Submitter :

Organization : The Society of Thoracic Surgeons - AATS

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

STS and AATS comments on Cardiothoracic surgery, Practice Expense and Other Issues attached.

.

CMS-1512-PN-2261-Attach-1.DOC

CMS-1512-PN-2261-Attach-2.DOC

Date: 08/21/2006

AMACHMENT 1 #2261





The Society of Thoracic Surgeons

American Association for Thoracic Surgery

August 21, 2006

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

Submitted electronically at http://www.cms.hhs.gov/regulations/ecomments

STS/AATS Response to CMS 2005 5-Year Review Proposed Rule

File Code: CMS-1512-PN DISCUSSION OF COMMENTS – CARDIOTHORACIC SURGERY

Dear Dr. McClellan:

The Society of Thoracic Surgeons and the American Association for Thoracic Surgery, which represent the overwhelming majority of cardiothoracic surgeons in the United States, have reviewed the proposed rule, and carefully evaluated the concerns and comments expressed by CMS. We believe that we can answer all of the stated concerns, and we are confident that upon further consideration, CMS will agree that the Relative Value Update Committee (RUC) 2006 five-year review recommendations represent the best valuations of work for cardiothoracic surgical procedures and will be incorporated into the CMS final rule.

We agree with the proposed work values for the Congenital Cardiac Surgery Codes.

In preparation for the five year review and in order to address significant rank order problems and procedure misvaluations in the current fee schedule, STS/AATS developed and the RUC

approved a new methodology to assist in estimating physician work, building on methods previously employed in RUC valuation and using standard definitions of intensity and physician work. The methodology was submitted to CMS as part of the 5-year review recommendation, and was approved by the 5-year review workgroup and the Research subcommittee of the RUC as well as by the full RUC.

Using the STS National Database, the characteristics of 1,084,466 operations performed since the 2nd 5 year review were compared to 1,129,243 operations performed from 1995-1999 to develop compelling evidence to justify code revaluation. The required compelling evidence, that the patient population and therefore the physician work involved had changed significantly, was accepted by the RUC. Additional compelling evidence regarding rank order anomalies was also presented for some codes.

Two different types of surveys were conducted to estimate operative intensity and assess the level and amount of perioperative patient care delivered. 659 thoracic surgeons responded (~19% of the US Thoracic Surgery active physician workforce), representing all states save Alaska, Montana, Rhode Island, and Wyoming, with 60% in private practice.

After completion of the survey process, 32 thoracic surgeons from representative geographic locations and practice types were constituted into two expert panels to separately review the cardiac and thoracic surgical codes. Professionally facilitated and RUC monitored sessions then evaluated the 72 codes, taking into consideration the STS database data for operative times, ICU and total lengths of stay, ventilator hours, and survey results on a code-by-code basis. The expert panels reviewed the intensity survey results and made recommendations for intraservice intensity. They also reviewed the database data and made recommendations for pre and post service time, and the number and type of postoperative visits for each code. All codes were ranked for each building block component, and considered individually and within their families to ensure consistency, relativity, and magnitude within the established RUC ranges.

Each panel met in continuous session for 12 hours, and at no point were the total code values (RVWs) calculated or expressed, nor were the codes ranked or sorted based on total value. The only criteria for ranking procedure intensity were the survey results and the expert opinions of these practicing cardiothoracic surgeons.

The panel recommendations were presented to a multidisciplinary RUC 5-year review workgroup in an 11 hour session. This workgroup adjusted time and visit levels as well as RVW recommendations after a code-by-code review. A secondary survey to assess the extent to which cardiothoracic surgeons provide critical care was recommended by the workgroup, and this was performed with 212 respondents. The workgroup recommendations and the additional survey results were then presented to the full RUC and approved without further adjustment of work values or time at the September 2005 RUC meeting.

Although we will respond in detail to concerns posed in the narrative of the proposed rule, we feel that it is important to note that each of the concerns raised in the proposed rule had been raised in the RUC process, responded to by the STS/AATS, carefully re-considered by the RUC and then accepted by the RUC. Further, we remind CMS that according to the operating rules of

the RUC this approval required at least a 2/3 majority of RUC members, and RUC approval was for both the methodology and the proposed work values. This level of endorsement of necessity requires the support of a combination of both surgical and medical specialty representatives.

A. Response to Specific CMS concerns regarding the employment of the STS database to determine physician work values

Despite the objections raised in the proposed rule, CMS has proposed to accept the RUC approved time and visit data derived from the STS database. Our responses to the CMS stated concerns support this decision and should allay the concerns expressed. STS/AATS remains committed to the use of objective data to determine physician work and surgical outcome, and is committed to continue to work with CMS and the RUC to define the characteristics of a clinical database that meet high standards of accuracy and validity.

1. CMS concerns on page 138 that the STS National Database is not representative:

These concerns were addressed in response to questioning from the RUC Research Subcommittee in February and March 2005. Subsequently, the database was accepted as representative by a vote of the full RUC in April of 2005. The supporting documentation follows:

STS Database Demographics

The materials used for these comparisons include: (1) The STS Adult Cardiac Database; (2) A report from the most recent available (2002) nationwide hospital survey conducted by the American Hospital Association (AHA); and (3) A published report from the STS Task Force on Workforce, a committee assigned to track the size, scope, and activity of the cardiothoracic surgical community in the US. For the reporting of clinical practices, responses were limited to US members in active practice. There were 1,189 such individuals who returned the workforce questionnaire out of a possible 2,717 practicing surgeons (43.8% response rate). This response level means that a reader can be 95% confident that all respondents would have answered within a 1.8% margin of the reported result.

Sample Size – Are Enough Practice Sites Represented In The STS Database?

The 2002 AHA survey indicates that there are 990 hospitals that provide cardiac surgery services. There are 619 STS database sites. Therefore, the STS database sites (619) represent 62.5% of the total national sites providing heart surgery (619/990).

Geographic Site - Are The STS Database Sites Distributed Proportionately?

The STS/AATS 2003 Workforce survey recorded geographic location. Table 1 compares the geographic distribution of practicing thoracic surgeons nationally, based on the workforce survey, to the geographic distribution of STS database sites. The geographic

regions in the two reports correspond closely to one another, but are not identical; they differ slightly with regard to names (i.e. Great lakes versus East North Central) and occasional switching of a state from one region to another. Overall, however, there appears to be reasonable correspondence and, more importantly, the STS reporting sites appear well distributed throughout the US.

Table 1						
Geographic Distribution of STS Database Sites and STS/AATS Practice Locations						
STS Database Sites	STS Database Sites STS Practice Locations					
Great Lakes	24.6%	16.9%	East North Central			
South Atlantic	19.1%	17.2%	South Atlantic			
Pacific	12.8%	12.6%	Pacific			
Plains	10.3%	8.4%	West North Central			
Middle Atlantic	9.8%	15.1%	Middle Atlantic			
East South Central	8.6%	6.9%	Pacific			
West South Central	5.7%	11.0%	West South Central			
Mountain	5.2%	4.6%	Mountain			
New England	3.9%	5.6%	New England			

Practice Types - Are Academic Practices Over-represented?

The Research Subcommittee of the RUC had previously requested additional information regarding the representativeness of the STS database, particularly with respect to disproportionate reporting of more complex procedures performed at academic institutions. At the February 2005 RUC meeting, STS/AATS reported that, for the period 1995-2003, 41.7 percent of the database sites were identified as "Academic." However, the definition of "academic" is germane and requires further clarification. For the purposes of the AHA survey, "academic" means that the site either:

- Reported a medical school affiliation in the 2002 American Hospital Survey;
- Reported the presence of an ACGME approved residency (any specialty) in the survey;
- Reported that the hospital was a member of the Council of Teaching Hospitals; or
- Reported that the hospital had an osteopathic or dental residency.

With this definition, 24.0 percent of all US Hospitals were *academic in 2002*. During this period and in 2003 the STS database sites meeting the definition of *academic* had decreased from 41.7% to 21% (129/619), principally through the recruitment of additional *non-academic* sites. Academic sites recorded 27.5 percent (144,216/523,780) of the procedures mapped to CPT codes submitted for refinement.

The STS/AATS Workforce Survey found that 29 percent of respondents reported themselves to be in full time academic practice and 6 percent in part-time academic roles. These figures are consistent with the above noted distribution within the STS database, suggesting that the proportion of *academic* sites in the STS database is similar to the

cardiothoracic community at large and that the STS database does not contain an overrepresentation of cases from academic medical centers. In fact, over 70% of the cases entered into the database are from non-academic centers.

		Table 2		
	STS Workf	orce Survey	STS Dat	tabase
	By Physician	By Adult Cardiac Procedures	By Site	By Adult Cardiac Procedures
Academic	29%	22%	21%	28%
Non-academic	60%	67%	79%	73%
Part-time Academic	6%	6%		
Other	5%	5%		·
Survey Characteristics				
Year	2003		2002	
Respondents	1189	Practicing Thoracic Surgeons	619	STS Database Sites
Total US	2717	STS/AATS Members	990	Hospitals performing OHS*
Percent	43.8%		62.5%	

These characteristics are summarized in Table 2:

*Source American Hospital Association 2003 Survey

2. On page 138 of the proposed rule, CMS raised the issue as to whether cases are selectively reported to the database (for example: containing a disproportionate number of complex cases)

There is no evidence to support this concern.

STS is concerned, however, about an erroneous interpretation of data at the September 2005 RUC meeting. At that meeting it was suggested that published data demonstrate that the STS database is 20% inaccurate in mortality reporting, citing a published paper (Mack MJ, J Thorac Cardiovasc Surg. 2005 Jun;129(6):1309-17) comparing audited STS data to administrative data in the state of Texas. In fact this peer-reviewed paper showed that the STS database mortality reporting was accurate; the discrepancies resulted from differing definitions in the clinical and administrative databases (i.e. 30 day mortality was measured in the 30 day interval following the day of surgery in the STS database instead of the 30 day interval beginning the day of discharge in the administrative database). The paper also noted that the STS clinical database was more inclusive and identified more valid heart surgery cases when compared to the administrative database. Similarly, a direct comparison of the STS data with administrative claims data in Iowa showed that the STS database is more accurate and complete (Welke, KF. Ann Thorac Surg 2004; 77:1137-9).

First, in direct response to CMS' stated concern, The STS National Cardiac Database has many control and quality assurance elements. Participants are provided with prompt

feedback regarding the quality of their data, including information on missing data, outlier data, and inaccurate data. Based on this feedback, participants are afforded the opportunity to provide missing data and/or improve data accuracy. As part of each participant's biannual report, a data quality section is included. This section outlines those variables with the most, if any, missing data, data considered outliers based on low and high thresholds, and risk model performance.

STS has an on-site external audit program whereby a random sample of database participants is audited on a regular basis. Trained auditors visit participant programs and perform chart abstraction and compare the data abstracted with the data that were submitted to the database. The accuracy of more than 60 data fields is checked, missing data are noted, and <u>note is also made as to whether all eligible cases were submitted</u> to the database. Interviews are conducted with personnel at the site to examine the process of data collection. A summary conference is held to inform each site about the general findings of the audit. Subsequently, a final report is generated by STS and provided to the audited programs.

Second, there are no incentives present that would promote selective reporting of complex cases. The database has long been recognized to have a primary role in quality assurance/continuous improvement. Its main strength is the ability to risk-adjust outcome, which encourages total reporting rather than selective reporting. In addition, in essentially all institutions and practices, the data collection and reporting are done by data coordinators, not by the surgeons themselves.

Third, this is the first instance in which the data from the STS Database have been employed as a data source for the estimation of physician work directly. Surgeons submitting data had no knowledge or understanding that this would occur, and therefore no incentive to selectively report more complex cases in order to enhance physician payment.

3. On page 138, CMS states that it would like information regarding the types of hospitals that chose not to participate:

Of course, we would like that information as well, and are also interested in the reasons for non-participation. The only reason for non-participation of which we are aware is the additional uncompensated expense of participation (estimated to be a minimum of \$40,000 -50,000 per practice site). We believe that the number and percentage representation of reporting sites in the current database are more than sufficient to ensure validity of the measurements used. The question of the nature of the non-participants of course is fundamentally unanswerable and would impose an impossible standard for any evaluation of a new data source. By comparison, there has never been a requirement for proof that respondents to a RUC survey are representative of all the physicians in the specialty, and the question about the characteristics of non-responding physicians has never been asked by either the RUC or CMS.

4. On page 138 CMS notes that the database was not robust for non-cardiac thoracic surgery.

This is a relative criticism that we recognized prior to our presentation of these codes to the RUC, and we had therefore chosen to utilize median values for reporting these procedures. The lack of robustness is only in relation to the cardiac database, however. The number of patients in the database used to support the general thoracic patients (31,000) is still very large in comparison to standard RUC methodology where 25 to 30 survey responses are typically required, particularly in view of the relatively low frequency of performance of the general thoracic procedure codes submitted for the 5-year review. Since 75% of the typical practice volume for all of cardiac surgery is represented by the adult cardiac codes submitted for review, it is not surprising that the procedure numbers for the general thoracic codes are smaller in comparison.

We agree with the RUC recommendation based on median time values that the general thoracic data are valid as submitted.

We would also note that the RUC has recognized the value of the information that can be obtained from large clinical databases such as the STS database, and we suggest that CMS strongly consider supporting the development of similar databases by other specialties. This could be facilitated were CMS to recognize explicitly the direct and indirect costs of development and participation in these databases as valid practice expense. We believe that such a practice expense decision would provide strong incentives for the development of current and future databases into robust sources of information which will lead to improvements in patient care and will serve as more valid sources of information upon which to make reimbursement decisions.

5. On pages 138 and 139 CMS raises concerns regarding the use of mean as opposed to median time values as in the standard RUC survey. CMS also states the belief that the median value of a set of observations is a superior measure of central tendency than is the mean value.

We remind CMS that in considering our recommendation that mean values be utilized for measured data, expert statistical consultation was obtained from the Duke Clinical Research Institute, and that the DCRI statistician addressed the concerns raised by the RUC Five Year Review and Research committees.

Statisticians agree that the determination as to whether the mean or median values are more appropriate to best capture a central tendency depends upon two factors:

First, how accurate are the observations in question? Are the observations <u>estimates</u> (opinions) or a collection of <u>measurements</u>?

Second, is there a systematic source of bias?

If the observations are <u>estimates</u>, the accuracy will depend on the presence or absence of bias. In this situation systematic bias can come from the participants' knowledge that their responses will affect the outcome and their well being. It could also arise if the respondents are not representative of those with knowledge to provide estimates. Bias is evident if a collection of <u>estimates</u> are not normally distributed about a central tendency.

This pattern of non-normally distributed estimates is present in most RUC surveys in which there is a shift of the distribution curve to the right, with more of the <u>estimates</u> high rather than low. The source of this bias could be the knowledge that physician payment is related to the result, or more charitably, that the respondents systematically recall more complex examples in making their estimates. In the absence of characterization of the representative nature of the respondents, the RUC appropriately employs the median value to estimate the central tendency, since the median minimizes the impact of inappropriately high <u>estimates</u>.

However, if the observations are measurements, systematic bias would arise only due to either selective sampling (ie, measurements not representative of the entire population) or inadequate sampling (insufficient number of measurements to accurately represent the entire population). Thus, bias would be evident if a collection of measurements (rather than estimates) can be shown to have been sampled selectively rather than randomly. If the sample is random and of sufficient size, however, a shift in the distribution curve to the right indicates the presence of true outlier measurements rather than bias. Any effort to measure the true value for all the work performed must take into account these real values and the resultant rightward shift of the distribution curve. Therefore, in this instance, the use of the mean to estimate the central tendency is more accurate since the mean will appropriately include the effects of all of the data. We understand that it is the intention of CMS to reimburse accurately for all physician work. Thus it is more valid to use the mean value and therefore include all physician work when measurements are employed. The use of the median in this setting would be inappropriate, as it would introduce its own negative bias by systematically excluding *real* physician work done to provide services for outliers that actually exist.

The STS database is indeed a collection of verifiable <u>measurements</u> that are obtained both prospectively and objectively. The database is representative in terms of geography and practice type and is of more than adequate sample size. The distribution of the observations shows that outliers usually occur more frequently above the mean value than below when measuring operative time or length of stay. These outliers represent valid, performed physician work and should be included (<u>using the mean value</u>) rather than systematically excluded (<u>using the median value</u>).

We could agree with CMS' statement (page 139) that compared to the mean the median is an equal (not better) measure of central tendency "when more extreme cases occur in either direction." However, this conclusion would only apply under the conditions as exactly stated, with equal number and magnitude of outliers in either direction. In such a case, the data would be normally distributed from a statistical standpoint and the median and mean would have the same value. The STS database results show that these conditions do not exist for the <u>measurements</u> in question. Graphs 1 and 2 demonstrate that the measurements of intraoperative time and length of stay are not normally distributed and therefore that the mean value is a superior measure of central tendency.





Finally, we would note for CMS that the outliers contributing to the mean value are predominantly Medicare Beneficiaries. An analysis of our data to respond to the proposed rule indicates that, for all the cardiothoracic codes, there is an increase of LOS of 0.6 days, an increase in ICU hours of 6.3 and an increase of mechanical ventilation hours of 2.5 for patients over 65 years of age, compared to the same data for the entire

population of patients that were used to calculate the overall mean values. The average Medicare Beneficiary is 8.7 years older than the average age of all patients operated on by cardiothoracic surgeons, accounting in part for the increased physician work required for their surgical management.

6. CMS raises concern that the mean values reported will tend to overestimate time systematically and alter the relationship of these services to the remaining codes in the fee schedule.

The question here is answerable directly.

Following (Table 3) is a comparison of STS/AATS mean values to existing RUC database values for intraservice times for each of the submitted CPT codes that have been RUC surveyed previously. These data are sorted by the difference between STS data and RUC survey data with the largest negative differences first and thereafter in ascending magnitude through positive variances at the end of the list:

Table 3					
CPT Code	STS Intraservice Time	RUC Intraservice Time	STS vs RUC		
32651	70	150	-53%		
32657	60	120	-50%		
32665	105	200	-48%		
32662	98	180	-46%		
32654	71	120	-41%		
32663	145	240	-40%		
32655	73	120	-39%		
33141	19	30	-37%		
32488	194	300	-35%		
32484	139	210	-34%		
32540	120	180	-33%		
33464	205	300	-32%		
32652	160	210	-24%		
33863	287	360	-20%		
33414	240	300	-20%		
33427	221	270	-18%		
33463	231	280	-18%		
33405	198	240	-18%		
33505	200	240	-17%		
33665	200	240	-17%		
33684	200	240	-17%		
32653	77	00	-11%		
32445	310	360	-14%		
32771	260	300	-14%		
33688	200	270	-13%		
33548	233	210	-10%		
JJJ40 J3118	327	240	-10%		
33426	205	220	-9 %		
33770	203	220	-7 /0		
22791	200	300	-7 /0		
33534	102	300	-7 %		
33140	112	200	-0 /0		
33140	250	275	-0%		
33442	209	275	-0%		
32442	200	300	-5 %		
33533	151	155	- 4 70 20/		
33/12	207	300	-370		
22496	29/	240	-170		
43121	240	240	0%		
33/30	240	240	10/		
33860	223	220	170		
33510	15/	300	2%		
33510	104	100	3% 20/		
33512	100	100			
33516	210	200	-+ /0 		
	204	200	470		

Table 3					
CPT Code	STS Intraservice Time	RUC Intraservice Time	STS vs RUC		
33945	325	300	8%		
33406	282	260	8%		
43113	391	360	9%		
33411	283	260	9%		
33410	229	210	9%		
33513	231	210	10%		
33514	248	225	10%		
43124	243	210	16%		
33475	234	200	17%		
33400	211	180	17%		
43123	442	360	23%		
33425	254	200	27%		
43108	461	360	28%		
43116	561	300	87%		

A comparison of STS mean values to existing RUC database intraservice times for the 17 submitted CPT codes that have only Harvard data follows. These data are sorted in ascending magnitude as above by the difference between STS data and Harvard data in Table 4:

Table 4				
CPT Code	STS Intraservice Time	Harvard Intraservice Time	STS vs Harvard	
33530	70	92	-24%	
32141	116	149	-22%	
32815	155	194	-20%	
33545	236	271	-13%	
33460	164	184	-11 <u>%</u>	
33465	211	220	-4%	
39220	124	127	-2%	
39400	45	46	-2%	
33415	186	182	2%	
33542	207	192	8%	
33416	205	181	13%	
33641	164	139	18%	
33300	144	118	22%	
35820	136	111	23%	
43135	164	122	34%	
33305	296	153	93%	

The RUC database has no time data for 33141 (Add on code for Transmyocardial Laser Revascularization) or for the CABG vein add on codes (33517-33523).

As can be seen, there is considerable variation between the <u>measured</u> intraservice times from the STS database and the estimated times in the RUC database. As to the overall impact of the differences, the aggregate time differences between the mean STS data and the two RUC data sources were annualized according to the CMS Medicare Utilization file in Table 5:

Table 5						
1	Total Medicare Intraservice Time					
	RUC Data STS Data Difference					
RUC Survey	33,202,172	30,813,895	-7.2%			
Harvard	2,803,968	2,710,486	-3.3%			
Total	36,006,140	33,524,381	-6.9%			

The STS measured values accurately reflect the intraoperative times for cardiac surgical procedures while the RUC database appears to include systematic overestimates of time. The overestimation appears to be of greater magnitude for the RUC surveyed codes than for the Harvard data. Thus there appears to be no validity to the concern expressed by CMS that STS time measurements would systematically exceed those values attained through RUC magnitude estimation methodology. In point of fact, it appears that <u>it is the currently utilized RUC methodology</u> that results in a significant potential for over estimation of time.

This finding should not be surprising given the imprecision inherent in determining time by opinion survey. Time data enter the RUC database <u>after</u> adjudication of the survey results for RVW and time. To correct for obvious RVW overestimation in the survey, it is common practice for the accepted RVW data to be derived from a "facilitated" value that is less than the median survey value (often the 25th percentile value). It is also common practice to accept the median time value regardless of the method used to develop an acceptable RVW value. We believe that this is the likely source of time overestimation in the current RUC database and, as we will describe, is an important source of code misvaluation. The impact of the uncorrected bias in time estimation is to systematically and incorrectly reduce the IWPUT when the standard RUC methodology is employed. In addition, since time is factored into practice expense calculations, the overestimate of time reduces the accuracy of practice expense calculations as well.

We believe that the measurement data from the STS database for intraservice time as well as time in ICU, time in hospital, and time on mechanical ventilation in the aggregate more accurately reflects physician work than what is extant in the RUC database. We agree with the RUC that the mean is appropriate when there is a large sample size (as in the STS database data) of objective observations (time recorded in the operating room or recorded length of stay) and when the observations are not "normally distributed" as a matter of fact. For intraservice time (as well as length of hospital stay, ventilator time, etc) the STS database data conclusively demonstrates the rightward-skewed, non-normal distribution that warrants employment of the mean value as the best and fairest measure. Clearly, at least one element (time) can be measured accurately when used in a process in which time and intensity are considered together to estimate physician work. By its very nature, intensity must be estimated by expert opinion. However, there is no justification for using opinion to determine time when measurement data are available, or, as in the proposed rule, to hypothesize that the employment of time <u>measurements</u> will somehow disturb relativity in the Physician Fee Schedule.

The continued use of inaccurate time estimates when more accurate measurements are available is unfair to all physicians. Therefore, we recommend that CMS explore and support methods of time <u>measurements</u> for future code valuations. Time measurement data is readily obtainable for virtually all major and most minor procedures, regardless of specialty, through the support information systems that are obligatory in most facility settings.

Further, there is no reason that the time values used in the determination of the Physician Fee Schedule should be static. As we have stated, and will discuss further, an accurate value of intensity in the RUC database can be used with accurate time data to adjust the RVW value directly. If the value of intensity (IWPUT) for a given code is accepted, there can be no argument or need for additional opinion if new time data for that code become available. An additional benefit is that this approach would reduce the workload for the RUC and would allow the RUC to adjust RVW for procedures without waiting 5 years for code value refinement. This approach would greatly enhance the flexibility of the fee schedule, allow CMS and specialties to react promptly to technology change (for example, digital imaging), adaptation to new procedures (learning curve), and allow the RUC and CMS to adjust RVW fairly and expeditiously.

7. For the above reasons it should be clear that use of the median time data in place of the RUC recommended mean time data would be statistically incorrect and would be directly counter to the CMS and RUC shared goal of accurate capture of all physician work. Further, we believe that any use of the median data for these codes where true measurements are available would result in inaccurate valuation, and therefore should be eschewed.

B. Response to CMS Concerns Regarding the Building Block Methodology and Determination of IWPUT.

On page 140, CMS describes the RUC approved methodology that was utilized to determine intraservice work, and accordingly the building block method that was also approved by the RUC for the specific purpose of valuing the cardiothoracic surgical codes. The CMS concerns are that the intensity survey methods employed to estimate IWPUT for each code have not been approved by the RUC nor accepted by CMS in the past. Finally, CMS has indicated that they would like to review the survey methodology and instructions.

These concerns appear to be central to the decision to reject the RUC recommendations, and IWPUT is the <u>only element</u> of the RUC recommendations that CMS has proposed to alter.

We must reiterate that the entire methodology for IWPUT determination was <u>extensively and</u> <u>critically reviewed</u> by the RUC, the Research Subcommittee of the RUC, and the Five Year Review workgroup, and that all of these entities accepted the methodology after detailed and prolonged consideration. We have the following comments regarding the methodology

- 1. The building block methodology employed is similar to the methods that RUC members frequently employ to evaluate the validity of code valuations and to "facilitate" the value of most codes that are not approved immediately upon presentation by the specialty society.
- 2. The methodology employed was proposed to CMS in the original STS/AATS submission of codes for 5-year review in December of 2004 and no objections were raised at that time.
- 3. Each element of the methodology was presented to the Five Year Review Workgroup of the RUC and to the RUC research subcommittee, and approved. The recommendations of these subcommittees were subsequently approved by the RUC.
- 4. The survey methods and instructions were reviewed and approved by RUC staff, and <u>have been provided to CMS as requested in response to the proposed rule request</u>. We are certain that CMS will be satisfied with the instructions and methods, and that they did not create artificial conditions that might lead to bias.
- 5. The survey respondents were broadly representative in terms of geography and practice type. The survey respondent demographics were similar to the demographics of STS database participation and similar to the workforce survey demographics for all US practicing cardiothoracic Surgeons described in detail above.
- 6. There were a large number of survey respondents (659). The sample size represents approximately 19% of active practicing thoracic surgeons and far exceeds the typical number of responses for RUC surveys (20 to 50 respondents) and is thus more likely to be representative of the specialty as a whole.
- 7. The intensity survey method is similar to the RUC survey method in that respondents reference their estimates to procedures that have previously been reviewed by the RUC and therefore have approved intensity levels. These reference procedures were chosen to provide a suitable range of intensities, including codes maintained on the RUC Multiple Points of Comparison list as valid. The list of reference codes used for the intensity surveys can be found in Table 6. Since a large portion of the adult cardiac codes and many of the general thoracic surgical codes were being revalued, there were few adult cardiac or general thoracic surgical procedures that were available to serve as reference procedures. However, we note that since all cardiothoracic surgeons must first train as general surgeons and since a significant percentage (44.9%) of cardiothoracic surgeons practice vascular surgery as well, the reference code list contains peripheral vascular surgery codes as well as two cardiothoracic surgical codes that were not being revalued.

		Table 6			
Survey Reference Codes	СРТ	Descriptor	Intensity	RUC Review	MPC List
Adult Cardiac	35536	Bypass graft, with vein; splenorenal	120	2nd 5-yr	NO
Adult Cardiac	35560	Bypass graft, with vein; aortorenal	107	2nd 5-yr	NO
Adult Cardiac	33412	Replacement, aortic valve; transventricular annulus enlargement	102	2nd 5-yr	NO
Adult Cardiac	35518	Bypass graft, with vein; axillary- axillary	91	2nd 5-yr	NO
Adult Cardiac	32440	Removal of lung, total pneumonectomy;	80	1993	Yes - A
Adult Cardiac	44950	Appendectomy	78	1st 5-yr	Yes - A
Adult Cardiac	35301	Carotid Endarterectomy	77	lst 5-yr	NO
Adult Cardiac	35656	Bypass with other then vein; Femoral-Popliteal bypass	75	1st 5-yr	Yes - A
Adult Cardiac	99245	Level 5 outpatient consult	31	1st 5-yr	No
General Thoracic	35536	Bypass graft, with vein; splenorenal	120	2nd 5-yr	NO
General Thoracic	35560	Bypass graft, with vein; aortorenal	107	2nd 5-yr	NO
General Thoracic	33412	Replacement, aortic valve; transventricular annulus enlargement	102	2nd 5-yr	NO
General Thoracic	35256	Repair blood vessel with vein graft; lower extremity	100	2nd 5-yr	NO
General Thoracic	35646	Bypass graft with other then vein; aortobifemoral	92	2001	Yes - A
General Thoracic	32440	Removal of lung, total pneumonectomy;	80	1993	NO
General Thoracic	44950	Appendectomy	78	1st 5-yr	Yes - A
General Thoracic	43324	Esophagogastric fundoplasty (eg, Nissen, Belsey IV, Hill procedures)	76	2nd 5-yr	NO
General Thoracic	35656	Bypass with other then vein; Femoral-Popliteal bypass	75	1st 5-yr	Yes - A
General Thoracic	99245	Level 5 Outpatient Consult	31	1st 5-yr	No

- 8. Since the IWPUT surveys and their results are estimates rather than factual observations, the <u>median</u> IWPUT survey values for each code were used to correct for any potential bias.
- 9. Two estimation methods were employed and produced similar results. Concerns about the RASCH methodology are essentially moot, as it was employed primarily to validate and confirm the IWPUT survey. The elimination of the RASCH survey would have little impact on the results. (See Graphs 3 and 4 below).

- 10. The IWPUT survey results were reviewed on a code-by-code basis for appropriate rank order and dispersion by two 16-member expert panels. This review was independent of knowledge of the final building block work values that would result.
- 11. Each of the expert panels was monitored by an independent RUC proctor, who reported no problems or irregularities with the expert panel review process.
- 12. Because of the nature of the building block methodology and the utilization of database time, it was recognized that a method of IWPUT estimation would be required. Contrary to CMS assertion, one of the two methods (IWPUT magnitude estimation) was indeed accepted both by the RUC and by CMS in the last 5-year review and was RUC approved for use in the current 5-year review. The second method (RASCH) has been employed in the past and accepted by the RUC in order to confirm rank order and magnitude dispersion within families of related codes (as was done here). Use of this second methodology was also approved by the RUC research subcommittee and the full RUC for use in this 5-year review process.

To support the validity of the IWPUT survey results, we offer several elements of proof:

 The IWPUT results were internally consistent and an appropriate rationale could be developed, code by code, to explain the order and magnitude dispersion. These rationales were provided on multiple occasions at the Five Year Review Workgroup and at the full RUC deliberation over these codes. Given the opportunity to choose the result of one method (intensity survey) over the other (RASCH), the expert panels, workgroup, and RUC agreed that the average result for each code was the appropriate choice. These data are represented by Graphs 3 and 4:





2. The IWPUT results were within the range of previously accepted IWPUT for other RUC reviewed 090 day global procedures performed by all specialties. There are numerous examples of codes with similar intraservice intensities (IWPUT) for other surgical and procedural specialties as demonstrated in Table 7.

		Table 7		
	RUC R	eviewed 090 Globals, RVW >20, IW	PUT>0.0100	
		Other Specialties		
Specialty	CPT Code	Description	IWPUT	2006 Work RVU
PEDS	43314	Tracheo-esophagoplasty cong	0.2021	50.19
GYN	45126	Pelvic exenteration	0.1983	45.09
PEDS	43313	Esophagoplasty congenital	0.1741	45.21
Cardiology	37215	Transcatheter carotid stent	0.1347	18.71
Gen	47125	Partial removal of liver	0.1243	49.12
Vasc	35623	Bypass graft, not vein	0.1203	23.96
Cardiology	92987	Revision of mitral valve	0.1202	22.67
Vasc	35536	Artery bypass graft	0.1200	31.65
Neuro	61520	Removal of brain lesion	0.1175	54.76
Gen	47141	Partial removal, donor liver	0.1173	67.40
Vasc	35103	Repair artery rupture, groin	0.1168	40.44
Neuro	61682	Intracranial vessel surgery	0.1165	61.48
Neuro	61700	Brain aneurysm repr, simple	0.1163	50.44
Gen	47142	Partial removal, donor liver	0.1147	74.89
Vasc	35251	Repair blood vessel lesion	0.1147	30.15
Neuro	61526	Removal of brain lesion	0.1124	52.0 9

	Table 7		
	eviewed 090 Globals, RVW >20, IW	PUT>0.0100	
	Other Specialties		
CPT Code	Description	IWPUT	2006 Work RVU
22804	Fusion of spine	0.1123	36.22
22802	Fusion of spine	0.1120	30.83
35091	Repair defect of artery	0.1107	35.35
43880	Repair stomach-bowel fistula	0.1097	24.61
61686	Intracranial vessel surgery	0.1097	64.39
61692	Intracranial vessel surgery	0.1088	51.79
43644	Lap gastric bypass/roux-en-y	0.1083	27.83
35189	Repair blood vessel lesion	0.1074	27.96
35560	Artery bypass graft	0.1073	31.95
35111	Repair defect of artery	0.1072	24.96
34800	Endovas aaa repr w/sm tube	0.1071	20.72
61702	inner skull vessel surgery	0.1059	48.34
35121	Repair defect of artery	0.1042	29.96
61518	Removal of brain lesion	0.1038	37.26
44207	L colectomy/coloproctostomy	0.1037	29.96
34803	Endovas aaa repr w/3-p part	0.1036	24.00
35626	Artery bypass graft	0.1035	27.71
34804	Endovas aaa repr w/1-p part	0.1029	22.97
61545	Excision of brain tumor	0.1024	43.73
35182	Repair blood vessel lesion	0.1023	29.96
47140	Partial removal, donor liver	0.1010	54.92
35631	Artery bypass graft	0.1010	33.95
47122	Extensive removal of liver	0.0997	55.05
61512	Remove brain lining lesion	0.0995	35.04
	CPT Code 22804 22802 35091 43880 61686 61692 43644 35189 35560 35111 34800 61702 35121 61518 44207 34803 35626 34804 61545 35182 47140 35631 47122 61512	Table 7RUC Reviewed 090 Globals, RVW >20, IWOther SpecialtiesOther SpecialtiesCPT Code Description22804Fusion of spine22802Fusion of spine35091Repair defect of artery43880Repair stomach-bowel fistula61686Intracranial vessel surgery61692Intracranial vessel surgery43644Lap gastric bypass/roux-en-y35189Repair blood vessel lesion35560Artery bypass graft35111Repair defect of artery34800Endovas aaa repr w/sm tube61702Inner skull vessel surgery35121Repair defect of artery61518Removal of brain lesion44207L colectomy/coloproctostomy34803Endovas aaa repr w/3-p part35626Artery bypass graft34804Endovas aaa repr w/1-p part61545Excision of brain tumor35182Repair blood vessel lesion47140Partial removal, donor liver35631Artery bypass graft47122Extensive removal of liver61512Remove brain lining lesion	Table 7RUC Reviewed 090 Globals, RVW >20, IWPUT>0.0100Other SpecialtiesCPT Code Description IWPUT22804Fusion of spine0.112322802Fusion of spine0.112035091Repair defect of artery0.110743880Repair stomach-bowel fistula0.109761686Intracranial vessel surgery0.108843644Lap gastric bypass/roux-en-y0.108335189Repair blood vessel lesion0.107435560Artery bypass graft0.107161702Inner skull vessel surgery0.105935121Repair defect of artery0.107161518Removal of brain lesion0.103344207L colectomy/coloproctostomy0.103734803Endovas aaa repr w/3-p part0.103635626Artery bypass graft0.103534804Endovas aaa repr w/1-p part0.102961545Excision of brain tumor0.102347140Partial removal, donor liver0.101047122Extensive removal of liver0.099761512Remove brain lining lesion0.0995

Table 8 shows cardiothoracic codes that have been previously approved for value and IWPUT by CMS, in relation to the codes of other specialties:

		Table 8			
	RUC Re	eviewed 090 Globals, RVW >20, IWP	UT>0.0100		
		All Specialties			
Specialty CPT Code Description IWPUT 2006 Wor					
PEDS	43314	Tracheo-esophagoplasty cong	0.2021	50.19	
GYN	45126	Pelvic exenteration	0.1983	45.09	
PEDS	43313	Esophagoplasty congenital	0.1741	45.21	
СТ	33681	Repair heart septum defect	0.1369	30.56	
СТ	33533	CABG, arterial, single	0.1352	29.96	
Cardiology	37215	Transcatheter carotid stent	0.1347	18.71	
Gen	47125	Partial removal of liver	0.1243	49.12	
Vasc	35623	Bypass graft, not vein	0.1203	23.96	

<u> </u>	RUC Re	eviewed 090 Globals, RVW >20, IWP	UT>0.0100	
<u> </u>		All Specialties		
Specialty	CPT Code	Description		2006 Work RVU
Cardiology	92987	Revision of mitral valve	0.1202	22.67
Vasc	35536	Artery bypass graft	0.1200	31.65
Neuro	61520	Removal of brain lesion	0.1175	54.76
Gen	47141	Partial removal, donor liver	0.1173	67.40
Vasc	35103	Repair artery rupture, groin	0.1168	40.44
Neuro	61682	Intracranial vessel surgery	0.1165	61.48
Neuro	61700	Brain aneurysm repr, simple	0.1163	50.44
Gen	47142	Partial removal, donor liver	0.1147	74.89
Vasc	35251	Repair blood vessel lesion	0.1147	30.15
СТ	33534	CABG, arterial, two	0.1129	32.15
СТ	33475	Replacement, pulmonary valve	0.1127	32.95
Neuro	61526	Removal of brain lesion	0.1124	52.09
ORT	22804	Fusion of spine	0.1123	36.22
ORT	22802	Fusion of spine	0.1120	30.83
Vasc	35091	Repair defect of artery	0.1107	35.35
Gen	43880	Repair stomach-bowel fistula	0.1097	24.61
Neuro	61686	Intracranial vessel surgery	0.1097	64.39
СТ	33427	Repair of mitral valve	0.1093	39.94
Neuro	61692	Intracranial vessel surgery	0.1088	51.79
Gen	43644	Lap gastric bypass/roux-en-y	0.1083	27.83
Vasc	35189	Repair blood vessel lesion	0.1074	27.96
СТ	33413	Replacement of aortic valve	0.1074	43.43
Vasc	35560	Artery bypass graft	0.1073	31.95
Vasc	35111	Repair defect of artery	0.1072	24.96
Vasc	34800	Endovas aaa repr w/sm tube	0.1071	20.72
СТ	33535	CABG, arterial, three	0.1060	34.45
Neuro	61702	Inner skull vessel surgery	0.1059	48.34
СТ	33430	Replacement of mitral valve	0.1047	33.45
Vasc	35121	Repair defect of artery	0.1042	29.96
Neuro	61518	Removal of brain lesion	0.1038	37.26
Gen	44207	L colectomy/coloproctostomy	0.1037	29.96
Vasc	34803	Endovas aaa repr w/3-p part	0.1036	24.00
Vasc	35626	Artery bypass graft	0.1035	27.71
СТ	33536	Cabg, arterial, four or more	0.1034	37.44
СТ	33660	Repair of heart defects	0.1031	29.96
Vasc	34804	Endovas aaa repr w/1-p part	0.1029	22.97
СТ	33426	Repair of mitral valve	0.1024	32.95
СТ	33412	Replacement of aortic valve	0.1024	41.94
Neuro	61545	Excision of brain tumor	0.1024	43.73
Vasc	35182	Repair blood vessel lesion	0.1023	29.96
Gen	47140	Partial removal, donor liver	0.1010	54.92
Vasc	35631	Artery bypass graft	0.1010	33.95

Table 8

		Table 8			
	RUC Re	eviewed 090 Globals, RVW >20, IW	PUT>0.0100		
	All Specialties				
Specialty	CPT Code	Description	IWPUT	2006 Work RVU	
СТ	33406	Replacement of aortic valve	0.1008	37.44	
Gen	47122	Extensive removal of liver	0.0997	55.05	
Neuro	61512	Remove brain lining lesion	0.0995	35.04	

A graphical display of the RUC recommended IWPUT compared to the extant RUC database IWPUT for all 090 RUC reviewed codes with RVW > 10 is shown in graph 5:



These observations clearly show that the RUC recommended IWPUT is appropriately within the RUC and CMS accepted range of IWPUT. There is appropriate variation by procedure, and the recommendations are consistent with the previously acceptable IWPUT magnitude for the complex and demanding procedures submitted for refinement.

3. The results from direct IWPUT survey were <u>consistent with the IWPUT values for the</u> <u>congenital cardiac surgery codes</u> approved by the RUC and by CMS in the proposed rule. These IWPUT values were <u>obtained by the traditional RUC survey method</u> and are shown with the RUC recommended values in the Graph 6:



This chart clearly illustrates that the RUC recommended IWPUT values for Adult Cardiac and General Thoracic codes (shown in blue) are consistent with those found acceptable to CMS (shown in Yellow) by a contemporaneous standard RUC survey of similar procedures performed by the same specialty (Congenital Codes in center box). In fact, the similarity is due to the similarity in intensity estimated by surgeons who are familiar with all the procedures either through practice or training.

The CMS recommended IWPUT values for Adult Cardiac and General Thoracic surgery codes, shown in yellow, are in stark contrast. The CMS recommendations bear no discernable relationship to expert opinion, the adjudicated multi-specialty opinion of the RUC, or the RUC survey-based, CMS proposed intensity for congenital heart surgery.

4. The intensity values do not depend significantly on time alone, indicating that respondents did not substantially confuse time required to do a procedure with an estimate of the intensity value for the procedure. This is a technical point, but an important one as these data refute the historical notion that intensity survey respondents cannot independently estimate intensity separate from total work. This information is represented in Graph 7.



5. The intensity values obtained by magnitude estimation bear a consistent relationship to other intensity measures approved by the RUC and <u>accepted by CMS</u> in the current 5-year review. The RUC recommended intensity for cardiothoracic surgery is on average 2 to 3 times higher than the RUC recommended intensity of office and hospital based non-critical care evaluation and management codes. This relationship is consistent with studies of relative intensity that are the foundation of the RBRVS [Hsiao WC. Braun P. Kelly NL. Becker ER "Results, potential effects, and implementation issues of the Resource-Based Relative Value Scale." JAMA. 260(16):2429-38, 1988 Oct 28 and Hsiao WC. Couch NP. Causino N. Becker ER. Ketcham TR. Verrilli DK. "Resource-based relative values for invasive procedures performed by eight surgical specialties." JAMA. 260(16):2418-24, 1988 Oct 28.] The consistency of this relationship <u>maintains rather than disrupts work relativity</u> across the physician fee schedule as represented in Graph 8:



The upper and lower boundaries of the office and hospital based Evaluation and management IWPUT, multiplied by two, are shown as horizontal boundaries. These boundaries exclude Emergency Department and Critical Care codes, which have higher IWPUT. The RUC recommended IWPUT's for cardiothoracic codes clearly comfortably reside in appropriate relationship to the CMS proposed values for E&M.

Response to CMS regarding fairness issues

On page 140 of the proposed rule, CMS expresses concern that the relativity of the fee schedule will be compromised by selective use of the STS database. CMS has expressed concerns that selective use of the STS database is unfair on two grounds:

- 1. It provides a selective advantage for Cardiothoracic codes
- 2. It creates imbalance in relativity to other codes for which the work value is based on survey results.
 - The current RUC recommendations for the cardiothoracic surgical codes are based on data measurements and not estimations. The RUC recognized the <u>superiority</u> of the use of real data, and therefore accepted the methodology proposed by STS/AATS in part because of the inclusion of these data. If there is any imbalance that is created, it can and should be corrected by obtaining data for other codes rather than by making arbitrary "adjustments" to cardiothoracic code values on the assumption that existing

time data is accurate for other codes. Our own experience demonstrates this latter assumption to be invalid (see Tables 3, 4, and 5 above).

It is axiomatic that time is the one measurable quantity in the relationship of time and intensity to work. With the accurate establishment of time measurement through use of validated databases, only intensity need be estimated. This, in our opinion, is preferable as it will greatly simplify and clarify the process of code valuation and improve rather than detract from the fairness of the process. As well, it should enhance confidence in the accurate relativity of the system and provide a superior framework for future code valuation.

We believe that accuracy is at the root of fairness and that the employment of STS data is an important step toward improving accuracy. We emphasize that use of this methodology resulted in decreases in work values for some procedures. Additionally, we would point out that the change in work values recommended by the RUC are not simply due to intraservice time and intensity, but are in part also due to proper allocation of post-service work value. These changes are not related to selective use of a database as much as the use of a database to bring forward evidence (ICU length of stay and hours of mechanical ventilation, for example). Similar evidence through published peer reviewed data has been frequently employed to support code valuation. We would submit that the STS data is more accurate in this regard, since published reports are frequently biased and non-representative. It is therefore hard for us to understand why CMS would want to selectively exclude objective evidence when the overall objective is accuracy rather than result. More importantly, for CMS to propose a standard whereby data sources and code valuation methodologies must be available to all medical specialties prior to their utilization will essentially freeze the RUC process and the ability of the RUC to adopt new techniques and methods for code valuation. The history of the RUC process has been - and should be - one of evolution and improvement in methods and accuracy. Many of the commonly employed thought processes and techniques for code valuation were not utilized or even imagined as the RUC was formed and began to advise HCFA on code valuations. The STS/AATS believes that CMS restrictions on the ability of the RUC to utilize new and improved methods will have important negative policy implications and is therefore ill-advised.

We believe that the valuations derived from our methodology and data measurements are a far more accurate representation of the work involved in cardiothoracic procedures than those available from estimation methods used in the past. The data should drive the work estimates, not the other way around.

Finally, we would again comment that our methodology, although in part based on a database that few other specialties have chosen to develop and support, was not selectively applied to the STS/AATS codes. All codes that could be addressed by extant STS data (recall that the database was not designed to comprehensively provide data for all CPT codes) were brought forward for refinement. Only one code was withdrawn (36500, radial artery graft harvest), which was related to an inability

to calculate intraservice time from STS data. This inability to provide time data was due to the fact that the radial harvest is performed in parallel with the base operation and the operative time is not recorded separately. All codes happened to also have compelling evidence for change due to altered patient characteristics since the last 5year review. The result, therefore, was not predetermined by selective code submission for refinement and in fact the ultimate results could not be, and were not known.

C. STS/AATS Concerns with the Proposed CMS Relative Work Values for the Adult Cardiac and General Thoracic codes:

The CMS proposed work values, and the "rationale" revealed by CMS in the proposed rule, have been carefully evaluated and considered by STS/AATS. We find the proposed rationale to be confusing, inconsistently applied, and therefore unsupportable. The resulting CMS proposed values are inaccurate, fail to reflect data-demonstrated physician work, are inconsistent with RUC recommendations, are counter to RUC and CMS precedent, and if implemented will eliminate nearly all relativity within the cardiothoracic code families and in relation to the overall Physician Fee Schedule (PFS).

The root cause of the problem with the CMS proposed work values is the failure of CMS to accept the recommended work values for the more complicated, longer duration cardiac and general thoracic procedures. These procedures are associated with significant postoperative evaluation and management services performed by thoracic surgeons within the global period. The addition of the work value of a long, complex operation to the work value of managing a demonstrably critically ill patient to recovery, while acceptable to the RUC does not appear to be acceptable to CMS. This is evident in Graph 9:



From inspection of this graph, it appears that the RUC recommended work values (in blue) above approximately 30 RVW were selectively reduced by CMS (in yellow), with an underlying supporting rationale that was not articulated in the proposed rule.

In order to accomplish this, CMS appears to have assigned new work values. The CMS proposed values are lower than those developed by the RUC in collaboration with STS/AATS based upon the most comprehensive surveys and database information ever employed to estimate physician work under the RBRVS.

The CMS process, if applied to the Final Rule, will have devastating unintended consequences for the PFS in general and cardiothoracic surgery in particular.

If the proposed values are incorporated in the final rule, Graph 10 displays the resulting intraservice work intensity that will be used in the future to value all codes:



The CMS proposed IWPUT's are shown in yellow in direct comparison to the RUC recommended IWPUT's in blue. It is appropriate to emphasize that the ordered and continuous spectrum of intensity values depicted in blue resulted from the systematic analysis of survey results from several hundred practicing clinicians who actually perform these procedures. These values were verified by two expert panels, proposed to and accepted by both the RUC Research Subcommittee and the RUC as a whole.

By comparison, the CMS proposed intensity values are for the most part not only lower but vary widely in either direction from the RUC recommendations. At the lower ranges of CMS IWPUT, some procedures have less intensity than an established patient office visit, and some procedures have no proposed intraservice physician work at all (negative IWPUT). The values CMS has proposed are in fact illogical and contrary to the considered opinion of hundreds of experts in the field.

With the imprimature of CMS approval, these codes will become accepted as a standard by which other codes in the PFS are measured. It will be a natural process to utilize these code values to assign values to newly proposed codes in the future. Such use would render the current valuation scheme nonsensical, result in gross rank order anomalies and effectively preclude any valid attempt at estimating relative intensity or relative value in the future.

STS/AATS therefore questions the validity of the CMS IWPUT proposed values and recommends the adoption of the RUC recommended IWPUT values. This recommendation, in addition to the other elements already proposed by CMS, will simply restore the overall RUC RVW recommendations and correct all of the flaws inherent in the proposed rule.

The CMS Proposed Work Values for the CABG Code Families

The CMS proposal for physician work associated with the CABG code families exemplifies many of the problems that STS/AATS and others have identified in the proposed rule. Therefore, we will comment on these code families separately here, as this family demonstrates most clearly the key features of the building block methodology used and the compelling nature of the RUC recommended values.

STS/AATS data on 520,395 patients were employed to arrive at the RUC recommended values, as were intensity surveys from 533 cardiothoracic surgeons. An expert panel of 16 cardiothoracic surgeons recommended no changes in the results, as did the RUC 5-year workgroup and subsequently the full RUC.

The STS/AATS analysis began with the evaluation of the arterial bypass grafting codes (33533-33536) which provide payment for 1, 2, 3 and 4 arterial bypass grafts respectively. Patients who had these procedures, <u>and no other procedure</u> (i.e. no additional vein grafts, reoperative status, concomitant valve procedures, etc) were analyzed for all collected STS variables.

The results were analyzed for each arterial bypass grafting code, and then weight averaged by Medicare utilization data to create the "typical" arterial bypass grafting patient (N=39,920).

Then, patients who had additional vein bypass grafts and no other procedures or procedure qualifiers were assessed for the same STS variables (N=480,475). The results were subtracted from the values obtained from the "typical" arterial bypass grafting patient to yield the incremental change due to each additional vein bypass graft as shown in Table 9:

		<u> </u>				
СРТ	Description	N Observations	Intraservice Time (Min)	LOS (days)	ICU Hours_	Ventilator Hours
33533	CABG 1 Artery	10,394	151	5.67	44.03	12.34
33534	CABG 2 Arteries	3,294	193	5.33	38.23	11.92
33535	CABG 3 Arteries	2,984	231	5.95	43.48	12.91
33536	CABG 4 Arteries	2,652	259	6.18	45.13	13.05
	Average Arterial Only CABG	39,920	168	5.66	42.76	12.35
		·/	Incremental	fime abov	e Base Co	de Value
33517	1 Additional Vein Graft	72,419	23	0.30	4.73	0.80
33518	2 Additional Vein Grafts	178,252	50	0.68	8.60	2.66
33519	3 Additional Vein Grafts	158,961	70	0.76	9.69	3.09
33521	4 Additional Vein Grafts	56,829	88	0.79	9.04	3.10
33522	5 Additional Vein Grafts	11,694	102	0.91	7.66	2.57
33523	6 or more	2,320	110	1.04	9.56	3.82

Table 9

These results indicate that additional bypass grafts necessitate not only additional intraoperative time to perform them, but also additional recovery time in intensive care, additional time on mechanical ventilation, and additional time in the hospital.

This incremental post service work is due to the fact that these patients selected for additional vein have additional co-morbidity as well as longer operations. For example, compared to patients treated with additional vein grafts as opposed to arterial grafts were older (65 vs 62) and more likely to be diabetic (36% vs 27%).

These data are shown graphically, with a shift in the distribution of length of stay to the right with each additional add-on vein graft as shown in Graph 11:



The data supporting allocation of additional time and post-operative evaluation and management physician work for add-on codes also support different allocations for arterial bypass grafting compared to vein-only bypass grafting. Table 10 shows the resulting recommendations, compared to current valuation:

				Table IV				·	
			Current	Values			RUC Pro	posed	
СРТ	Descriptor	Total Pre/ Post Work	Intra- service Work	IWPUT	Total RVW	Total Pre/ Post Work	Intra- service Work	IWPUT	Totai RVW
	CABG, vein								
33510	only; 1 Vein	15.804	13.16	0.0877	28.96	16.81	14.94	0.0970	31.75
33511	CABG, vein only; 2 veins	15.804	14.16	0.0786	29.96	16.81	18.41	0.0990	35.22
33512	CABG, vein only; 3 veins	15.804	15.95	0.0778	31.75	18.32	21.94	0.1030	40.26
33513	CABG, vein only; 4 veins	15.804	16.15	0.0769	31.95	18.32	23.33	0.1010	41.65
33514	only; 5 veins	15.804	16.90	0.0751	32.70	18.32	26.04	0.1050	44.36
22516	only; 6 or	15 904	10.15	0.0757	24.05	18 22	27 72	0 1050	46.04
33310	CABG, using arterial	_13.004	19.15	0.0737	34.33	10.52	<u>_</u>	0.1030	
33533	graπ(s); 1 arterial graft	9.01	20.95	0.1352	29.96	15.75	15.10	0.1000	30.85
	CABG, using arterial graft(s); 2							1	
33534	arterial grafts CABG, using	9.01	23.14	0.1129	32.15	15.75	21.23	0.1100	36.98
33535	arterial graft(s); 3 arterial grafts	9.01	25.44	0.1060	34.45	15.75	26.10	0.1130	41.85
	CABG, using arterial								
33536	arterial grafts	9.01	28.43	0.1034	37.44	15.75	29.79	0.1150	45.53
	1 additional								
22547	vein graft with		2 57	0 1117	2.57	1 25	2 4 4	0 0017	2 26
00540	2 additional	0	<u> </u>	0.0000	2.37	1.23	4.11	0.0917	3.30
33518	vein gratts	0	4.84	0.0968	4.84	2.46	4.95	0.0989	/.41
33519	vein grafts	0	7.11	0.1016	7.11	2.74	7.17	0.1024	9.91
33521	4 additional vein grafts	0	9.39	0.1067	9.39	2.71	9.30	0.1057	12.01
33522	5 additional vein grafts	0	11.65	0.1142	11.65	2.65	10.88	0.1067	13.53
	6 or more additional								
33523	vein grafts	0	13.93	0.1266	13.93	3.11	12.28	0.1117	15.39

The current valuations in the RUC data base are flawed for a variety of reasons, which is why the codes were submitted for refinement in the 5-year review and why we do not support CMS' recommendation that the current IWPUT (from the last 5-year review) be used to calculate intraservice work. As illustrated, the existing IWPUT for vein only bypass grafting

(0.0751-0.0877) is dramatically less than for arterial bypass grafting (0.1034-0.1352), although the actual procedures are not strikingly different (supported by the RUC recommended intensities for each code).

The actual reason to value vein grafting higher than arterial grafting relates to the increased pre- and post-operative work required as demonstrated by the STS database, and as reflected in the RUC recommendations.

CMS proposed to utilize these IWPUT values from the 2000 5-year review, with the RUC proposed time and visit data, to recommend values for these codes rather than to accept the RUC recommendations. Table 11 shows these calculations, and the actual CMS proposed values, compared to the RUC recommended values:

	Table 11	CMS Pro	posed Recom	mendatio	15	RUC Pr	oposed		
		1000	Coloulated	Total			Total		
CPT	Descriptor	2000 IM/DUT		DVW	IWPUT	IWPUT	DVW		
		10101							
33510	CABG, vein only; 1 Vein	0.0877	30.31	30.37	0.0881	0.0970	31.746		
	CABG, vein only; 2								
33511	veins	0.0786	31.44	31.51	0.0790	0.0990	35.222		
	CABG, vein only; 3								
33512	veins	0.0778	34.89	35.16	0.0791	0.1030	40.257		
	CABG, vein only; 4								
33513	veins	0.0769	36.08	36.12	0.0771	0.1010	41.649		
	CABG, vein only; 5								
33514	veins	0.0751	36.94	36.93	0.0750	0.1050	44.358		
	CABG, vein only; 6 or								
33516	more veins	0.0757	38.30	38.39	0.0760	0.1050	46.038		
	CABG, using arterial								
33533	graft(s); 1 arterial graft				900 - 1000 				
[CABG, using arterial	ļ							
33534	graft(s); 2 arterial grafts	0.1129	37.53	36.06	0.1052	0.1100	36.978		
	CABG, using arterial								
33535	graft(s); 3 arterial grafts	0.1060	40.23	38.73	0.0995	0.1130	41.851		
	CABG, using arterial								
33536	graft(s); 4 arterial grafts	0.1034	42.52	38.04	0.0861	0.1150	45.533		
	1 additional vein graft								
33517	with artery graft(s)	NA	NA	2.57	0.1117	0.0917	3.36		
33518	2 additional vein grafts	NA	NA	4.84	0.0968	0.0989	7.41		
33519	3 additional vein grafts	NA	NA	7.11	0.1016	0.1024	9.91		
33521	4 additional vein grafts	NA	NA	9.39	0.1067	0.1057	12.01		
33577	5 additional vein grafts		NA	11 65	0 1142	0 1067	13.53		
33322	6 or more additional	A		11.00	0.1174	0.1007	10,00		
33523	vein grafts	NA	NA	13.93	0.1266	0.1117	15.39		
1000000		1121		10.70	0.1200		*****/		

TELL 1

As can be seen, CMS did not actually use the 2000 IWPUT for the arterial bypass codes, as it stated it would do in the proposed rule, but reduced each IWPUT by a method that we cannot

discern. This approach resulted in values that were greater than those recommended by the RUC for 33533, but less than recommended by the RUC for 33534-33536. The method also resulted in a rank order anomaly, whereby performance of a 4th arterial bypass graft would result in reduced payment compared to performing three arterial grafts.

In some sense, it appears that CMS has incorporated much of the value of arterial bypass grafting into 33533, deducted this value from 33517-33523 (the vein add-on codes) and neglected to account for the documented increased work for additional vein grafts or for vein bypass grafting alone.

The result is an untenable relationship of intraservice intensity across the family of codes, whereby the work of arterial bypass grafting diminishes with each additional graft and is more intense than vein bypass grafting. This can be seen in Graph 12:



The RUC proposed values and intensities, in contrast, include appropriate gradations of RVW and intensity, appropriate RVW for perioperative physician work (more for vein only CABG, included for additional grafts), and no anomalies that provide counterintuitive work valuations and unusual incentives.

Furthermore, the RUC proposed values are tightly integrated and have appropriate relationships to all the other refined codes at RUC proposed values.

Finally, it is worth noting that compared to the CMS proposal, the RUC proposal would produce a smaller increase in Medicare payment for coronary bypass grafting.

In summary, STS/AATS does not agree with the methodology employed to propose new values for these codes, and therefore does not agree with the proposed new values.

STS/AATS recommends that CMS accept the RUC proposed values for these codes, including the values for the ZZZ or add-on codes included in the family. Since the RUC valuation process was similar for the other two add on codes that were submitted for refinement (33141, TMR add-on and 33530, Reoperation add-on) STS/AATS also recommends that CMS adopt the RUC recommended values for these codes.

STS/AATS has many additional specific concerns with the CMS proposed work values that will be outlined in the following section.

1. CMS Proposed Work Values Create Rank Order Anomalies

The CMS proposed work values significantly and substantially overvalue as well as undervalue many codes without discernable rationale and will render future code valuation problematic if not impossible.

The most glaring and frankly unbelievable anomaly is 33536 vs 33535, which has already been described in detail, where a surgeon performing 4 arterial grafts should simply just bill for 3 to be paid more.

				Table	12				
			Current			RUC	Recommen	ded	CMS Proposed
		IWPUT	Intra- service Time	RVW		IWPUT	Intra- service Time	RVW	RVW
33405	Replacement aortic valve; with prosthetic valve	0.0989	240	34.95		0.1050	198	37.82	36.64
33410	Replacement aortic valve; with stentless tissue valve	0.0802	210	32.41		0 1130	229	42.91	35 36

The most egregious and inexplicable anomaly is the relationship between 33405 and 33410 is shown in detail in Table 12:

To understand these relationships is to understand the basis of the flaws in the CMS proposal.

To begin, 33410 is by universal consent a more difficult procedure requiring two intraaortic suture lines and exacting precision to assure valve competency, compared to 33405 which involves a mechanical prosthesis and only one suture line.

33410 was the unintended anchor code for the entire 2000 5 year review, which is also universally agreed upon to have been flawed, and in our opinion has produced an

unsuitable set of RVWs for the past 5 years. We believe that the values from the 2000 five year review are certainly not suitable for use of any elements (although CMS proposes to use its IWPUT values, albeit selectively).

The 33410 RVW was determined by 23 respondents, who estimated the intraservice time to be <u>lower than for 33405</u>, but somehow managed to convince the RUC that 2 critical care visits were required (a unique event at the time). Because of the flawed survey, the IWPUT and work value were lower than the clearly more straightforward 33405, and a rank order anomaly was created. Since this code anchored all the cardiothoracic codes, in many senses all values from the 2000 5 year review were anomalous because of it.

33410 was specifically mentioned as an existing rank order anomaly in the submission of codes for this 5-year review, and used as an example of compelling evidence in <u>two</u> RUC presentations observed by CMS.

The RUC recommended appropriate IWPUT and RVW relationships, reduced the critical care to an appropriate 1 visit, and the STS database confirmed that 33410 was indeed a longer procedure than 33405 after all (based on data from 42,660 patients, despite the opinions of our 23 survey respondents in 2000). The RUC recommendations place the two codes in appropriate rank order.

However, CMS has determined in the proposed rule that the IWPUT relationship in 2000 was in fact correct, and applied it <u>while accepting every other element from the RUC</u> recommendations which had the effect of **preserving the rank order anomaly**.

For the general thoracic codes the CMS proposed values create a number of rank order anomalies in several families of codes including the esophagectomy and lung code families. Examples of these rank order anomalies are:

• In the esophagectomy family of codes, CMS and current values are as follows:

43113 McKeown with colon	CMS proposes	40.41 RVW
43112 McKeown with stomach	Currently valued	43.43 RVW
43118 Ivor Lewis with colon	CMS proposes	46.37 RVW

The CMS proposal creates rank order anomalies (ROA) within this family of codes. Code 43113 entails hours more work including a colon mobilization and two additional anastomoses and a higher intensity due to greater morbidity than 43112. The CMS proposed value is lower for the more complicated procedure. In addition, code 43118 is generally a less time consuming procedure than 43113 since it has one less incision and no intraoperative repositioning and it is valued 6 RVWs more

• For the thoracoscopy codes, the CMS also creates rank order anomalies:

32653	VATS removal fibrin	CMS proposes	18.05 RVW
32651	VATS partial decort	CMS proposes	14.26 RVW

The VATS partial decortication (32651) is the more difficult case. The RUC recommendation (32651=16.64 RVW vs. 32653=16.24 RVW) maintained relativity with regard to work values. The CMS proposal creates a rank order anomaly because it reverses the relative values with 32653 assigned 26% more RVW than 32651.

• Additional rank order anomalies created in the lung procedures by the CMS proposal include:

32663VATS lobeCMS proposes 18.44 RVW32480Open lobectomyCurrently23.71 RVW

32663 was included in the 5-year review process because it represents an existing rank order anomaly. Randomized trials have not demonstrated decreased operative time, decreased length of stay or morbidity for the thoracoscopic approach and yet it was reimbursed at about 75% of the value of the open procedure. The RUC recommended a value similar to the open code (23.00 RVW). The CMS proposal to maintain the value at 18.44 perpetuates another rank order anomaly.

2. Disturbs relativity of physician work values within the cardiothoracic codes

Rank order anomalies are discernable even by a casual reader of the CPT code vignette, as in the example of 3 arterial coronary bypass grafts being valued higher than 4 grafts. Disturbances in relativity are more subtle, where the more complex operation is assigned a higher value, but the difference in value between simpler and more complex procedures is inappropriately low (the order is right, but the degree of separation is insufficient). Another example is an operation that appears simpler, but is actually typically performed in a much sicker patient, so that the work value should be higher than for a healthier typical patient even if the operation is more complex.

Table 13 shows most common cardiac procedure, an arterial coronary artery bypass with 2 additional vein grafts, the "3 vessel CABG," highlighted along with other cardiac and general thoracic surgery codes. Also shown are the proposed CMS work values, length of operation, number of ICU days, hours of mechanical ventilation, and total hospital length of stay, all from the STS database, and all indicators of physician work:

		able 13				
	Anomalous RVW Relations	hips in Table C	MS Propos	sed Rule		
CPT Text	Long Descriptor	CMS Proposed 2007 RVW	Intra Service Time	ICU days	Vent Hours	Total LOS
33863	Ascending aorta graft, with cardiopulmonary bypass, with or without valve suspension; with aortic root replacement using composite prosthesis and coronary reconstruction	44.93	287	2.5	19.7	9.0
33945	Heart transplant, with or without recipient cardiectomy	42.04	325	6.0	37.0	16.0
43113	Total or near total esophagectomy, with thoracotomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es)	40.41	391	3.0	NA	15.0
33533+ 33518	CABG X 3 (Artery + 2 Veins)	39.47	201	2.2	15.0	7.7
33516	Coronary artery bypass, vein only; six or more coronary venous grafts	38.39	264	2.7	22.3	9.0
33536	Coronary artery bypass, using arterial graft(s); four or more coronary arterial grafts	38.04	259	1.9	13.0	7.0
33545	Repair of postinfarction ventricular septal defect, with or without myocardial resection	36.72	236	4.7	68.5	9.0
33513	Coronary artery bypass, vein only; four coronary venous grafts	36.12	231	3.1	26.0	9.0
32445	Removal of lung, total pneumonectomy; extrapleural	34.95	310	3.0	NA	13.0
33425	Valvuloplasty, mitral valve, with cardiopulmonary bypass;	34.55	254	2.5	27.0	9.0
33305	Repair of cardiac wound; with cardiopulmonary bypass	27.05	296	8.0	121.3	14.0
33464	Valvuloplasty, tricuspid valve; with ring insertion	26.78	205	2.5	18.7	10.0

Even a casual review of table 13 shows the compression and distortion of value for these complex procedures, compared to the '3 vessel CABG'. All the procedures shown here have either more intraservice time, more ICU time, more ventilator time and more hospital length of stay (and usually all 4 elements) than the '3 vessel CABG', but an inaccurate and usually smaller RVW. The latter even includes 4 vessel CABG whether performed with all arteries or all vein or even 6 vessel CABG with vein.

3. Low IWPUT and Negative Intraservice Work

The proposed rule creates work values for 16 cardiac surgery codes with an IWPUT that are less than the intermediate established patient office visit (99213), a service designated as having a low level of medical decision making. This outcome is illogical and represents an obvious rank order anomaly and is shown in Table 14.

CPT code	Long Descriptor	CMS Calculated Intraservice Work	CMS Recommended IWPUT
99213	Established Patient Office Visit, Level 3	0.74	0.0494
33140	Transmyocardial laser revascularization, by thoracotomy	4.65	0.0410
35820	Exploration for postoperative hemorrhage, thrombosis or infection; chest	5.53	0.0405
33463	Valvuloplasty, tricuspid valve; without ring insertion	8.76	0.0378
33542	Myocardial resection (eg, ventricular aneurysmectomy)	7.79	0.0374
33474	Valvotomy, pulmonary valve, open heart; with cardiopulmonary bypass	7.49	0.0336
32445	Removal of lung, total pneumonectomy; extrapleural	9.76	0.0312
32540	Extrapleural enucleation of empyema (empyemectomy)	3.72	0.0305
43113	Total or near total esophagectomy, with thoracotomy; with colon interposition or small intestine reconstruction	10.58	0.0269
39400	Mediastinoscopy, with or without biopsy	1.19	0.0260
33465	Replacement, tricuspid valve, with cardiopulmonary bypass	4.55	0.0214
32815	Open closure of major bronchial fistula	2.80	0.0176
33945	Heart transplant, with or without recipient cardiectomy	-0.78	-0.0028
32141	Thoracotomy, major; with excision- plication of bullae, with or without any pleural procedure	-0.53	-0.0049
33460	Valvectomy, tricuspid valve, with cardiopulmonary bypass	-0.89	-0.0085
33300	Repair of cardiac wound; without bypass	1.55	-0.0109
33305	Repair of cardiac wound; with cardiopulmonary bypass	-13.56	-0.0459

Table 14

Five codes, including 33945 (Orthotopic Heart Transplant) have proposed work values that are less than would result from typical pre- and post-operative evaluation and management, resulting in calculated <u>negative intraservice work</u>. This implies that the surgeon would be better reimbursed by CMS if the procedure were not billed, removing the global period restrictions on evaluation and management billing.

4. Fails to follow consistent methodology

Other codes are proposed at higher levels than the present (2006) valuations but appear unrelated to the RUC recommendations, the supporting STS/AATS data presented, or the work described in the CPT description.

We believe an illustrative example may be helpful. The repair of penetrating trauma to the heart (such as a gunshot wound or knife wound) is coded using CPT codes 33300 and 33305, Repair of Cardiac Wound with or without cardiopulmonary bypass. Data from 240 of these relatively rare patients were presented to support new values for these codes. These wounds can sometimes be repaired directly (N=95) but more frequently require cardiopulmonary bypass support (N=145). These patients require extensive postoperative critical care to recover from the surgery and from the organ damage related to profound shock after trauma and before surgery. The STS database mortality rate is 17%.

When the cardiac wound can be simply repaired, the average patient is maintained on a ventilator for 3 days and in ICU for 5 days. When cardiopulmonary bypass is needed (usually for more extensive cardiac injury or for patients in extremis) the average mechanical ventilation time is 5 days, and ICU stay is 8 days.

The CMS proposed values for these codes are 25.09 and 27.05 for cardiac wound repair, with and without cardiopulmonary bypass respectively. These values are less than those proposed for an elective single vessel CABG, and provide an <u>additional 1.96 RVW</u> for:

- Using cardiopulmonary bypass
- An average additional 2.5 hours of intraservice time
- An additional 2 days of mechanical ventilation
- An additional 3 days of intensive care stay

There are numerous other examples that indicate that the CMS proposed values, in departing from the RUC recommendations, were not based on the evidence provided to it through the RUC process. Adhering to the CMS proposed values will guarantee rather than prevent rank order anomalies as evidenced by the above example.

5. Failure to include pre- and post-service work in the ZZZ codes

As detailed in the discussion of the CABG family of codes, the STS methodology showed that there was significant postoperative work involved in the performance of the vein add-on codes. The total work is not only related to the performance of each additional graft, but also due to patient characteristics associated with the need for additional grafts (older, more diabetes, more generalized vascular disease) and the additional perioperative morbidity associated with the prolonged operation. Discounting this work would be inappropriate, since it is clearly performed as evidenced by data from 480,475 patients. Attempting to add the work to the base arterial bypass code would also be inappropriate, as it would misalign incentives in allocating work that may not be performed for the individual patient. And, as CMS has overlooked, it has the potential to create rank order anomalies (which occur when work done is discounted, or when work not done is allocated).

The same analysis was performed for 33530 (Reoperation for coronary bypass or valve, N=16,756) and 33141 (Transmyocardial Laser Revascularization add-on N=1,609), showing significant additional ICU, LOS and ventilator time for the former for a recommended work increase, and despite additional pre and postoperative work a short, less intense intraservice period for TMR for a recommended work decrease.

Neither RUC recommendation was accepted by CMS, with the stated basis that there is no precedent for incorporating work other than intraservice work in these codes. Our analysis clearly demonstrates the rationale for including this work, and we refer CMS to its own precedent in the Federal Register:

The definition of a ZZZ global period will be revised as follows: "ZZZ = Code related to another service and is always included in the global period of the other service (Note: Physician work is associated with intraservice time and in some instances the pre- and post-service time)" Federal Register, December 31, 2002

Therefore, STS/AATS recommend that CMS accept the RUC recommendations for the submitted add-on codes 33517-33523, 33141 and 33530.

6. CMS has failed to employ its stated alternate methodology for determining work value for the Cardiac and General Thoracic codes.

As detailed above, CMS proposed to adjust the RUC recommendations by incorporating RUC recommendations for time and visits, replacing the IWPUT with values from the 2000 5-year review that it assumed were valid.

In fact, CMS did not consistently employ this methodology, instead using it selectively, for example reducing the IWPUT of 33533 (single vessel arterial CABG) from 0.135 to 0.125. The IWPUT chosen by CMS is compared to the 2^{nd} 5-year value as follows:

Arterial Grafts	Code	2 nd 5-year IWPUT	CMS IWPUT
1	33533	0.135	0.125
2	33534	0.113	0.105
3	33535	0.106	0.099
4	33536	0.103	0.086

The IWPUT choices here created a rank order anomaly, as described above. CMS did not state a rationale for work recommendations for codes submitted but which were not reviewed in the 2000 5-year review. Reviewing the proposed values for these codes fails to reveal a discernable, logical methodology, with some code work values unchanged and some increased without apparent relationship to the old IWPUT, old values, RUC recommended values, or any of the supporting data adjudicated through the current 5-year review process.

For example, 33945, Orthotopic Heart Transplant, is proposed by CMS to have no change in RVW despite additional time and visit allocation as per the RUC recommendations. This decision results in negative intraservice work for heart transplant, and leaves one of the most demanding cardiac procedures performed at an anomalous low work value, similar to that proposed for many cardiac procedures that have been conclusively demonstrated to require less physician work.

These decisions were apparently arbitrary, and have led to numerous anomalies in these code values. Requests to CMS for an explanation of the methodology employed have gone unanswered.

STS/AATS therefore recommend that CMS accept the RUC recommended IWPUT for all the submitted codes, which in combination with the CMS proposed time and visit information accepted from the RUC recommendations will reconstitute the RUC recommended values in the Final Rule.

7. Anomalous values due to implementation of the refined E&M services within the surgical global period

STS/AATS agrees with CMS' decision to adjust the E&M services present in the global period of all 090 and 010 global period codes at 100% of the new values. A review of codes that are frequently performed by cardiothoracic surgeons shows that this intention has not been accurately implemented. The value changes proposed for these codes are not predictably related to the new E&M proposed values for RUC database E&M services in the global periods.

STS/AATS therefore recommend that CMS review its policies and procedures for implementing code value change before publishing the Final Rule, to ensure that its intended changes are in fact reflected in the code values.

8. Inaccurate translation of time and visit information into PE Direct Input tables

Although CMS proposes the time and visit information recommended by the RUC for all the cardiothoracic codes, the outpatient visit information was apparently not carried through to the direct cost inputs for calculation of PE. This will result in <u>overpayment</u> for practice expense for the cardiothoracic codes, since the outpatient visit number and level

was generally reduced by the STS expert panels and these recommendations were approved by the RUC.

Therefore, STS/AATS recommend that CMS carefully review the direct cost input tables to ensure that they are correctly aligned with the CMS proposed changes in physician work components.

Additional Recommendations:

• STS/AATS request regarding 35820

STS/AATS request that CMS propose edits to eliminate the -78 modifier deduction being applied to code 35820 (Return to the operating room for thoracic complications, bleeding, infection, etc). This code is by definition a related procedure for complications that occurs during the global period. Valuation for this code was performed using methodology similar to that for the add-on codes for additional grafts. Its value, therefore, was constructed by a building block method that measured the incremental <u>difference</u> in postoperative evaluation and management services attributable to the re-exploration procedure itself (eliminating the value of the services associated global period of the operation originally performed). Thus, the value of 35820 is already discounted to account for the fact that the physician is being credited with baseline postoperative evaluation and management services performed for the baseline procedure. Thus no further alteration in reimbursement should be made through application of the -78 modifier deduction.

STS/AATS request regarding 33548

We would also ask that CMS approve the RUC recommended RVW of 49.41 for 33548 (Systolic Left Ventricular Reconstruction). This recommendation was submitted by the RUC as part of the 5-year review process, since the 2005 April valuation by the RUC was based on a reference code (33542) that was in the refinement process. This code received no comment in the proposed rule. Supporting documentation and rationale, as approved at the September 2005 RUC meeting, are as follows:

SVR Rationale Provided to the RUC at the September 2005 Meeting:

The SVR code 3354X was valued by the RUC at its April 2005 meeting. The reference code most frequently chosen by standard RUC survey respondents was 33542, which had been submitted for 5-year refinement and has never been RUC reviewed.

The recommended RVW was 37.97, resulting in an IWPUT of 0.085, a value which was felt to be too low by our society. The E&M services assigned to the global period were also distorted by derivation from the Harvard assigned visits of the reference code. Accordingly, 3354X was noted to be subject to revision by the RUC after the reference code value and composition had been refined.

At the time of the September 2005 RUC meeting, 33542 has been refined and RUC consensus achieved on a new value and new time and visit assignments. Its putative work value is now 44.20 RVW. Additionally, intraservice time, length of ICU and regular hospital stay, and duration of mechanical ventilation has been acquired for 3354X from the STS database, which recently added this new procedure to its procedure list. 3354x was also surveyed for intensity along with the other adult cardiac codes submitted for refinement. A comparison of the STS data and IWPUT between 3354X and 33542 for the period 2001-4 is attached. It indicates that 3354X is significantly more intense in intraservice work, more complicated and is associated with significantly more postoperative management physician work (confirming the relationship between the two codes determined by the standard RUC survey) than the reference code.

In recommending a new value for 3354X, we have considered the following factors:

- 1. Establishing the new value based on the ratio of refined 33542 and Harvard 33542, adjusting the RUC-approved value of 3354x proportionately. This results in a recommendation of ((44.20/28.21)*36.46) = 57.13
- 2. Establishing a new value through the utilization of data from the RUC survey performed for the April 2005 RUC meeting, data from the consensus achieved by the RUC for the new reference code value, data from the STS national database, and intensity data from the survey that was used in the 5 year refinement process. This method led to a recommendation of 49.41 The new value includes an additional 99292 visit compared to the RUC recommendations for the reference code, consistent with the additional ICU stay and ventilator hours for 3354X and consistent with several of our workgroup approved codes with similar ICU stay and ventilator hours. We maintained the RUC approved 99239 discharge for 3354X, and this was consistent with other work group recommendations for similar codes. Otherwise, the number and level of the in-

hospital visits are the same as for the reference code.

The society would recommend the lower value, 49.41, for several reasons:

- 1. The higher value of 57.13 could only be "built" through increasing perioperative time and E&M services to levels above those recommended by our specialty for similar codes.
- 2. The higher value would create rank order anomalies with other procedures, should the refinement process interim results be finalized. For example, 3354X would have a higher work value than 33545 (Repair of post-myocardial infarction VSD, 52.49)
- 3. The value 49.43 is an appropriate relative value compared to the refined value of 33542 (49.43), and the relationships of intraservice time, IWPUT, and post-operative E&M services are consistent with STS national database data for both procedures.

The RVW of 49.41 was approved by the RUC and forwarded to CMS with the remainder of the September 2005 RUC recommendations for the 5 year review.

STS/AATS therefore recommend that CMS accept the RUC recommended work value of 49.41 for CPT 33548.

The SVR Calculations are provided below in tables 15 -18:

	Table 15					
	IWPUTHvd Reference CPT code:ANALVSIS33542					
	ow / Column	D	E	F		
				MFS RVW for Ref: 28.81		
		Databas e Data	RUC Standard	RVW		
	Pre-service	Time	Intensity	(=time x intensity)		
	Pre-service eval & positioning	59	0.0224	1.32		
	Pre-service scrub, dress, wait	25	0.0081	0.20		
	Pre-service total			1.52		
	Post- service	Time	Intensity	(=time x intensity)		
	Immediate post	59	0.0224	1.32		
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)		
	ICU 99291	0	3.99	0.00		
	ICU 99292	0	2.00	0.00		
	NICU 99296	0	16.00	0.00		
	NICU 99297	0	8.00	0.00		
	99233	0	1.51	0.00		
-	99232	4.5	1.06	4.77		
	99231	8	0.64	5.12		
	Discharge 99238	1	1.28	1.28		
	Discharge 99239	0	1.75	0.00		
	99215	0	1.73	0.00		
	99214	1.5	1.08	1.62		
	99213	0	0.65	0.00		
	99212	0	0.43	0.00		
	99211	0	0.17	0.00		
	Post-service total			14.11		
		Time	IWPUT	INTRA- RVW		
	Intra- service:	192.00	0.069	13.17		

	Table 16						
	IWPUT Workgroup 5 Refined Reference CPT						
	ANALYSIS		code: 3354	42			
R	ow / Column	D	E	F			
-			Workgroup 5 RVW	44.20			
		Databas e Data	RUC Standard	RVW			
	Pre-service	Time	Intensity	(=time x intensity)			
	Pre-service eval & positioning	75	0.0224	1.68			
	Pre-service scrub, dress, wait	20	0.0081	0.16			
	Pre-service total			1.84			
	Post- service	Time	Intensity	(=time x intensity)			
	Immediate post	40	0.0224	0.90			
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)			
	ICU 99291	2	3.99	7.98			
	ICU 99292	0	2.00	0.00			
	NICU 99296	0	16.00	0.00			
-	NICU 99297	0	8.00	0.00			
	99233	3	1.51	4.53			
	99232	2	1.06	2.12			
Γ	99231	1	0.64	0.64			
	Discharge 99238	1	1.28	1.28			
	Discharge 99239	0	1.75	0.00			
	99215	0	1.73	0.00			
	99214	1	1.08	1.08			
	99213	1	0.65	0.65			
	99212	0	0.43	0.00			
	99211	0	0.17	0.00			
	Post-service total			19.18			
		Time	IWPUT	INTRA- RVW			
	Intra- service:	207.00	0.112	23.18			

Table 17					
	IWPUT 4_2005 RUC Recommendation				
	ANALYSIS		3354A		
1	Row / Column	A .	B	С	
				MEDIAN Svy RVW: 37.97	
		Survey Data	RUC Standard	RVW	
	Pre-service	Time	Intensity	(= Time x intensity)	
	Pre-service eval & positioning	75	0.0224	1.68	
	Pre-service scrub, dress, wait	20	0.0081	0.16	
	Pre-service total			1.84	
	Post- service	Time	Intensity	(=time x intensity)	
	Immediate post	60	0.0224	1.34	
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)	
	1CU 99291	1	3.99	3.99	
	ICU 99292	0	2.00	0.00	
	NICU 99296	0	16.00	0.00	
	NICU 99297	0	8.00	0.00	
	99233	1	1.51	1.51	
	99232	1	1.06	1.06	
	99231	6	0.64	3.84	
	Discharge 99238	0	1.28	0.00	
	Discharge 99239	1	1.75	1.75	
	99215	0	1.73	0.00	
	99214	1	1.08	1.08	
	99213	2	0.65	1.30	
	99212	0	0.43	0.00	
	99211	0	0.17	0.00	
	Post-service total			15.87	
		Time	IWPUT	INTRA- RVW	
	Intra- service:	240.00	0.084	20.25	

		Tab	le 18	
	IWPUT	Revised Recommendation		
ANALYSIS		3354X		
R	ow / Column	A	В	С
				New Rec RVW 49.41
		Survey Data	RUC Standard	RVW
	Pre-service	Time	Intensity	(= Time x intensity)
	Pre-service eval & positioning	60	0.0224	1.34
	Pre-service scrub, dress, wait	20	0.0081	0.16
	Pre-service total			1.51
	Post- service	Time	Intensity	(=time x intensity)
	Immediate post	40	0.0224	0.90
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
	ICU 99291	2	3.99	7.98
	ICU 99292	1	2.00	2.00
	NICU 99296	0	16.00	0.00
	NICU 99297	0	8.00	0.00
	99233	3	1.51	4.53
	99232	2	1.06	2.12
	99231	1	0.64	0.64
	Discharge 99238	0	1.28	0.00
	Discharge 99239	1	1.75	1.75
	99215	0	1.73	0.00
	99214	1	1.08	1.08
	99213	2	0.65	1.30
	99212	0	0.43	0.00
	99211	0	0.17	0.00
	Post-service total			22.30
		Time	IWPUT	INTRA- RVW
	Intra- service:	217.00	0.118	25.61

Svy-T* indicates insert survey time data. Svy-V* indicates insert survey visit data. Ref-T* indicates insert ref. time data, from RUC database. Ref-V* indicates insert ref. visit data, from RUC database

From 4_2005 RUC Recommendation

From Consensus of Workgroup 5 for 33542

**Note: Office visit RVW's shown reflect RUC/CMS "discounted" values.

D. DISCUSSION OF COMMENTS – GENERAL, COLORECTAL AND VASCULAR SURGERY

The STS/AATS would like to offer comments supporting the RUC recommendation of 64.04 RVWs for code 33877, rather than the CMS recommended work value of 53.00. Cardiothoracic surgeons provide 41% of these services and it falls within a family of codes that STS has developed recommendations for during this 5-year review.

The intra-service time of 324 minutes is supported by the STS database data on 108 patients, which shows an intra-service time of 326 minutes. The surveyed intensity from the STS for this code was .124 which was blended with the SVS intensity of .110 for an intensity factor of .117.

The STS database shows that there is a 6 day ICU LOS with 83 ventilator hours. Compared to the cardiac codes submitted for refinement, 33877 was the number 2 ranked code for these features, confirming the extensive and intensive postoperative care evaluation and management that is recommended by the RUC in the surgical global period.

The RUC recommendation from the SVS is in rank order with the recommendations for codes 33860 and 33863, which are in the same code family. The RUC recommended 55.45 RVWs for code 33860, which has an intra-service time of 305 minutes, an ICU LOS of 2.7 with 25.8 ventilator hours, and a total LOS of 9 days and a surveyed intensity of .114.

The RUC recommendation for code 33863 is 55.10 RVWs. This procedure has an intraservice time of 287 minutes, an ICU LOS of 2.5 days with 19.7 Ventilator hours, a total LOS of 9 days, and surveyed intensity of .121.

The CMS recommended value will create a rank order anomaly, wherein the additional 3.5 days of ICU stay, 20 minutes of intraservice time, and 60 hours of mechanical ventilation of 33877, compared to 33860 and 33863, are provided with no additional physician work value.

CMS acceptance of the RUC recommendations would result in an appropriate rank order within the family.

Therefore, STS/AATS recommend that CMS accept the RUC recommended value for 33877, 64.04 RVW.

E. DISCUSSION OF COMMENTS - OTHER ISSUES

1. Anesthesia Services

STS/AATS believe that the projected large reductions in Medicare payments for anesthesia services may lead to future anesthesia manpower shortages. This would have serious negative consequences for the ability of cardiothoracic surgeons, as well as other surgical specialists, to provide surgical care for our patients. We urge CMS to work with the RUC and the ASA in a timely fashion to find improved methods for correctly valuing the services provided by anesthesiologists, perhaps building upon the results of the building block model presented by ASA at the last 5-Year Review.

2. Global Period

CMS had asked for comments about the advisability of altering the current scheme regarding the postsurgical global period. Presently most major surgical procedures have a 90-day global period. During this time the operating physician receives no additional reimbursement for any routine services associated with the primary procedure as long as they are provided outside the operating room setting. We understand that some had questioned whether it would be appropriate to separate the reimbursements for the preoperative and intraoperative portions of the fee from those associated with postoperative services provided. The STS/AATS believes this would be inadvisable for several reasons. First, we believe this would encourage the practice of itinerant surgery, i.e. the circumstance in which a surgeon performs an operation and cedes all further care of the patient to another physician, commonly one in a non-surgical specialty. Much of the success of surgery depends upon the perioperative and postoperative management. Ceding such management to a physician less familiar with the special needs of patient in this critical postoperative period is potentially hazardous for the patient. We believe that for most procedures we perform, we as surgeons are optimally trained and suited to deliver perioperative care. Abdicating this responsibility would be contrary to the best interests of the patient and thus would be an inappropriate and undesirable practice, which contradicts our code of ethics. We do recognize that in view of the increasing complexity of patients due to advanced age and co-morbidities, many of our postoperative patients will benefit significantly from input by non-surgical specialists such as internists, cardiologists and pulmonologists. In such cases we believe that their services are additive and complementary to the postoperative care provided by surgeons rather than replacing the surgeon's postoperative care. We strongly encourage CMS to make a national coverage decision that services provided in the post-operative period by intensive care trained physicians be reimbursed.

Secondly, we believe that separating payment for the intraoperative and postoperative care might also increase the risk of the ethically prohibited practice known as "fee splitting". This fee splitting occurs when a non-surgical physician makes an agreement to refer his/her patients to a specific surgeon only if the surgeon agrees to return the physician a percentage of the surgical fee. In such cases, patients may be referred not to the surgeon that the physician believes is most qualified but rather to the surgeon who has agreed to a mutually beneficial financial arrangement. We believe this contradicts the ethical tenets of surgical practice and thus must be avoided. If a decision were made by CMS to eliminate the global surgical period and to allow for routine provision of and reimbursement for postoperative care by referring non-surgeon physicians, we believe that conditions will be created that would likely yield a situation in which de facto fee splitting occurs. In such cases, non-surgical physicians might refer patients only to surgeons who agree to "split" the perioperative care provided the patient and thus result in splitting the reimbursement. Once again, this could, in our opinion, lead to the referral

of patients on the basis of financial considerations alone and would constitute a potential breach of ethics. Thus, we believe that reimbursement in the postoperative period should remain governed by the principles of the global period.

Finally, the STS/AATS is concerned about the effect of separating out the global period would have with regard to resource utilization. Allowing surgeons to "operate and run" would tacitly encourage itinerant surgery (as noted above) and potentially promote financial incentives contrary to patient well-being. Surgical specialists, like all other doctors, are feeling increasingly severe economic pressures as costs rise and reimbursement falls. If reimbursement becomes attached only to the intraoperative portions of procedures then there could be increasing pressures to perform operations even when the indications are tenuous. This situation could, in turn, lead to significant increases in procedural volumes in all areas of medicine in which global periods are currently in effect.

STS/AATS supports the expansion of the use of global payments beyond surgical procedures into disease management. Like many observers, we believe the global period policy to have saved the Medicare program significant funds and believe it to be a major reason for such moderate growth in service volume in the surgical or "major procedures" area of Medicare.

F. DISCUSSION OF COMMENTS - PRACTICE EXPENSE

The STS/AATS believes that the proposed new methodology for practice expense calculations contains both positive improvements as well as areas where we would suggest alteration.

Clinical Staff Costs

We do not object that CMS has chosen to move from a top-down method to the bottom-up method for calculating and allocating these expenses as long as all direct expenses are considered. We believe that this methodology more accurately captures and fairly allocates direct PE costs. We are concerned however, that all direct practice expense costs from the CPEP pools are not being included in this methodology as required by the statute in section 4405(d) of the Balanced Budget Act of 1997 (Pub. Law 105-33) which requires CMS to:

"Utilize to the maximum extent practicable, generally accepted cost accounting principles which (i) recognize all staff, equipment, supplies, and expenses, not just those that can be tied to a specific procedure, and (ii) use actual data on equipment utilization and other key assumptions." (emphasis added)

We firmly believe that CMS's decision in 1999 to remove the actual costs of non-physician clinical staff employed by cardiothoracic surgeons to improve quality in the hospital from its accepted CPEP data is a clear and continuing violation of this statutory requirement.

At the time, CMS (then HCFA) claimed it was not typical (more than 50% of the time) that CT surgeons bring their employed non-physician providers (NPPs) to the hospital. STS submitted data to the contrary. In 2002 HHS OIG found that 74% of CT surgeons brought employed staff to the hospital. This input was not heeded or acted upon by CMS.

In the 1999 proposal and subsequently, CMS claimed that hospitals were paying for these staff. This belief was proven false by the HHS OIG finding that in 81% of cases, hospitals did not pay *even partial* costs for these NPPs. In fact, we are currently seeing an increasing number of instances where the hospital is charging the cardiac surgeon for the use of clinical staff in the hospital, while the hospital is simultaneously paid under the DRG **and** billing for the PA work directly through the Medicare Part B payment system. This type of triple-billing has been fostered by CMS's refusal to specifically designate one part of our Medicare system to pay these costs. We believe that for quality purposes and the importance of maintaining a consistent care team, these costs should be paid to the surgeon for their employed clinical staff through direct practice expense costs as the statute requires.

Unfortunately, our ability to refine the CPEP data through the PEAC was unfairly precluded by CMS when they instructed the Practice Expense Advisory Committee (PEAC) – the very committee created to provide input on such matters – that it was *not to consider* the questions of NPP staff brought by surgeons to the hospital. This instruction to the PEAC has assured that their refinement of PE data has taken place without consideration of the costs incurred by CT surgeons as a legitimate practice expense, even while these same clinical staff costs are included in the PE calculations for other office-based specialties.

We remind CMS that previous estimates are that \$50,000,000 to \$100,000,000 per year have been diverted away from cardiothoracic surgical reimbursement and into all of the remainder of medicine since the adoption of the revised practice expense methodology in 1998.

We would like CMS to consider the inequity in the fact that clinical staff in the office are included in PE calculation (regardless of their ability to bill directly), yet if those same staff assist even part time in the hospital, where team care has been shown to improve quality, they have been excluded by CMS. We believe that the systematic exclusion of the costs of clinical staff who accompany cardiothoracic surgeons to the hospital represents unequal enforcement under the law since the expenses for similarly educated allied health professionals who provide services in the office or clinic setting have been allowed in the calculation of total costs for these office based specialists.

Without main-frame computing capability and access to all of the Medicare data, it is not possible for us to determine if the bottom-up methodology for practice expense has eliminated the "pool leakage" phenomenon which CMS staff have described with the previous top-down practice expense methodology. Although to the extent that indirect practice expenses are still based on top down methods, we believe that there is still the potential to continue to divert funds from the cardiothoracic surgery practice expense pool into other specialties using codes common to cardiothoracic surgery and to the other specialties.

Last, and perhaps most importantly on this matter, CMS (then HCFA) responded to concerns raised by Members of Congress about the removal of clinical staff costs from the CPEP data being a violation of the above statute, by claiming that section 4505(d) applied to the bottom-up method of calculating PE, but not to the (then in-use) top-down method.

Now that CMS is proposing to return to that prior methodology (the bottom-up method) we believe it is critical that CMS restore the CPEP-determined costs to the cardiothoracic surgery pools to come into compliance with the governing statute.

Supplemental Survey Data

STS/AATS are also concerned that the acceptance of supplemental surveys provided by only a few specialties and employing differing methodologies to obtain cost data has produced results that raise questions about the credibility of the values. To our knowledge, these methods and data have not had RUC or PERC oversight and yet will have a marked impact on the PFS. We are supportive of the proposal to engage in a new process to measure practice expense costs across all of the medical specialties simultaneously, and we suggest that CMS delay acceptance of any supplemental practice expense information until this survey process is completed. We recognize and are appreciative that CMS has previously accepted the STS supplemental practice expense information from 1998, but we wish to remind CMS that STS/AATS is the <u>only specialty</u> to have provided supplemental practice expense data using the then existing AMA/SMS survey mechanism. This AMA/SMS survey mechanism continues to serve as the basis for practice expense valuations for the majority of medical specialties today. All other practice expense information has been obtained by different survey methods and different surveyors.

Medical Equipment Utilization Rate

STS/AATS believe that the utilization assumptions for DME are too low. The current utilization rate of 50% does not reflect the current reality in the utilization of most equipment in medical practices. A 74% or 90% utilization assumption would be more appropriate for most equipment. A recent Medicare Payment Advisory Commission analysis recently found that the utilization rate for high value, high volume imaging equipment such as CT scanners and MRIs, averages close to 95%. We recommend that CMS raise the default utilization rate for this equipment to reflect actual practice patterns.

Interest Rate Assumption

We believe that the assumed interest rate of 11 percent which CMS uses to determine practice expense for financing costs is much higher than current market rates and has been for a decade. A more realistic, yet flexible interest rates assumption such as prime plus 2% would be more appropriate and reflect actual market conditions.

Practice Expense Budget Neutrality Adjustment

STS/AATS supports the CMS proposal to apply budget neutrality adjustment for practice expense within practice expense rather than to the conversion factor.

G. Conclusion

Two and a half years ago the STS/AATS assessed the Medicare Fee Schedule critically and identified a myriad of codes that were misvalued either due to changes in patient profile, evolving technology or rank order anomalies. In reviewing the codes values, it became clear that the RBRVS process, driven more by opinion than by data, had eroded the work value of our codes culminating in a failed 5-year review in 2000 primarily due to an inability to deliver data. In reality, these codes had not been refined for 10 years, a period of time during which no specialty has experienced more adverse change in patient characteristics or adverse selection of patients for its procedures.

Encouraged by the enthusiasm for utilization of hard data by CMS, third party payers and regulatory agencies, we decided to undertake the 2005 5-year review in as objective and data-driven a fashion as possible. It was our hope to achieve accurate valuations on the basis actual data and realistic assessments of time, effort and intensity. Rather than try to "protect" overvalued codes, a practice that MedPAC asserts to be widespread, we brought forth for revaluation the majority of the procedures we perform in hopes that that careful and accurate measurements of work and effort would lead to rational and logical valuation of our procedures both in relation to one another and compared to those codes outside our specialty.

In order to make this assessment as objective as possible we utilized and RUC accepted a building block methodology in conjunction with hard data from our nationally recognized clinical databases and survey data from a large fraction of all practitioners within our specialty. Over a 9 month period, these data were exhaustively scrutinized by the multi-specialty RUC and its standing subcommittees and the 5-year Review Workforce, as observed by CMS. The end result was a series of RUC recommendations that we believe correctly valued these codes for the first time, placing the entire family of Cardiothoracic codes in order and in a proper relationship to the PFS.

We are concerned that throughout this 5-year review process, since December 2004 when we notified the administrator of our intended process and methodologies, CMS has been present and involved in the discussion and deliberation on the cardiothoracic codes at each step, yet raised no concern or objection about any of these issues that were subsequently raised in the proposed rule while the RUC debated and adopted them. The ultimate concern is that CMS' rejection of the RUC recommendations for the entirety of adult CT surgery codes will be construed as disregard for the RUC process and will dramatically reduce the integrity and effectiveness of that committee - which most observers believe is the best method of bringing physician expertise to create appropriate work values in a fixed dollar allocation model.

Publication of the proposed values in the Final Rule will eliminate the work relativity of the Cardiothoracic codes, adversely impact the relativity of the entire Physician Fee Schedule, and result in perverse financial incentives that could adversely effect patient care and access to qualified thoracic surgical specialists. In summary, we believe that through

implementation of this proposed rule CMS will not meet its obligation to protect the health and welfare of Medicare beneficiaries.

Additionally, unlike other specialties who have recourse to adjust volume and level of service to meet the demands of an aging population, cardiothoracic surgeons would continue to have their services incorrectly reimbursed for another 7 years. The impact of the 2000 5-year review is already being felt, with three consecutive years of an inability to recruit qualified residents into training programs and a projected severe shortfall in the number and possibly even the quality of practicing cardiothoracic surgeons.

We are concerned that a perceived theme emerging in these proposals by CMS is a reluctance to assign work values at a level that cardiothoracic surgeon experts and the RUC believe is appropriate (and within the range of the PFS) for these complex, high risk, high intensity procedures that require demanding and intensive perioperative preparation and physician management. This reluctance is at odds with the evidence, shown in table 19 for the typical cardiac surgery patient as a profile constructed from the average data for all the cardiac codes submitted (weighted for Medicare utilization):

All Submitted Cardiac Codes N=6	660,380
Preoperative	
Age	65.0
% Diabetes	33%
%_CHF	17%
% Peripheral Vascular Disease	14%
% Cerebrovascular Disease	13%
% Inotropic Agents (preop)	2%
% Cardiogenic Shock (preop)	2%
% Resuscitation to OR	1%
% ADP Blocker (preop)	10%
% Ilblla Inhibitor (preop)	5%
Intraoperative	
Intraservice Time	220
Cardiopulmonary Bypass Time	95
Aortic Clamp Time	65
Postoperative	
Mechanical Ventilation (Hours)	
Rea Blood Cell Units	<u>4.2</u>
	2.7
	1.4
Cryoprecipitate Units	0.5
Intensive Care Unit Stay (Hours)	53
Postoperative Length of Stay (Days)	6.5

Table 1	19
---------	----

As can be seen, the typical patient is a Medicare Beneficiary with multiple comorbidities. These comorbidities are either causative (ie, diabetes and heart disease) or the result of the physiologic impact of the heart disease itself. The average patient is supported by the heart-lung machine for one and a half hours and has the heart arrested without blood supply for over an hour. After surgery, the patient is universally managed in an intensive care unit for an average of 2 days with 16 hours of mechanical ventilation. Despite the extreme physiologic stress associated with these procedures over 97% of these critically ill patients survive.

As a result of these procedures, the patients experience prolonged life and enhanced quality of life, a standard that has been subjected to extensive scientific scrutiny and met. This statement can be made for very few procedures or specialties other than for Thoracic surgery, which treats the #1 and #2 killers of Medicare beneficiaries, heart disease and cancer.

Accordingly, CMS should have no trepidation in taking the correct course of action here by accepting the work values demonstrated by the evidence and approved by the multi-specialty RUC. As you will see in other comments, support for these recommendations is virtually universal amongst medical and surgical specialties.

Therefore, STS/AATS respectfully request that CMS <u>seriously reconsider</u> its proposed recommendations and accept the RUC recommended values for the cardiothoracic surgery codes.

Sincerely yours,

Peter K. Smith, M.D., Chairman STS/AATS Workforce on Nomenclature and Coding

Frederick L. Grover, MD, President The Society of Thoracic Surgeons

NM

Bruce W. Lytle, MD, President American Association for Thoracic Surgery

Submitter : Dr. Brett Coldiron

4

Organization : American Academy of Dermatology Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

Date: 08/21/2006

file:///TI/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

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

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

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

Submitter : Murray Gorgon

Organization : Murray Gorgon

Category : Physician

Issue Areas/Comments

Background

Background

Against rate cut on procedure code 76075,76076

Regulatory Impact Analysis

Regulatory Impact Analysis

Comments against the decrease in reimbursement of codes 76075, 76076.

CMS-1512-PN-2263-Attach-1.DOC

Date: 08/21/2006

22.63

Allegheny Endocrinology Associates, P.C. East Wing Office Building 420 East North Avenue, Suite 205 Pittsburgh, PA 15212 412-359-3426

August 21, 2006

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

RE: Medicare Physician Fee Schedule (CMS-1512-PN)

To Whom It May Concern:

This letter is being submitted as formal comments/objections to the proposed changes to the Physician Fee Schedule for procedures codes CPT 76075, 76076, 76077 related to DXA scanning for osteoporosis.

Due to the increased awareness of the benefit of early detection and treatment of osteoporosis there have been significant enhancements to the DXA equipment from a pencil-beam technology to a more advance fan beam technology. The abilities of the new equipment allow for more detailed bone density scans on patient populations that are at risk for osteoporosis or significant risk of bone loss due to other medical conditions and treatments. The availability of this advanced DXA technology in our office has increased the detection of early stages of osteoporosis to allow for early treatment of at risk patients. This early treatment not only provides the highest quality of care for the patient but will subsequently reduce future healthcare costs due to the effective treatment of a potential disabling condition of osteoporosis.

With the proposed decrease in reimbursement for codes 76075, 76076, and 76077 the accessibility of this state of the art technology will be minimized due to the ability to afford and maintain the equipment. Greater access to at risk patients is a key factor in making sure that patients receive the earliest possible screening and diagnosis.

The reimbursement for procedure codes 76075, 76076, and 76077 need to increase or remain the same for the healthcare community to continue to provide open access to patient populations at risk. Thank you.

Sincerely,

Murray B. Gordon, M.D.

Submitter : Dr. Michael Repka

Organization : American Academy of Ophthalmology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Date: 08/21/2006

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

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

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

Submitter : Dr. Myron Gerson

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attchment

CMS-1512-PN-2265-Attach-1.DOC

Date: 08/21/2006

.

1265



4550 Montgomery Avenue Suite 780 North Bethesda, Maryland 20814 Telephone: 301-215-7575

Website: www.asnc.org Email: admin@asnc.org Fax: 301-215-7113

August 21, 2006

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

Dear Dr. McClellan:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to offer comments on the notice of proposed rulemaking entitled Medicare Program: Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (CMS 1512-PN) published in the Federal Register on June 29, 2005.

ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Practice Expense

ASNC is extremely pleased that CMS modified the informal proposals for revising the practice expense methodology presented at the February 15 Town Hall meeting. ASNC joined with other cardiovascular organizations in expressing grave concern about the magnitude of the impacts on some specialties, as well as the inadequacy of the methods of allocating indirect practice expenses to codes with no physician work RVUs, which were unveiled during the Town Hall meeting. We appreciate that CMS has made some efforts to moderate the effect of the practice expense revisions. Nevertheless, we remain concerned about the impact of large payment decreases for a number of critical nuclear cardiology diagnostic services -- particularly at a time when medical imagers already face increasing economic pressures. Our comments on several aspects of the proposed methodology follow.

Supplemental surveys

ASNC appreciates that CMS proposed implementation of the supplemental survey data submitted by seven specialties. We believe that the agency should make use of the best available data in determining the practice expense RVUs. ASNC joined with a number of other cardiology specialty societies in devoting considerable staff and physician volunteer time and significant financial resources to submitting supplemental survey data to provide CMS with a more updated picture of the practice costs incurred by cardiologists on a daily basis. Incorporating these data into the CY 2007 fee schedule will increase the accuracy in determining the PE RVUs for the services our members provide, as well as improving the overall accuracy of the practice expense component of the fee schedule.

Multi-specialty survey

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

Transition

ASNC supports CMS's proposal to provide a four-year transition for the proposed practice expense changes. This will allow specialty societies and the RUC an opportunity to: identify any issues with the current PE data; make any further appropriate revisions; and collect additional data as needed prior to the full implementation of the proposed changes,

Clinical labor in indirect cost allocation formula

ASNC strongly supports CMS's proposal to use clinical labor costs in the indirect allocation for a service when the clinical labor costs are greater than the physician work RVUs. This proposal represents an important improvement in the indirect cost allocation methodology as the existing allocation formula is wholly inadequate for fairly assigning practice expense relative values to codes with little or no physician work. And while ASNC remains troubled over the agency's decision to continue utilizing work RVUs for allocating indirect costs for services outside of the NPWP, we do appreciate CMS recognition of the necessity of a different allocation approach for those services inside the NPWP.

Five Year Review

ASNC appreciates that CMS accepted the AMA RUC's recommendations regarding the nuclear cardiology codes that were evaluated as part of the fiveyear review of physician work values.

Budget neutrality adjustment for Five Year Review

The Medicare physician payment statute requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what the expenditures would have been in the absence of these changes. In the proposed rule, CMS indicates that the proposed changes in work RVUs resulting from the 5-year review of physician work RVUs will be \$4 billion. Consequently, CMS is required to make adjustments to preserve budget neutrality.

ASNC supports CMS' recommendation that budget neutrality should be achieved by applying a separate adjustment of approximately -10 percent to the work RVUs. Under this approach, the published RVUs would not be changed. Rather, the adjustment would be made at the time payment is determined for a given service.

We strongly support this approach because it fairly applies the required budget neutrality adjustment to the portion of the fee schedule that was the subject of review. It would be unfair to make the budget neutrality adjustment to the conversion factor which would reduce payment for nuclear cardiology and other important services that do not involve physician work. In addition, this approach is consistent with the agency's proposal for achieving budget neutrality regarding practice expense RVUs. ASNC believes the proposed adjustment of the work RVUs is sound -- both from a policy and fairness perspective and we urge CMS to make it final for 2007.

Again, we appreciate the opportunity to comment on the proposed rule. Should you have any questions, please contact Christopher Gallagher, ASNC's Director of Health Policy at 301-215-7575 (ext 210) or via email at Gallagher@asnc.org.

Sincerely,

Mujon C. Jevan

Myron Gerson, MD President American Society of Nuclear Cardiology

Submitter : Hemlata Moturi MD

Organization : Hemlata Moturi MD

Category : Physician

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

Objection to reduction of procedure code 76075,76076

CMS-1512-PN-2266-Attach-1.DOC

Date: 08/21/2006

2266

Allegheny Endocrinology Associates, P.C. East Wing Office Building 420 East North Avenue, Suite 205 Pittsburgh, PA 15212 412-359-3426

August 21, 2006

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

RE: Medicare Physician Fee Schedule (CMS-1512-PN)

To Whom It May Concern:

This letter is being submitted as formal comments/objections to the proposed changes to the Physician Fee Schedule for procedures codes CPT 76075, 76076, 76077 related to DXA scanning for osteoporosis.

Due to the increased awareness of the benefit of early detection and treatment of osteoporosis there have been significant enhancements to the DXA equipment from a pencil-beam technology to a more advance fan beam technology. The abilities of the new equipment allow for more detailed bone density scans on patient populations that are at risk for osteoporosis or significant risk of bone loss due to other medical conditions and treatments. The availability of this advanced DXA technology in our office has increased the detection of early stages of osteoporosis to allow for early treatment of at risk patients. This early treatment not only provides the highest quality of care for the patient but will subsequently reduce future healthcare costs due to the effective treatment of a potential disabling condition of osteoporosis.

With the proposed decrease in reimbursement for codes 76075, 76076, and 76077 the accessibility of this state of the art technology will be minimized due to the ability to afford and maintain the equipment. Greater access to at risk patients is a key factor in making sure that patients receive the earliest possible screening and diagnosis.

The reimbursement for procedure codes 76075, 76076, and 76077 need to increase or remain the same for the healthcare community to continue to provide open access to patient populations at risk. Thank you.

Sincerely,

Hemlata Moturi, M.D.