey data compared to original survey data makes for an unfair playing field. Finally, unlike the five-year review of work that involved less than six percent of the codes of the fee schedule, all practice expense RVUs have been modified under the new methodology. Because of these



issues, we believe the budget neutrality adjustments for practice expense should be made within practice expense. At some point in the future, after the methodology has been tested and is wellaccepted and there is an established, consistent source for data, we encourage CMS to make all monetary adjustments to the conversion factor.

Conclusion

The College appreciates the opportunity to comment on this important rule. We look forward to working with CMS to further improve the RBRVS.

Sincerely,

Flow a Rund

Thomas R. Russell, MD, FACS Executive Director

Submitter : Denise Garris

Organization : American College of Cardiology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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CMS-1512-PN-2248-Attach-1.DOC

Date: 08/21/2006



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* es officio

Interim Chief Staff Officer and General Counsel Thomas L. Arend Jr. August 21, 2006

Submitted Electronically: http://www.cms.hhs.gov/erulemaking/

Mark McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS 1512-PN Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-8018

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 30,000 member nonprofit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled Medicare Program: Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (CMS 1512-PN) published in the *Federal Register* on June 29, 2005. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

Practice Expense

The ACC is pleased that CMS modified the informal proposals for revising the practice expense methodology presented at the February 15 Town Hall meeting. In our response to the Town Hall information, the ACC and other cardiovascular organizations expressed grave concerns about the magnitude of the impacts on some specialties, as well as the inadequacy of the methods of allocating indirect practice expenses to codes with no physician work RVUs.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

#2248

Heart House 9111 Old Georgetown Rd. Bethesda, MD 20814-1699 USA

(301) 897-5400 (800) 253-4636 Fax: (301) 897-9745 www.acc.org Mark McClellan, MD, PhD August 21, 2006 Page -2-

We appreciate that CMS has made some efforts to moderate the effect of the practice expense revisions. Nevertheless, we remain concerned about the impact of large payment decreases for key cardiovascular services at a time when physicians already face increasing economic pressures. Our comments on several aspects of the proposed methodology follow.

Supplemental surveys

The ACC is pleased that CMS proposed implementation of the supplemental survey data submitted by seven specialties. We believe that CMS should make use of the best available data in determining the practice expense RVUs. The ACC dedicated considerable staff and physician volunteer time and significant financial resources to submitting supplemental survey data, as provided by the Balanced Budget Refinement Act of 1999 (BBRA) and requested by CMS. Incorporating this data into the CY 2007 fee schedule will increase the accuracy in determining the PE RVUs for the services our members provide, as well as improving the overall accuracy of the practice expense component of the fee schedule.

Multi-specialty survey

The American Medical Association (AMA) is sponsoring a multi-specialty supplemental study of practice expense costs. A multi-specialty survey equal in rigor and quality to the supplemental surveys already submitted to and accepted by CMS is a worthwhile endeavor. It is important that the design and structure of the new survey be in compliance with all of the criteria established for the specialty specific practice expense supplemental surveys accepted by CMS. Such a survey will require a significant investment of time and funding. The ACC will continue to work with CMS, the AMA and the physician community to develop plans for updating the practice expense per hour data for all specialties.

Transition

The ACC supports CMS's proposal to transition the proposed Practice Expense changes in over a 4-year period. This provides specialty societies and the RUC an opportunity to identify any issues with the current PE data, to make any further appropriate revisions, and to collect additional data as needed prior to the full implementation of the proposed changes.

Clinical labor in indirect cost allocation formula

The ACC strongly supports CMS's proposal to use clinical labor costs in the indirect allocation for a service when the clinical labor costs are greater than the physician work RVUs. This proposal represents an important improvement in the indirect cost allocation methodology and is essential to an equitable approach to elimination of the nonphysician work pool. The existing indirect cost allocation formula is wholly inadequate for fairly assigning practice expense relative values to codes with little or no physician work.

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Cardiac catheterization services - non facility

Under CMS's proposed new practice expense methodology, non-facility payment rates for many cardiac catheterization procedures face drastic reductions by 2010. For example, the national average payment for CPT 93510 (Left heart catheterization) would fall from \$1750 in 2006 to \$964 in 2010, not accounting for any changes in the Medicare conversion factor. We note that in the Notice of Proposed Rulemaking released on August 8, CMS proposes carrier pricing for codes in this family when performed in the nonfacility setting. We understand that CMS has proposed this approach for 2007 because of concerns about the accuracy of the direct cost inputs. The ACC will provide more extensive comments about the direct cost inputs for the cardiac catheterization codes in our response to the August rule and will work though the PERC process to ensure the availability of accurate direct cost data for these codes.

We believe also that CMS's data on indirect practice costs may not be appropriate for cardiology practices that operate free standing cardiac catheterization labs. Nonfacility billing of the technical component of cardiac catheterization procedures is dominated by the Independent Diagnostic Testing Facility (IDTF) specialty classification because many non-hospital based cardiac catheterization facilities enroll in Medicare as IDTFs. Thus, the supplemental survey data for IDTFs are influential in determining the IPCI for cardiac catheterization procedures. The IDTF supplemental survey, however, was conducted in free standing imaging centers. Consequently, it may not reflect the costs of cardiology practices that operate outpatient cardiac catheterization labs.

Cardiac Monitoring Services

Under the proposed new practice expense methodology, payment rates for many cardiac event monitoring services drop dramatically, some even to zero in 2010. For example, the national average payment for CPT 93236 (ECG monitor/report 24 hrs) would fall from \$104.98 in 2006 to \$0 in 2010. We note that in the Notice of Proposed Rulemaking released on August 8, CMS acknowledges the lack of inputs for many of the codes in this family and encourages data submission. The ACC will continue to work CMS and the providers through the PERC process to ensure the availability of accurate direct cost data for these codes.

As with cardiac catheterization services – non facility, ACC believes that CMS's data on IDTF indirect practice costs do not reflect the costs of remote cardiac monitoring. Issues such as hours of operation, intense staffing needs and equipment variances are not taken into account. We encourage CMS to work with the cardiac monitoring provider community to determine accurate indirect cost data.

Five Year Review

CPT code 93325 - Doppler Color Flow Add-On

At the September 2005 meeting of the AMA RUC, the RUC could not recommend a change in the value of the code without CPT review of the code. The RUC recommended that code 93325 be referred to the CPT Editorial Panel for consideration for inclusion of the work of 93325 in the

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work of 93307. The NPRM, however, stated that (93325 was) referred to the CPT Editorial Panel by the RUC with the recommendation that this service be bundled with CPT code 93307(Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete). We believe that the NPRM statement mischaracterizes the RUC recommendation in a subtle, but important manner.

The ACC has sent correspondence to both AMA and CMS outlining the rationale for maintaining the current echocardiography nomenclature structure. The current structure allows for the most accurate reporting of the echocardiography procedures that are actually performed by cardiologists and other physicians.

Cardiothoracic Surgery

The ACC opposes CMS's proposal for revising the work RVUs for cardiothoracic surgical procedures. We urge CMS to instead adopt the RUC's recommendations for these codes for several reasons. First, the RUC developed and approved its recommendations for the cardiothoracic surgical procedures through the process developed for all specialties for the five year review. Although there were some differences between the Society of Thoracic Surgeons' data and methods and the RUC's standard methodology, most of the elements supporting the recommendations – for example, intensity surveys, building block methodology, expert panels – are approaches the RUC has used before to develop either recommendations or the rationale to support a recommendation. Moreover, both the five year review workgroup and the full RUC subjected the STS recommendations and data to a rigorous review and thorough debate before approving the recommendations.

We are concerned that CMS's proposed work RVUs for cardiothoracic surgery threaten to distort relative work intensity both within cardiothoracic code families and across specialties. The RUC recommended intensity for cardiothoracic surgery is on average 2 to 3 times higher than the RUC recommended intensity for office and hospital based non-critical care evaluation and management codes. This relationship is well within historical studies of surgical intensity as it relates to evaluation and management intensity. In addition, the CMS proposal creates rank order anomalies within cardiothoracic surgery . The ACC believes these flaws in the CMS-proposed RVUs will hinder future efforts to assign appropriate work RVUs to cardiothoracic surgery and cardiology procedures.

Finally, the ACC believes that the inappropriately low work RVUs CMS proposes could limit access to important lifesaving care. We are concerned about possible future shortages of qualified cardiothoracic surgeons. Medicare's physician payment system must support the full continuum of treatment options for Medicare beneficiaries with cardiovascular disease. Cardiothoracic surgeons are critical to that continuum of care.

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Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 301-498-2398 or <u>rkelly@acc.org</u> with any questions.

Sincerely,

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Steven E. Nissen, MD, FACC American College of Cardiology President