

Submitter : Ms. Barbara Peck
Organization : American College of Surgeons
Category : Physician

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Issue Areas/Comments

GENERAL

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See Attachment

CMS-1512-PN-2249-Attach-1.PDF



American College of Surgeons

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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 acnsqip.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 peer-reviewed 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



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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 estimate 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



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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 to 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-*



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total duodenectomy, choledochoenterostomy and duodenojejunosomy (pylorus-sparing, Whipple-type procedure); with pancreatojejunosomy. 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.



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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



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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



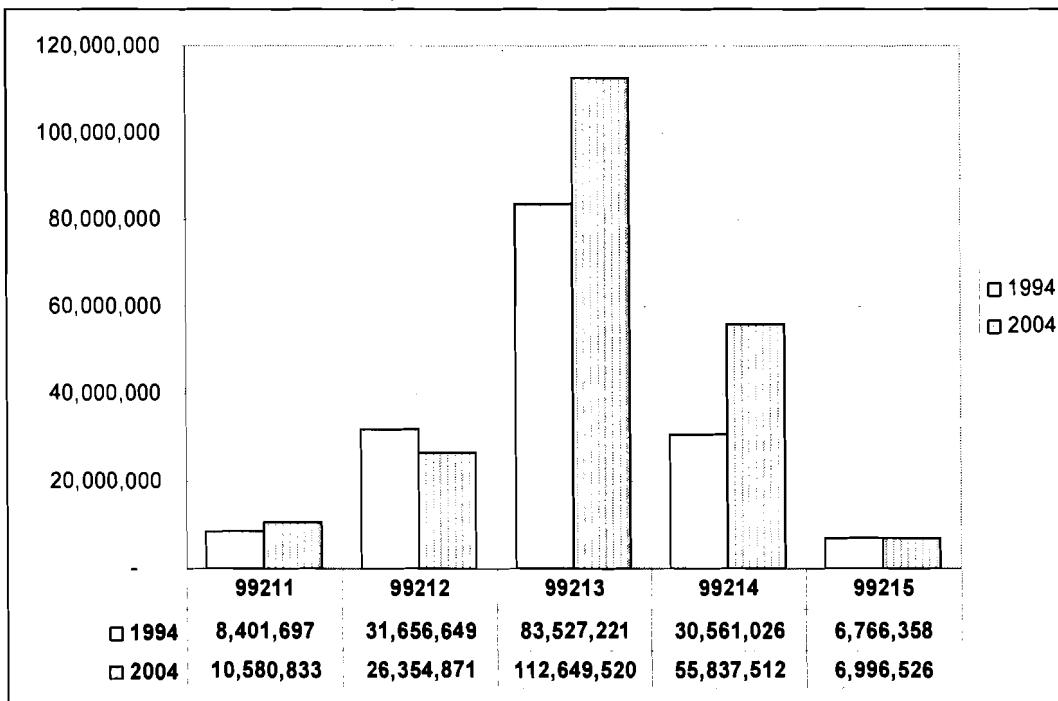
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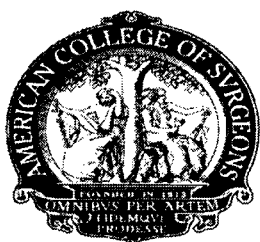
charges for 99213 alone between 1997 and 2004. In 2003, E/M services accounted for more than 30 percent of the growth in Medicare physician spending.

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 |



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| | |
|------|------|
| 2002 | 18.4 |
|------|------|

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 pre-, intra-, and immediate post-services are also made more difficult by a patient's advanced age or co-morbidity, yet there was no consideration for 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



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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.



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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 million patient records, with more than 70 percent 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



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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



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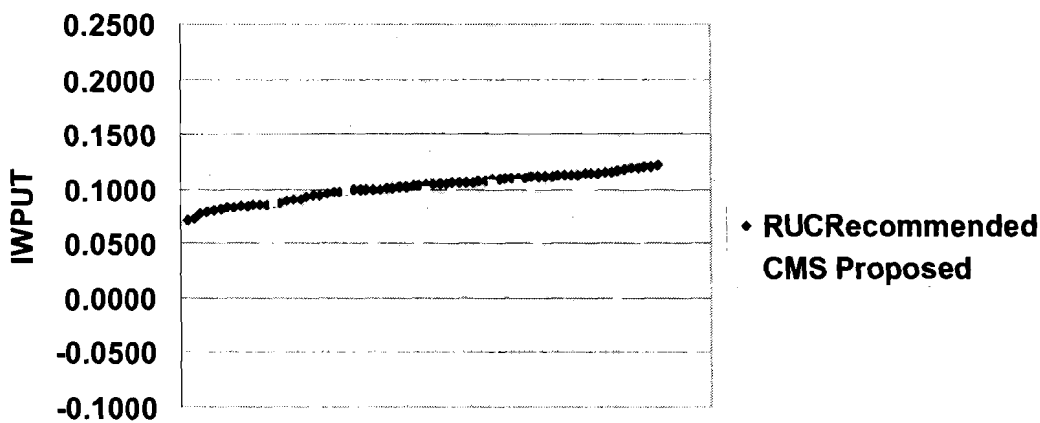
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the IWPUTs generated from a magnitude estimation survey and Rasch methods, recognizing that they were maintaining a relativity between procedures, as determined by the “experts.”

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



Codes by Ascending RUC IWPUT

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:



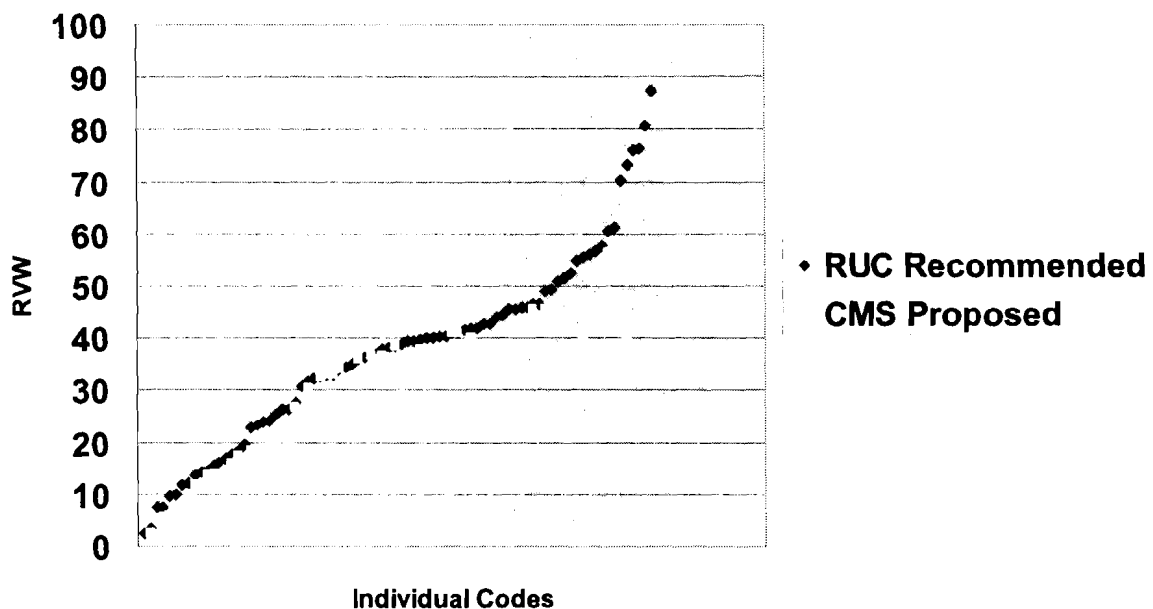
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33305, 33300, 33460, 32141, 33945, 32815, 33465, 39400, 43113, 32540, 32445, 33474, 33464, 33542, 33463, 35820, and 33140. We feel certain that CMS will agree that a cardiothoracic operation is still more intense and demanding than a mid-level follow-up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

RUC vs CMS RVW Recommendation (All Cardiothoracic Codes)



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:



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| <u>Esophagectomy codes</u> | <u>CMS Proposed work RVU</u> |
|----------------------------|------------------------------|
| 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 total 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.

| <u>CABG codes</u> | <u>CMS Proposed work RVU</u> |
|-------------------------------|------------------------------|
| 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.

| <u>Thoracoscopy codes</u> | <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.

| <u>Cardiac Wound codes</u> | <u>CMS Proposed work RVU</u> |
|----------------------------------|------------------------------|
| 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



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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

33945 orthotopic heart transplant

CMS Proposed work RVU

42.04

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 survey-based 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



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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 NSQIP 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 NSQIP 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



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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:

| CPT | 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 |



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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 CPT | B TOTAL TIME | C LOS | D PRE | E INTRA | F IM- POST | G VISITS 992- | | | | | | H 2006 WORK RVU | I SPEC REC RVW | J RUC REC RVW | K CMS RVW |
|----------|--------------------|----------|----------|------------|------------------|------------------|----|----|----|----|----|--------------------------|-------------------------|------------------------|-----------------|
| | | | | | | 33 | 32 | 31 | 38 | 13 | 12 | | | | |
| 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. Intra-operatively, 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



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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 | B | C | D | E | F | G | | | | | | H | I | J | K | | | | |
|-------|-----|---|----|-----|----|-------------|----|----|-------|----|---|-------|-------|-------|-------|---------------------|--------------------|------------|------------------|
| | | | | | | VISITS 992- | | | | | | | | | | 2006 WORK RVU | SPEC REC RVW | CMS RVW | corrected RVW |
| | | | | | | 33 | 32 | 31 | 13 | 12 | | | | | | | | | |
| 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



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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 NSQIP 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 NSQIP 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



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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



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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



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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 adjuster to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare.” (Federal Register, Vol. 68, No. 216, Pg. 63246)

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 adjuster 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.



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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, while disproportionately affecting those areas with limited growth, including major 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 for only 90 percent of the work they do at a time when CMS is trying to encourage physicians to take on more work is contrary and incompatible.



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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



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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 driven 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)



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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



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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



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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 well-accepted 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,

A handwritten signature in cursive script, which reads "Thomas R. Russell".

Thomas R. Russell, MD, FACS
Executive Director

Submitter : Mr. Ronald S. Owen
Organization : Southeast Alabama Medical Center
Category : Hospital

Date: 08/21/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1512-PN-2250-Attach-1.TXT

August 21, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Administrator McClellan:

This comment letter is written in response to the proposed changes in physician fee schedules in the June 29th Federal Register. It is my understanding that under these proposed changes anesthesiology would receive a 10% cut in Medicare payments over the next four years. Any cuts to anesthesia professional reimbursements will be passed on to hospitals. Cuts to anesthesiologists will cause hospitals to pick up these costs to maintain current staffing levels. For us to continue the level of surgical services to all patients, a reduction of 10% in anesthesia payments will drastically affect our ability to recruit and maintain adequate anesthesia staffing.

In addition, the MGMA reports that 70% of hospitals in the United States are subsidizing the cost of anesthesia practices. Proposed reductions will certainly exacerbate hospital costs.

This reduction is especially egregious since anesthesia reimbursement is based on data that CMS uses to calculate overhead expenses that is outdated and appears to significantly underestimate actual expenses. These outdated data cause anesthesia reimbursements to already be drastically low compared to other specialties.

I am certainly in favor of better reimbursements for primary care specialties, however, the change in these reimbursements should not effect already low reimbursements to anesthesia.

Respectfully,
Ronald S. Owen
Chief Executive Officer

Copies to:
Representative Terry Everett
Senator Richard Shelby
Senator Jeff Sessions

1108 Ross Clark Circle, Dothan, AL 36301 - www.samc.org - (334) 793-8111

Submitter : Ms. Tracey Moorhead
Organization : Disease Management Association of America
Category : Health Plan or Association

Date: 08/21/2006

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1512-PN-2251-Attach-1.WPD



#2251

August 21, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
75000 Security Boulevard
Baltimore, MD 21244-1850

Re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology; Proposed Notice (CMS-1512-PN)

The Disease Management Association of America (DMAA) is pleased to offer its comments on the Centers for Medicare and Medicaid Services (CMS) notice of proposed rulemaking titled, *"Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and the Proposed Changes to the Practice Expense Methodology"* (CMS-1512-PN), which the agency issued June 29, 2006.

DMAA represents the disease management and care coordination community, including disease management organizations, health plans, physician groups, hospital systems, employers, benefit managers and consultants, pharmacy benefit managers, pharmaceutical manufacturers, health care professionals, and academicians. DMAA envisions a health care system in which every person has access to coordinated, comprehensive, quality care.

DMAA strongly supports CMS' proposal to adopt the recommendations of the American Medical Association's Relative Value Update Committee (RUC) to increase physician payments for "evaluation and management" services. DMAA recognizes and supports the need to adequately reimburse physicians for evidence-based services to help patients better manage health conditions and to achieve better health outcomes.

DMAA believes the proposed revisions for evaluation and management services are in accordance with recent MedPAC findings that the current physician fee schedule undervalues these services. DMAA supports efforts to ensure that the services of the physicians with whom our members work and provide support for established plans of care are appropriately valued in the fee schedule.

DMAA would be glad to provide you or your staff with any additional information on the clinical and financial benefits of chronic disease management and care coordination programs.

Thank you for your consideration of these comments.

Sincerely,

Tracey Moorhead
Executive Director

Submitter : Mr. Paul Farmer

Date: 08/21/2006

Organization : The Chattanooga Heart Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1512-PN-2253-Attach-1.DOC



August 21, 2006

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

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

Dear Dr. McClellan:

The Chattanooga Heart Institute 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.

The Chattanooga Heart Institute represents 21 physicians and 200 employees who serve more than 70,000 patients in the greater Chattanooga area. We, along with more than 220 private practices and 3,700 cardiologists as represented by the Cardiology Advocacy Alliance (CAA), are concerned that the changes currently proposed by CMS to the practice expense portion of the Relative Value Unit (RVU) system are based on incomplete data and a flawed methodology. The Chattanooga Heart Institute requests that CMS delay implementation of the rule for one year until (1) data are corrected to accurately reflect the direct and indirect costs of providing care, and (2) the methodology is updated to better reflect the ratio of direct to indirect costs. Our comments on the five-year review of the Work RVUs under the Physician Fee Schedule also are included below.

Comments regarding Proposed Changes to the Practice Expense Methodology

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

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



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

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

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

Direct Costs

The estimate of direct costs is 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

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

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

Indirect Costs

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

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

Summary of The Chattanooga Heart Institute comments on the Proposed Rule re: Practice Expense changes

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

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

1. Insufficient reimbursement would force outpatient cath labs to close. Medicare patients would be directed back to the inpatient setting for cath services. This runs counter to CMS’ long-term goal of providing care in the outpatient setting whenever clinically appropriate.
2. Hospitals are not prepared to handle a large influx of catheterization cases, and the resulting wait times may very well endanger Medicare beneficiaries who need these critical cardiac services.
3. Medicare beneficiaries’ out-of-pocket costs would increase, as hospital co-pays are up to 40 percent higher than those in the outpatient setting.
4. Medicare patients also would be inconvenienced by longer drive times and increased waiting periods for test results.
5. Driving Medicare patients back into the hospital setting for imaging tests also would include increased costs to the Medicare program as a whole.



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

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

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

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

Sincerely,

Paul G. Farmer

Paul G. Farmer
Chief Executive Officer
pfarmer@chattanoogaheart.com
On behalf of The Chattanooga Heart Institute
2501 Citico Avenue
Chattanooga, Tennessee 37404
423-697-2103

Submitter : Dr. Brett Coldiron
Organization : American Academy of Dermatology Association
Category : Health Care Professional or Association

Date: 08/21/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2255-Attach-1.DOC



American Academy of Dermatology Association

2255

Physicians Dedicated to Excellence in Dermatology

Stephen P. Stone, MD, FAAD
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Diane R. Baker, MD, FAAD
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David M. Pariser, MD, FAAD
Secretary-Treasurer

Mary E. Maloney, MD, FAAD
President-Elect Past President

Ronald A. Henrichs, CAE
Executive Director & CEO

August 21, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
C5-25-25
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1512-PN**

Dear Administrator McClellan:

On behalf of the 15,000 members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to submit written comments regarding the five-year review of work relative value units under the physician fee schedule and proposed changes to the practice expense methodology. As advocates for dermatologists and their patients, we support modifications to the current physician fee schedule to ensure fairness and continued beneficiary access to quality, specialty health care services.

Discussion of Comments – Dermatology and Plastic Surgery

There were forty six dermatology codes placed by CMS on the American Medical Association (AMA) Relative Values Update Committee (RUC) 5 Year Review (5YR) List. This list included all of the benign and malignant excision codes (114XX and 116XX) as well as two key Mohs codes (17304-17305). The CMS rationale for placing these codes on the RUC 5YR list is: 1) physician work time is still based on the Hsaio/Harvard Study in 1992; or 2) increase in volume of procedures submitted to Medicare for payment. AMA RUC protocol required that AADA as well as other specialty societies e.g., American College of Surgeons, American Association of Otolaryngology- Head and Neck Surgeons) with significant utilization of these codes survey each code in order to justify the current level of physician time and work intensity.

We are pleased that current work values were confirmed for the benign and malignant excisions. However, the survey data collected by the AADA and the American College of Mohs Micrographic Surgery and Cutaneous Oncology (ACMMSCO) also met RUC 5 YR requirements and supported a moderate increase to the current level of physician time and work intensity for Mohs surgical procedures. However, the AMA RUC 5 YR Work Group recommended that the Mohs Micrographic Surgery codes go back to AMA CPT for clarification. AADA and ACMMSCO continue to work with AMA CPT and AMA RUC to bring this process to completion.

The Academy is disappointed that CMS has not accepted the AMA RUC recommendations for valuation of CPT 17004. The Academy supports the AMA RUC recommendation for a decrease in physician work from 2.79 PW/RVUs to 1.80 PW/RVUs for CPT 17004 which appropriately values the surveyed code in relation to CPT 17111. The AMA RUC reviewed CPT 17004 as part of its identification of rank order anomaly process. The RUC identified this procedure as being overvalued after reviewing CPT 17003 - *Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettment), all benign or premalignant lesions (e.g., actinic keratoses) other than skin tags or cutaneous vascular proliferative lesions; second through 14 lesions, each (List separately in addition to code for first lesion).*

CMS states "For CPT 17004, we believe that the work associated with benign and premalignant lesions is comparable and therefore, should be more similar to CPT 17111 - Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettment), of flat warts, molluscum contagiosum or milia; 15 or more lesions (PW/RVU=0.92)."

In the AMA RUC review of this procedure, it was evident that the work associated with benign and pre-malignant lesions was not comparable. This was reflected in the RUC action of recommending that the CPT Editorial Panel modify the CPT descriptors for these procedures to reflect that all procedures performed on pre-malignant lesions should be addressed in the 17000 family of codes, while all procedures performed on benign lesions (other than skin tags or cutaneous vascular lesions) would be addressed in the 17110 family of codes. Furthermore, the RUC noted that the surveyed code 17004 requires greater mental effort and judgment, technical skill, intensity and time in comparison to CPT 17111.

Other Issues Under the 5-Year Review – Budget Neutrality

The proposed notice requires budget neutrality adjustments as a result of changes in relative value units (RVU) from the five-year review process and other payment policy revisions. Application of the budget neutrality adjustment to the conversion factor would impact all physician services, whereas the application of the budget neutrality adjustment to the work RVUs would impact only those services that have physician work RVUs.

As noted in the proposal, CMS believes it is more equitable to apply the adjustment across services that have work RVUs, and is therefore proposing a budget neutrality adjustor that would reduce all work RVUs by an estimated 10 percent to meet the budget neutrality provisions of the Medicare law. The Academy strongly disagrees with applying a budget neutrality adjustment to the work RVUs. We instead urge CMS to apply the budget neutrality adjustment to the 2007 conversion factor rather than the work RVUs. In the past, application of the budget neutrality adjustor to the work RVUs has led to confusion in the Medicare and private payer systems and confounded the work of the RUC. For these reasons, CMS itself has had to reverse itself and revert to applying the adjustor to the conversion factor. Rather than repeating the mistakes of history, CMS is urged to learn from these past examples by avoiding the confusion and applying the adjustor to the conversion factor in the final rule for implementing the 2007 Medicare physician fee schedule.

Furthermore, in a feature of the proposal sure to exacerbate the problems with the application of the budget neutrality adjustment in this proposal, an adjustment is applied *three times* in the newly-proposed PE methodology – to the direct inputs, to the indirect allocations, and also as a final step. The Academy seeks clarification on the impacts of applying three separate budget neutrality adjustments in the new methodology instead of simply one final step.


Practice Expense

The Academy appreciates the CMS proposal to incorporate our practice expense supplemental survey data in the 2007 fee schedule. Our Association 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 CY2007 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. Again, we appreciate CMS at last including the supplemental survey data into the proposed rule and request that the data be implemented in the final rule.

As you know, the AMA is sponsoring a multi-specialty supplemental study of practice expense costs. The AADA has already agreed to participate in and contribute to this additional practice expense survey. However, we are deeply concerned 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. Additionally, the new multi-specialty practice expense survey results must be held to the same standard relating to the level of precision as the supplemental surveys already accepted by CMS.

Thank you for the opportunity to comment on this proposed notice. For further information, please contact Jayna Bonfini at jbbonfini@aad.org or 202-842-3555 or Norma Border at nborder@aad.org or 847-330-0230.

Sincerely,



Brett Coldiron, MD, FAAD
Chairman, Health Care Financing Committee

Cc: Stephen P. Stone, MD, FAAD, President
Diane R. Baker, MD, FAAD, President-Elect
David M. Pariser, MD, FAAD, Secretary-Treasurer
Ronald A. Henrichs, CAE, Executive Director and CEO
Daniel Siegel, MD, FAAD, AADA RUC Representative
Michael Bigby, MD, FAAD, AADA RUC Representative
Bruce Deitchman, MD, FAAD, AADA RUC Representative

AADA Comment Letter - CMS-1512-PN

John Zitelli, MD, FAAD, Chair, AADA CPT Committee
John D. Barnes, Deputy Executive Director
Judy Magel, PhD, Senior Director, Practice, Science & Research
Laura Saul Edwards, Director, Federal Affairs
Cyndi Del Boccio, Director, Executive Office
Jayna Bonfini, Assistant Director, Federal Affairs
Norma Border, Senior Manager, Coding and Reimbursement
Vernell St. John, Senior Coding and Reimbursement Specialist
Peggy Eiden, Coding & Reimbursement Specialist

Submitter : Mr. Andrew Whitman
Organization : The National Electrical Manufacturers Association
Category : Device Association

Date: 08/21/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-2258-Attach-1.DOC



Setting Standards for Excellence

Andrew Whitman

Vice President, Medical Products

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

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August 21, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

The National Electrical Manufacturers Association ("NEMA") submits the following comments regarding the Centers for Medicare & Medicaid Services ("CMS") Proposed Notice entitled "Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology." See 71 Fed. Reg. 37169 (June 29, 2006).

NEMA was established in 1926 and is the largest U.S. trade association representing the U.S. electrical manufacturing industry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 95% of the market for X-Ray Imaging (including mammography), CT, Radiation Therapy, Magnetic Resonance, Diagnostic Ultrasound, Nuclear Medicine Imaging and Medical Imaging Informatics equipment. NEMA is also the world's primary standards-development organization for medical imaging equipment.

NEMA appreciates the opportunity to submit these comments on the "Practice Expense" ("PE") portion of the proposed notice. NEMA is committed to working with CMS to ensure it has accurate and complete information so it can make informed decisions that may affect millions of Medicare beneficiaries and providers.

Below, NEMA provides its specific comments to the components of the proposed PE methodology. Overall, NEMA's comments seek to promote stability and predictability in Medicare reimbursement for technical components of medical imaging, to provide for access to and quality of medical imaging services, and to ensure transparency in CMS reimbursement decision processes.

ISSUE 1. Bottom-up method to calculate the direct Pes

Under the current payment methodology, CMS calculates PE RVUs for specific services by allocating aggregate specialty practice costs to specific procedures. This method is referred to as a "top-down" approach. See 71 Fed. Reg. at 37242. The current top-down approach uses a six-step process for calculating the PE for each service. By its very nature, a top-down

approach is less susceptible to dramatic changes or to economic distortions, thereby providing greater stability in payment rates.

CMS is now proposing to change its approach by adopting a “bottom-up” methodology for calculating the direct practice expense for each service and a separate method for calculating indirect practice expense. Under the bottom-up approach, CMS proposes adding the direct expenses--clinical labor, medical supplies, and medical equipment--for each service. The data would be obtained from the Socioeconomic Monitoring System (SMS) cost pool for each specialty. *See* 71 Fed. Reg. at 37245.

NEMA COMMENT:

While NEMA has not had sufficient time to fully analyze the direct costs obtained from the Practice Expense Advisory Committee (PEAC) process, we note that substitution of a “bottom up” methodology for the current “top down” methodology eliminates the direct cost scaling factors that may create too many unknowns. This factor contributes to the instability and unpredictability of the current system.

Our primary concern with CMS’s proposal to move toward a “bottom up” methodology is the failure of CMS to include representatives of technical component providers in the CMS process. We suggest that CMS confer closely with these providers on PEAC recommendations as the system continues to be refined in the future.

We also suggest that once CMS is satisfied with the direct cost inputs, it should establish a periodic process for updating these inputs. We would advise that the review be conducted frequently enough to ensure that allowances reflect current pricing. The primary objective overall should be to ensure that technical component payments are relatively stable from year to year. This is particularly important for technical component services, which require significant capital expenditures. Annual fluctuations in payment rates for these services preclude providers from engaging in effective financial planning and budgeting. In this regard, the need for stability is at least as great--if not greater--for physicians’ practice expenses than for physician work, which is reviewed every five-years. Therefore, NEMA requests CMS review the impact of this new methodology specifically on the technical component to ensure the payments are stable.

ISSUE 2. Use of PE/HR survey data

CMS is proposing to use the PE/HR data from eight surveys, including data from the survey submitted by the National Coalition of Quality Diagnostic Imaging Services (“NCQDIS”) as a factor in calculating the PE RVUs for 2007.¹

CMS would incorporate the indirect PE/HR surveys into the methodology through the use of specialty-specific indirect scaling factors. The Agency would continue to use the specialty-specific indirect scaling factors. However, to apply those in a simpler manner CMS proposes to create a new index.² CMS states this index would reflect the relationship between each

¹ Proposed Notice at 37245. The surveys include data submitted from: ACC; ACR; ASTRO; AFROC; AUA; AAD; JCAAI; NCQDIS; and AGA.

² Proposed Notice at 37247.

specialty's indirect scaling factor and the overall indirect scaling factor for the entire Physician Fee Schedule ("PFS").³

NEMA COMMENT:

NEMA commends CMS for using the supplemental survey data submitted by the eight organizations. We encourage CMS to continue to use this data for the foreseeable future, going so far as to compare the results of the current supplemental survey data for these eight specialties to the results from the new AMA survey, ensuring that no wide variation is occurring.

We appreciate CMS' concern that some medical specialties have submitted supplemental survey data, while a number of others have not. We believe that CMS has taken the right approach by incorporating the supplemental survey data and indexing the PE/hour for all specialties to 2005 rather than moving all the numbers backwards to 1998 levels. However, we are concerned that CMS may have made errors in the PE per hour calculations when adjusting the PE per hour figures to the 2005 values. It would be useful for CMS to show the increase in number for each year for each specialty's PE per hour, rolling up to 2005. This needs to be corrected prior to the final rule. Further, to the extent these calculations reveal errors in the PE/hr calculations, CMS should republish for comment any necessary revisions to the proposed CY 2007 allowances.

ISSUE 3. Budget Neutrality

CMS is required to impose a budget neutrality adjustment if changes in RVUs will cause an increase or decrease in overall fee schedule outlays of more than \$20 million, compared with what they would have been in the absence of the changes. CMS estimates the proposed work RVU changes would increase expenditures by approximately \$4.0 billion. CMS is proposing to create a separate budget neutrality adjuster that can be applied just to the work RVUs for Medicare purposes, without changing the number of work RVUs assigned to a particular service. Practice Expense RVUs are adjusted for budget neutrality separately. The proposal is intended to preserve the integrity of the existing work RVU structure.

NEMA COMMENT

On the whole, we believe that the budget neutrality methodology proposed by CMS is reasonable.

We understand that some in the medical community are urging CMS to impose the budget neutrality adjustment which is necessary as the result of the five-year review on a fee schedule-wide basis while continuing to have the practice expense budget neutrality adjustment absorbed solely by the practice expense relative value units. It is our understanding that the practice expense budget neutrality/scaling adjustment is already considerably larger than the 10% reduction in W-RVUs proposed. Thus, it clearly would be unfair to further reduce Medicare payment for technical component and other PE-RVU-heavy services by shifting part of the five-year review budget neutrality adjustment to these services.

³ Proposed Notice at 37245-46.

A more equitable alternative would be to make all budget neutrality adjustments on a fee schedule-wide basis, and to phase in both the PE-RVU changes and the W-RVU changes over a period of four-years. However, we understand that there may be practical impediments to this solution. In any event, we urge CMS not to adopt any budget neutrality methodology that further disadvantages TC and other PE-RVU-heavy services.

We also urge CMS to consider phasing in the results of the five-year review over the same four-year transition period used to phase in the changes in practice expense methodology. This would ease the burden on professional component and other services that do not benefit from the increases in Evaluation & Management services resulting from the five-year review, but must bear the cost of this change in a single year. While we understand that five-year review changes historically have been integrated into the PFS in a single year, none of the prior changes have had the impact of shifting \$ 4 billion in Medicare payment among various fee schedule services.

ISSUE 4. Modification of indirect PE RVU calculation

Indirect expenses would include administrative labor, office expense, and all other expenses. In the Proposed Notice, CMS combined these indirect expenses into a single category.⁴ For CY 2007, CMS proposes to allocate indirect expenses by applying a specialty-specific indirect percentage factor to the direct expenses in order to recognize the varying proportion that indirect costs represent of total costs by specialty.⁵

With the changes proposed to PE RVUs, CMS states that it is now appropriate to use updated utilization data in the calculation of the indirect PEs. Specifically, CMS is proposing to use the 2005 utilization data in the calculation of the 2007 indirect PE RVUs.⁶

CMS seeks comments on whether the utilization data should be updated yearly, which would increase the accuracy of the PE calculations, or less often, which would increase the stability of the PE RVUs.⁷

NEMA COMMENT:

The use of W-RVUs as an allocator for indirect costs substantially disadvantages technical component services, since technical component services have no W-RVUs. We do not believe that there is any evidence that a service's W-RVUs are related to the indirect practice costs (e.g., overhead and administrative costs) involved in providing that service. While all indirect cost allocation methodologies are to some extent arbitrary, we believe that using W-RVUs as an allocator is more arbitrary than most.

We are especially concerned because our best estimates suggest that W-RVUs are actually the **primary** allocator of indirect costs under the CMS proposal. Based on the data provided, W-RVUs may be the allocator for about two-thirds of indirect expenses. Since indirect expenses

⁴ Proposed Notice at 37243.

⁵ Proposed Notice at 37247.

⁶ Proposed Notice at 37246.

⁷ Proposed Notice at 37247.

account for more than half of all practice expenses, the decision to use W-RVUs as an allocator has significant consequences for the resulting allowances.

It is our understanding that CMS's use of W-RVUs as an allocator is intended to ensure that some indirect expenses are allocated to services provided outside the office. Since these services have no direct expenses, allocating indirect expenses *solely* on the basis of direct expenses would disadvantage these services. We urge CMS to at least limit the use of physician work to that portion of indirect expenses that can be reasonably apportioned to out-of-office services or to otherwise limit the use of W-RVUs as an allocator such that it is not used as the primary basis for allocating indirect costs.

NEMA urges CMS to:

- Finalize its proposal to use non-physician staff time in lieu of physician work for technical component and other services with no physician work RVUs;
- Consider eliminating the "direct adjustment" to direct costs that has the effect of further reducing the impact of direct costs as an indirect cost allocator; and
- Reconsider the issue if any changes are made to direct cost data or methodologies that have the impact of significantly reducing Medicare payment for technical component services.

ISSUE 5. Access and Quality

NEMA identified a number of services that would incur such substantial payment reductions that the proposed changes may jeopardize access and quality. For example, under the Proposed Notice, payment for cardiac catheterization provided in non-hospital settings and cardiac monitoring services would be reduced by over 40%, potentially jeopardizing access to these important services. Similarly, payment for bone densitometry procedures will decrease by more than 70% over the next four-years.

Questions have been raised about whether the direct cost data for these services is accurate and complete. Therefore, NEMA urges CMS to maintain current allowances for these services until the direct cost data can be confirmed.

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

ISSUE 6. Transparency

One of CMS's stated primary priorities in the Proposed Notice was to increase the transparency of the methodology used in its calculations. While the proposed methodology is more transparent in some respects (e.g., the elimination of certain scaling factors), it is more unclear in others (e.g., the practice expense budget neutrality methodology). We urge CMS to continue to work with all affected groups, including manufacturers of major medical equipment, to further improve the transparency of the process. In addition, CMS might


consider making its programming available to the affected community, to facilitate a more complete understanding of the methodology and its implications.

CONCLUSION


Thank you for consideration of our comments. NEMA is committed to working with CMS on this proposed notice. We hope that these comments assist CMS in its rulemaking activities.

Please contact us if we can provide additional information. I can be reached at (703) 841-3279 or by email at andrew_whitman@nema.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Whitman", with a long horizontal flourish extending to the right.

Andrew Whitman



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Urological
Association**

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August 21, 2006

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Administrator
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Department of Health and Human Services
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P.O. Box 8014
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Re: CMS-1512-PN – Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, we are pleased to submit comments on the proposed notice for changes to the work and practice expense (PE) relative value units (RVUs) under the Medicare physician fee schedule. The AUA is pleased in general with the outcome of the five-year review of work values and the proposed changes to the PE methodology as they relate to urology. We have spent much time and effort over the past few years providing to CMS input and data that led to the proposed changes, both by our participation in the five-year review of work RVUs and by conducting a supplemental PE survey. However, there are certain aspects of the proposal which we feel could be improved and/or clarified and we offer specific comments and recommendations below.

I. FIVE-YEAR REVIEW PROCESS

DISCUSSION OF COMMENTS-GYNECOLOGY, UROLOGY, PAIN MEDICINE, AND NEUROSURGERY

The AUA applauds CMS for adopting the American Medical Association Relative Value Update Committee's (RUC) recommendations for the seven urology procedures which CMS identified as being potentially misvalued and also for adopting increases in many evaluation and management services. The AUA has participated in the RUC process since the

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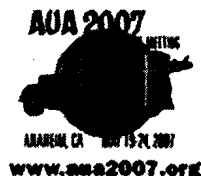
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beginning, was intimately involved in each of the three five-year reviews of work RVUs and places a high value on the accuracy and rigor of the process. We also appreciate the valuable help and guidance that CMS contributed to the arduous five-year review process that has been ongoing for more than a year.

OTHER ISSUES

Post-Operative Visits Included in the Global Surgical packages

The AUA strongly supports the application of the RUC-recommended new values for the evaluation and management services to all surgical services with a 10- or 90-day global period and applauds CMS for extending the E&M increases so that they are reflected in the office visits that are included in 10- and 90-day global service packages. However, when reviewing the work values for 10- and 90-day urology procedures, we identified some possible errors in how the E&M increases were applied. Therefore, we urge CMS to carefully review all of the codes that received an increased work RVU due to E&M work value increases to ensure that the increases were applied correctly and uniformly.

Changes to global policy

Although we currently do not have any specific comments about advantages or disadvantages that might be associated with proposing a change to CMS's global policy in the future, we expect that the RUC would review any such proposals and that we would provide input through our participation in the RUC. However, as long as the global surgery policy is still in place in its current form, CMS should consider the number of post-operative visits based on RUC surveys as representing the typical post-operative care for a procedure and should factor 100 percent of the E&M work value of those visits into the work RVU for the procedure.

Budget neutrality

According to the notice, CMS expects that budget neutrality-adjustments will be required as a result of changes in RVUs resulting from the five-year review as well as other fee schedule payment policy revisions that will be finalized later this year. CMS considered two options for making the statutorily required budget-neutrality adjustment to account for the five-year review of physician work: reducing all work RVUs by an estimated 10 percent, or reducing the physician fee schedule conversion factor by an estimated five percent.

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

The AUA strongly disagrees with applying a budget neutrality adjustment to the work RVUs. To preserve the integrity and relativity of the work RVUs, the AUA urges CMS to apply the budget neutrality adjustment to the 2007 conversion factor rather than the work RVUs.

Applying a budget neutrality adjustor to the work RVUs counteracts the purpose of updating the evaluation and management and other codes in the first place and thwarts the progress made by specialty societies, the RUC and CMS, all of which dedicated a tremendous amount of time and effort to develop accurate changes to the E&M and other work RVUs.

In addition, many private payers use the Medicare RVUs, modifying payment through application of a different conversion factor. Therefore, the proposed adjustments to the work RVUs may have an unintended negative payment impact as private payers would have to recalculate their payment formulas to the CPT code level. It is problematic to believe that it would be possible to maintain two separate lists of work RVUs, one adjusted for budget neutrality and one not adjusted for budget neutrality, without generating unnecessary confusion and administrative hassles.

We also urge CMS to consider the history of how it has applied budget neutrality adjustments and the problems that arose in the past from applying it directly to the work RVUs. Subsequent to adoption of the fee schedule in 1992, CMS achieved budget neutrality by uniformly reducing all work RVUs each year. These adjustments to the work relative values caused confusion among private payers and physician practices. Also, constantly changing work RVUs hindered the process of establishing work RVUs for new and revised services. Therefore, the AMA RUC argued that any necessary budget neutrality adjustments should be made to the conversion factor, rather than the work RVUs. In 1996, CMS reversed its policy and applied the budget neutrality adjustment to the conversion factors.

In 1997, following the first Five-Year Review of the RBRVS, CMS reversed its policy once again and went back to applying budget neutrality directly to the work RVUs in the form of a separate work adjuster. However, due to problems with this approach, CMS began in 1998 to apply budget neutrality adjustments to the conversion factor and has continued to do so to date. According to CMS, "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." (68 Fed. Reg. at 63246).

We are not sure why CMS is proposing to revert back to a policy of applying budget neutrality adjustment to the work RVUs, especially when CMS itself has admitted that it causes problems and confusion. Therefore, we urge CMS to reconsider this proposal.

Effect on practice expense inputs stemming from the 5-year review

As a result of the five-year review, the RUC recommended changes in the times associated with the intra-service portion of certain procedures, and CMS is proposing to adjust the clinical labor time assigned for assisting the physician in the nonfacility setting for those procedures. In addition, if an accepted new work RVU reflects a change in the number or level of post-operative visits, CMS is proposing to modify the clinical staff time to reflect the change. This adjusted time is also applied to the equipment used in the post-operative visits. Also, where the number of post-operative visits has changed, the number of minimum multi-specialty visit packs will also be adjusted accordingly. The AUA supports incorporating all of these work changes

into the PE but urges CMS to ensure that all of the changes are accurately applied.

II. RESOURCE-BASED PRACTICE EXPENSE RVUs

Bottom-up methodology for direct costs

The AUA strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it helps CMS to make progress towards its stated goals of ensuring that PE payments reflect the relative resources required for each procedure, simplifying the practice expense methodology and increasing the stability of the practice expense payments. We also agree with CMS's proposal to eliminate the nonphysician work pool and to calculate the indirect portion of the PE RVUs using current AMA Socioeconomic Monitoring System (SMS) data and supplementary survey data, as this simplifies and finally allows for uniform application of the methodology across all codes.

The AUA is especially pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. Since 1999 when the PEAC began its work, the methodology used to refine practice expense RVUs has caused annual shifts in RVUs, and thus in Medicare fees. For urology, these shifts were quite significant in some years due to refinement of a large number of CPT codes related to urology's ten most utilized CPT codes. Not only were these shifts very confusing and frustrating for physicians, they also made it harder for practices to do planning and budgeting. Therefore, we applaud CMS for taking this issue into consideration and proposing a change in the methodology that will allow the PE RVUs to become more stable over time.

For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and the AUA strongly supports the change in methodology that eliminates the need for scaling factors. However, as we have stated previously, now that the direct cost PE RVUs are developed solely based on direct cost inputs, it is vitally important to have a clear and reliable process for making any necessary changes to direct cost inputs. Also, as discussed below, we are concerned that certain aspects of the proposed PE methodology are causing direct cost inputs to be inappropriately scaled down, especially for in-office procedures that require high-cost disposable supply items.

Application of budget neutrality adjustments in practice expense methodology

As stated above, we support the change in methodology for calculating PE RVUs and believe that the changes are an improvement towards meeting CMS's stated goals for PE. However, we do have some concerns that certain aspects of the proposed methodology will still not allow CMS to fully meet its stated goals for PE and we seek clarification on why CMS chose to apply budget neutrality as proposed. For example, in the newly-proposed PE methodology, CMS applies three budget neutrality adjustments: one to the direct inputs, one to the indirect allocators and one as a final step. It is unclear why CMS does not apply budget neutrality just once as a

final step in the methodology. Therefore, we seek more information on whether CMS analyzed alternate methods for achieving budget neutrality among the PE RVUs and what the impacts of the various methods would be.

In addition, the methodology that CMS proposes with regard to the split between direct and indirect costs and how those calculations are used to determine a budget neutrality adjustment for direct costs does not seem to fully support CMS's goal of reflecting relative PE resources to the greatest extent possible. Also, despite the fact that the new methodology eliminates the need to scale the costs of the direct-cost inputs (which is an improvement), the proposed methodology still does not allow the full cost of PE direct-cost inputs to be reflected in the formula.

Instead, the proposed methodology changes seek to reallocate the split between direct and indirect PE costs based on the average percentage breakdown from each specialty's practice expense per hour data. However, the use of an average PE percentage split for direct and indirect costs is inherently unfair to procedures with high cost disposable supplies or higher than average equipment costs, because it weights the split between direct and indirect costs towards office visit practice expenses, which constitute the majority of volume for any specialty. Use of a median split for procedures with more expensive supplies and equipment may be more appropriate, and we urge CMS to explore this alternative.

Under the proposed bottom-up PE methodology, the budget-neutrality adjustment to the direct inputs of greater than 30 percent is in effect causing physicians to assume a 30 percent discount off the cost of the disposables for which they have already incurred costs. In the previous top-down methodology, there were only a few specialties that did not have a supply scaling factor of close to or greater than one. Thus the cost of the supplies to the physician was included in the PE calculation. However, under this proposed methodology, physicians are forced to pay a discount for supplies.

We are concerned that urology practices will not be able to absorb the discounts for supplies that are assumed in the budget neutrality formula on top of significant other reductions, including the budget neutrality adjustment resulting from the five-year review of work RVUs and a projected 5.1 percent reduction in the conversion factor for 2007. This could cause many procedures that are now safely and effectively being provided in a physician's office to be shifted to other more costly sites of service. Site of service should be chosen based on the most timely, cost-effective, safe environment for the patient and based on the physician's clinical judgment in concert with patient preference. Therefore, we recommend that, prior to the implementation of the proposed methodology, CMS meet with interested parties regarding office-based procedures with high-cost disposable supplies to discuss alternatives for dealing with this issue under the new PE methodology.

Use of supplemental survey data

The AUA applauds CMS for proposing to use the urology supplemental survey data that we submitted originally for use in calculating PE RVUs for the 2006 fee schedule. Although CMS accepted our data last year based on Lewin's recommendation that the data met all of the necessary criteria, an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually *use* the data in calculating the PE RVUs for 2006. The AUA was

extremely disappointed that the urology supplemental data was not used for 2006 and we continue to believe that CMS did not correctly interpret the provisions of the 2003 Medicare Modernization Act as they related to the use of urology's supplemental survey data. Nevertheless, we strongly support the use of our supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

Modification of current methodology for calculating indirect PE RVUs

Use of budget-neutrality adjusted work RVUs in calculating service level allocators for indirect practice expense RVUs

In the practice expense methodology changes outlined in the notice, CMS notes that the work RVUs used in the calculation of service level allocators for the indirect PEs include the separate work budget neutrality adjustment from the 5-year review of the work RVUs. The AUA disagrees with using the adjusted work RVUs in this PE calculation, as this arbitrarily and unfairly penalizes physicians by resulting in lower PE RVUs for procedures with work RVUs. We urge CMS to use the full newly-proposed work RVUs in calculating the indirect PE service-level allocators. In general, for any calculations used to allocate indirect costs, we urge CMS to use non-budget neutral values in those calculations.

The AUA strongly disagrees with using the adjusted work RVUs in this calculation. The intent of this adjustment is to maintain budget neutrality. By using the adjusted work RVUs in this part of the calculation, CMS is unfairly applying a budget neutrality adjustment where it is not required and inappropriately reducing payments.

Use of 2005 utilization data

For utilization data used in the PE calculations, the AUA supports the use of data that maximizes the stability of the PE RVUs yet provides a mechanism to account for cost fluctuations of any type that affect the relativity among procedures.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,



Lawrence S, Ross, M.D.
President

Submitter : Dr. Lawrence Ross
Organization : American Urological Association
Category : Physician

Date: 08/21/2006

Issue Areas/Comments


GENERAL

GENERAL

See Attachment

CMS-1512-PN-2259-Attach-1.DOC

2259



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August 21, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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P.O. Box 8014
Baltimore, MD 21244-8014

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

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Budget neutrality

According to the notice, CMS expects that budget neutrality-adjustments will be required as a result of changes in RVUs resulting from the five-year review as well as other fee schedule payment policy revisions that will be finalized later this year. CMS considered two options for making the statutorily required budget-neutrality adjustment to account for the five-year review of physician work: reducing all work RVUs by an estimated 10 percent, or reducing the physician fee schedule conversion factor by an estimated five percent.

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

The AUA strongly disagrees with applying a budget neutrality adjustment to the work RVUs. To preserve the integrity and relativity of the work RVUs, the AUA urges CMS to apply the budget neutrality adjustment to the 2007 conversion factor rather than the work RVUs.

Applying a budget neutrality adjustor to the work RVUs counteracts the purpose of updating the evaluation and management and other codes in the first place and thwarts the progress made by specialty societies, the RUC and CMS, all of which dedicated a tremendous amount of time and effort to develop accurate changes to the E&M and other work RVUs.

In addition, many private payers use the Medicare RVUs, modifying payment through application of a different conversion factor. Therefore, the proposed adjustments to the work RVUs may have an unintended negative payment impact as private payers would have to recalculate their payment formulas to the CPT code level. It is problematic to believe that it would be possible to maintain two separate lists of work RVUs, one adjusted for budget neutrality and one not adjusted for budget neutrality, without generating unnecessary confusion and administrative hassles.

We also urge CMS to consider the history of how it has applied budget neutrality adjustments and the problems that arose in the past from applying it directly to the work RVUs. Subsequent to adoption of the fee schedule in 1992, CMS achieved budget neutrality by uniformly reducing all work RVUs each year. These adjustments to the work relative values caused confusion among private payers and physician practices. Also, constantly changing work RVUs hindered the process of establishing work RVUs for new and revised services. Therefore, the AMA RUC argued that any necessary budget neutrality adjustments should be made to the conversion factor, rather than the work RVUs. In 1996, CMS reversed its policy and applied the budget neutrality adjustment to the conversion factors.

In 1997, following the first Five-Year Review of the RBRVS, CMS reversed its policy once again and went back to applying budget neutrality directly to the work RVUs in the form of a separate work adjuster. However, due to problems with this approach, CMS began in 1998 to apply budget neutrality adjustments to the conversion factor and has continued to do so to date. According to CMS, "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." (68 Fed. Reg. at 63246).

We are not sure why CMS is proposing to revert back to a policy of applying budget neutrality adjustment to the work RVUs, especially when CMS itself has admitted that it causes problems and confusion. Therefore, we urge CMS to reconsider this proposal.

Effect on practice expense inputs stemming from the 5-year review

As a result of the five-year review, the RUC recommended changes in the times associated with the intra-service portion of certain procedures, and CMS is proposing to adjust the clinical labor time assigned for assisting the physician in the nonfacility setting for those procedures. In addition, if an accepted new work RVU reflects a change in the number or level of post-operative visits, CMS is proposing to modify the clinical staff time to reflect the change. This adjusted time is also applied to the equipment used in the post-operative visits. Also, where the number of post-operative visits has changed, the number of minimum multi-specialty visit packs will also be adjusted accordingly. The AUA supports incorporating all of these work changes

into the PE but urges CMS to ensure that all of the changes are accurately applied.

II. RESOURCE-BASED PRACTICE EXPENSE RVUs

Bottom-up methodology for direct costs

The AUA strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it helps CMS to make progress towards its stated goals of ensuring that PE payments reflect the relative resources required for each procedure, simplifying the practice expense methodology and increasing the stability of the practice expense payments. We also agree with CMS's proposal to eliminate the nonphysician work pool and to calculate the indirect portion of the PE RVUs using current AMA Socioeconomic Monitoring System (SMS) data and supplementary survey data, as this simplifies and finally allows for uniform application of the methodology across all codes.

The AUA is especially pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. Since 1999 when the PEAC began its work, the methodology used to refine practice expense RVUs has caused annual shifts in RVUs, and thus in Medicare fees. For urology, these shifts were quite significant in some years due to refinement of a large number of CPT codes related to urology's ten most utilized CPT codes. Not only were these shifts very confusing and frustrating for physicians, they also made it harder for practices to do planning and budgeting. Therefore, we applaud CMS for taking this issue into consideration and proposing a change in the methodology that will allow the PE RVUs to become more stable over time.

For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and the AUA strongly supports the change in methodology that eliminates the need for scaling factors. However, as we have stated previously, now that the direct cost PE RVUs are developed solely based on direct cost inputs, it is vitally important to have a clear and reliable process for making any necessary changes to direct cost inputs. Also, as discussed below, we are concerned that certain aspects of the proposed PE methodology are causing direct cost inputs to be inappropriately scaled down, especially for in-office procedures that require high-cost disposable supply items.

Application of budget neutrality adjustments in practice expense methodology

As stated above, we support the change in methodology for calculating PE RVUs and believe that the changes are an improvement towards meeting CMS's stated goals for PE. However, we do have some concerns that certain aspects of the proposed methodology will still not allow CMS to fully meet its stated goals for PE and we seek clarification on why CMS chose to apply budget neutrality as proposed. For example, in the newly-proposed PE methodology, CMS applies three budget neutrality adjustments: one to the direct inputs, one to the indirect allocators and one as a final step. It is unclear why CMS does not apply budget neutrality just once as a

final step in the methodology. Therefore, we seek more information on whether CMS analyzed alternate methods for achieving budget neutrality among the PE RVUs and what the impacts of the various methods would be.

In addition, the methodology that CMS proposes with regard to the split between direct and indirect costs and how those calculations are used to determine a budget neutrality adjustment for direct costs does not seem to fully support CMS's goal of reflecting relative PE resources to the greatest extent possible. Also, despite the fact that the new methodology eliminates the need to scale the costs of the direct-cost inputs (which is an improvement), the proposed methodology still does not allow the full cost of PE direct-cost inputs to be reflected in the formula.

Instead, the proposed methodology changes seek to reallocate the split between direct and indirect PE costs based on the average percentage breakdown from each specialty's practice expense per hour data. However, the use of an average PE percentage split for direct and indirect costs is inherently unfair to procedures with high cost disposable supplies or higher than average equipment costs, because it weights the split between direct and indirect costs towards office visit practice expenses, which constitute the majority of volume for any specialty. Use of a median split for procedures with more expensive supplies and equipment may be more appropriate, and we urge CMS to explore this alternative.

Under the proposed bottom-up PE methodology, the budget-neutrality adjustment to the direct inputs of greater than 30 percent is in effect causing physicians to assume a 30 percent discount off the cost of the disposables for which they have already incurred costs. In the previous top-down methodology, there were only a few specialties that did not have a supply scaling factor of close to or greater than one. Thus the cost of the supplies to the physician was included in the PE calculation. However, under this proposed methodology, physicians are forced to pay a discount for supplies.

We are concerned that urology practices will not be able to absorb the discounts for supplies that are assumed in the budget neutrality formula on top of significant other reductions, including the budget neutrality adjustment resulting from the five-year review of work RVUs and a projected 5.1 percent reduction in the conversion factor for 2007. This could cause many procedures that are now safely and effectively being provided in a physician's office to be shifted to other more costly sites of service. Site of service should be chosen based on the most timely, cost-effective, safe environment for the patient and based on the physician's clinical judgment in concert with patient preference. Therefore, we recommend that, prior to the implementation of the proposed methodology, CMS meet with interested parties regarding office-based procedures with high-cost disposable supplies to discuss alternatives for dealing with this issue under the new PE methodology.

Use of supplemental survey data

The AUA applauds CMS for proposing to use the urology supplemental survey data that we submitted originally for use in calculating PE RVUs for the 2006 fee schedule. Although CMS accepted our data last year based on Lewin's recommendation that the data met all of the necessary criteria, an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually *use* the data in calculating the PE RVUs for 2006. The AUA was

extremely disappointed that the urology supplemental data was not used for 2006 and we continue to believe that CMS did not correctly interpret the provisions of the 2003 Medicare Modernization Act as they related to the use of urology's supplemental survey data. Nevertheless, we strongly support the use of our supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

Modification of current methodology for calculating indirect PE RVUs

Use of budget-neutrality adjusted work RVUs in calculating service level allocators for indirect practice expense RVUs

In the practice expense methodology changes outlined in the notice, CMS notes that the work RVUs used in the calculation of service level allocators for the indirect PEs include the separate work budget neutrality adjustment from the 5-year review of the work RVUs. The AUA disagrees with using the adjusted work RVUs in this PE calculation, as this arbitrarily and unfairly penalizes physicians by resulting in lower PE RVUs for procedures with work RVUs. We urge CMS to use the full newly-proposed work RVUs in calculating the indirect PE service-level allocators. In general, for any calculations used to allocate indirect costs, we urge CMS to use non-budget neutral values in those calculations.

The AUA strongly disagrees with using the adjusted work RVUs in this calculation. The intent of this adjustment is to maintain budget neutrality. By using the adjusted work RVUs in this part of the calculation, CMS is unfairly applying a budget neutrality adjustment where it is not required and inappropriately reducing payments.

Use of 2005 utilization data

For utilization data used in the PE calculations, the AUA supports the use of data that maximizes the stability of the PE RVUs yet provides a mechanism to account for cost fluctuations of any type that affect the relativity among procedures.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,



Lawrence S. Ross, M.D.
President

Submitter : Dr. T. SIVARAJ

Date: 08/21/2006

Organization : HOLLY SPRINGS MEDICAL CENTER

Category : Physician

Issue Areas/Comments

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