



SOCIETY OF
CARDIOVASCULAR
COMPUTED TOMOGRAPHY

August 31, 2009

Ms. Charlene Frizzera
Acting Administrator
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-1413-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule- [CMS-1413-P]”

Comments submitted electronically via <http://www.regulations.gov>

Dear Ms. Frizzera:

The Society of Cardiovascular Computed Tomography (SCCT) is the recognized representative and advocate for physicians, scientists, nurses and technologists who work in the field of cardiovascular computed tomography. With nearly 4000 members, SCCT is nationally and internationally viewed as the principal independent organization committed to the further development of cardiovascular computed tomography through education, training, accreditation, quality control, and research.

SCCT is pleased to submit the following comments on the 2010 proposed Medicare physician fee schedule.

Practice Expense Changes – Physician Practice Information Survey (PPIS)

SCCT strongly encourages CMS to withdraw its proposal to implement the new PE/HR data obtained through the recent PPIS process. We believe there are grave data flaws and serious anomalies within the PPIS survey. As requested by the Agency, below we detail our concerns regarding the PPIS survey data, the data collection effort, and the implementation timeline.

As an alternative, we urge CMS to accept the cardiology supplemental survey data submitted by the American College of Cardiology.

Lack of Transparency

SCCT is an emergent specialty society with limited to no access to the American Medical Association's Relative Value Update Committee (RUC) processes. The PPIS survey was a joint project developed at the request of CMS by the AMA. This effort was developed and put into action with little interaction with the medical specialties that participate in the RUC processes and, to the best of our knowledge, was limited only to societies with representation on the AMA RUC.

The AMA has released data that raises more questions than answers. For example, AMA shared data that show fewer than half of cardiologists reported any costs for separately reported physician administered drugs. This significantly contrasts to known cardiology data which shows that more than 80% of cardiology practices provide myocardial perfusion imaging, which includes separate billing for the radiopharmaceutical element. In another example, in the PPIS survey it was reported that 23% of cardiologists surveyed had no clinical staff that can bill independently, meaning that they reported they employed neither a nurse nor a medical assistant. If, as CMS infers, this data is to be representative of practices across the country, we find it difficult to believe that one fourth of practicing cardiologists do not include a single nurse or medical assistant in their practice.

All affected medical specialties must have the opportunity to review and analyze the survey data obtained through the PPIS process. To date, we have not been provided the opportunity or appropriate level of detail needed to conduct a thorough analysis of the PPIS data. Inquiries to both the AMA and CMS seeking more detail regarding the analytical methods used in the PPIS process remain unanswered.

SCCT urges CMS to provide greater detail regarding the PPIS data and a solid description of the analytical methods used in analyzing the PPIS data.

Proposed Changes Do Not Reflect True Practice Expense

SCCT is aware of two outside sources of practice benchmarking data that substantiate and even exceed the cardiology supplemental survey data. Both MedAxiom and the Medical Group Management Association (MGMA) will share their data on the practice costs for their members over the past decade. The data show that cardiology practices had a substantial increase in practice expense in the late 1990s and early 2000s, and have had steady increases consistent with overall medical inflation since that time. A chart showing the total practice expense per physician over the last twelve years for MedAxiom practices is included as an attachment to this letter. SCCT suspects that the practice costs of the average cardiology practice would reflect similar patterns.

We urge the Agency to continue to accept the cardiology supplemental survey data submitted by the American College of Cardiology. This data was subject to rigorous precision criteria and represents a more accurate assessment of practice expense.

Incomplete and Inaccurate Data on CMS Website

SCCT found that Worksheet 2 and 3 (accessed 8/19/09 - [CMS MPFS website](#)) are inaccurate and reflect preliminary data. We called this to the attention of Agency staff to ensure they were aware that this incorrect data was posted for public review. CMS suggested that we contact the AMA for follow up to this concern. AMA however appeared unaware that the documents were posted to the CMS website. This creates enormous confusion when trying to compare and replicate data sources. The indirect practice expense per hour in the PPIS Worksheet 2, as released with the proposed rule, and the indirect practice expense per hour number in the Lewin Report do not match. This impedes the ability of interested persons to write fully informed comments on this issue during the open public comment period.

SCCT urges the Agency to correct the errors immediately and to extend the comment period by another two weeks. SCCT again urges CMS not to incorporate the PPIS data into the practice expense formula until all data and accompanying documents can be verified.

Poor Response Rates and Exclusion of Responses

From the limited data which we have been able to review, SCCT is very concerned that fully 2/3 of the responses received under the PPIS from the cardiology and radiology communities were excluded due to “error.” Also, 66.9 percent of the 56 accepted radiology responses were from radiologists who work solely in the hospital setting, meaning they bill only for the professional component and have no direct or indirect practice expense for the technical component. AMA and CMS have not provided adequate explanation to support the exclusion of so many responses. If the exclusion of the responses is warranted, such a high “error rate” is highly suspect, bringing into question the validity of the PPIS.

Throughout the PPIS process, the AMA tracked and reported on responses rates for all contributing specialties with two categories -- “incompletes” and “completes.” Yet, for the final calculations of the survey data, 2/3 of the responses received from the cardiology and radiology communities, previously identified as “completes,” were excluded from analysis. At no time was there an indication that a mass number of surveys would be excluded from the calculations.

SCCT respectfully recommends that CMS require a minimum response rate of $n = 100$ before using specialty specific data from the PPIS.

Survey Respondents

We believe the PPIS survey may be significantly skewed by the mix of facility and private practice respondents. In the PPIS, of the 55 completes for cardiology, 18 reported no staff or overhead costs. This is a suspect finding that may mean that teaching hospitals or other facilities represented a disproportionate number of survey respondents, thereby distorting true indirect costs for office based practices. We urge the Agency to separate responses by type and to conduct a separate analysis to calculate true indirect costs for office based practices.

Precision Testing Standards Not Met

SCCT believes that CMS should require the same precision criteria required for previously conducted and accepted practice expense data supplemental surveys. We do not understand CMS' rationale that because the PPIS is a contemporaneous, consistently collected and comprehensive multi-specialty survey, similar precision requirements are not necessary. It would seem the Agency should require the use of accurate precision testing criteria for any surveys it commissions.

Lengthy and Complexity of Survey

The PPIS Questionnaire included 93 items, and required at minimum 35 minutes to complete. We believe the length and complexity of the PPIS survey discouraged participation by private practitioners. Also, the four- page, 66 question PPI worksheet mailed to all candidates likely influenced the decision of a number of physicians not to participate in the survey due to the length and complexity implied by the volume of documents received.

Impact of New Data on Direct to Indirect Practice Expense Ratio

One issue of substantial importance not discussed in the rule is the impact of the new PPIS on the overall direct expense to indirect expense ratio. This ratio is used within the practice expense calculation to immediately reduce the payment for the calculated direct expenses of clinical staff, equipment, and supplies. The current methodology already immediately reduces the payment for direct expenses; the proposed implementation of the PPIS survey dramatically increases that percentage so that direct expenses are cut by 50%.

Step-by-Step Detail is Needed to Explain the Change between 2009 and 2010 RVU Rates

Due to the numerous changes being proposed for the 2010 RVU rates including the implementation of the final year of the four year transition to the "bottom-up" practice expense calculation methodology, the proposed implementation of the PPIS data and the proposed change in the equipment utilization rate, it is not possible to replicate how CMS arrived at the proposed RVUs for 2010.

SCCT respectfully requests that CMS provide detailed, step-by-step guidance to demonstrate how the Agency is arriving at the 2010 proposed RVU values.

The issues discussed above demonstrate that CMS should not have the confidence in this data to make such a dramatic readjustment in physician payment in a single year. We strongly encourage CMS to delay implementation of this proposal, fully engage all stakeholders and discuss with complete transparency the merits of the various data sources that are available for this information.

Alternatively, we urge the Agency to use data obtained from the supplemental survey process.

We urge the Agency to use data obtained from the supplemental survey submitted by the American College of Cardiology. This survey was subject to strict precision testing criteria and yielded a more robust response rate. Until there is further analysis and validation of the PPIS data, CMS should use the supplemental survey data.

Physician Administered Drugs

SCCT commends CMS for removing physician-administered drugs from “physician services” for the purposes of calculating the update under the SGR. We appreciate the benefit that this change will impart in 2011 and beyond.

Malpractice Relative Value Units (RVUs)

For 2010, CMS is proposing to update malpractice RVUs, specifically to alter policies relating to the valuation of technical component (TC) services. However, due to a lack of actual liability premium data for TC providers, CMS uses medical physicists’ malpractice premium data as a proxy. Upon looking at the proposed data for 2010, SCCT noted that the malpractice RVUs for the technical component of nearly ALL imaging services had been reduced to zero. We believe the proposal is unreasonable.

There is liability associated with the technical component of imaging services, a fact that CMS goes to great length to acknowledge in the proposed rule text. Within the cardiac computed tomography (CCT) setting, imaging centers bear the risks of lawsuits for adverse actions directly related to the liability of its employees in performing the TC. The majority of practices purchase umbrella liability policies to cover their imaging centers, as well as their staff, such as technologists and nurses. Umbrella liability policies provide necessary coverage to the practice and are purchased in addition to the physician's professional liability insurance policy. The cost of these umbrella policies is comparable if not greater than the premiums associated with professional liability insurance. By zeroing out this liability, physicians will not be able to sustain the growing costs of these coverage policies or the numerous others they carry (e.g., errors and omissions policies, property liability policies and general liabilities policies).

SCCT urges CMS to further study the types and costs of the various liability policies all physicians carry, especially those involved with medical imaging, prior to eliminating the technical component malpractice RVUs for the majority of imaging services. In addition, we respectfully request clarification from CMS on the disconnect between the rule text and the published tables.

Equipment Utilization Assumption

SCCT is strongly opposed to the CMS proposal to increase the equipment utilization rate assumption from 50 percent (25 hours per week) of the time a practice is open for business to 90 percent (45 hours per week). While we agree that CMS must make every effort to ensure the proper allowance of practice costs for equipment at the service level,

we continue to believe there are not adequate data to support the change proposed in the rule, particularly in the specific application of computed tomography.

First, SCCT notes that newly available Medicare data from 2008 show sharp reductions in the utilization of advanced diagnostic imaging services. Preliminary analysis indicates that growth in advanced diagnostic medical imaging is now in line with the rate of growth in other services provided under the Medicare program. Additional deep cuts in imaging, such as the proposed increase in the equipment utilization rate assumption from 50 percent of the times a practice is open for business to 90 percent, could serve to impede patient access to appropriate diagnostic imaging services.

Of major concern to SCCT is the fact there are currently no “actual data” on equipment use as required by federal law (and acknowledged by the Medicare Payment Advisory Commission (MedPAC) in the *MedPAC March 2009 Report to Congress*), to provide the Centers for Medicare and Medicaid Services (CMS) with an accurate determination of the amount of time that advanced diagnostic imaging equipment is in use. While it may not be accurate to assume that imaging equipment is in use 50 percent of the time, it is equally unrealistic to assume that equipment is in use 90 percent of the time (as stated in the MedPAC recommendation).

Of greater concern is the MedPAC statement that ‘CMS should establish a normative standard for expensive imaging equipment that is based on the level of use CMS wants to encourage.’ CMS should encourage the use of medical imaging when appropriate, and not determine “appropriateness” based on existing flawed and incomplete data on equipment utilization. As acknowledged by MedPAC, the study of imaging in six urban markets is not representative of the use of imaging in clinical practice across the country.

SCCT encourages CMS to establish a mechanism to work in consultation with stakeholders to collect accurate data before making significant policy changes in this area. We also encourage the Agency to collect data for all imaging modalities, not just those services that CMS described as advanced diagnostic imaging services. This could possibly be done through the CMS Office of Research or the Institute of Medicine. The proposed arbitrary reductions in practice expense reimbursement based on inaccurate data will only serve to limit patient access to care and does nothing to address inappropriate incentives.

Additionally, in its proposed rule, CMS stated “...Our understanding is that the PPIS survey did not produce information that can inform the utilization rate discussion” (pg. 63 NPRM 2010) However, on August 27, 2009, at the Agency’s request, AMA submitted to CMS a high-level overview of equipment utilization rate data from PPIS.

This data submitted was based on as few as 16 responses for some modalities and no detail was provided about indication for use (CT of head, chest, etc.) or site of service. The release of this data two business days prior to the close of a 60 day comment period is highly suspect and unacceptable. This data should not be included in any rule CMS implements for 2010.

Consultation Services

SCCT urges CMS to reconsider its proposal to eliminate the differential in payment between standard new patient office visit codes and consultation codes. This proposal disregards the additional training and expertise required of a consulting physician along with the additional intensity and time required to work with very sick patients with whom in many cases, no prior relationship exists.

Geographical Price Cost Indices (GPCI)

SCCT supports an extension of the 1.000 floor (authorized under the Medicare Improvements for Patients and Providers Act through December 31, 2009) to help ensure access to medical services in rural areas. While we recognize that Congress must act to extend the floor, we appreciate CMS' ongoing study of various options for revisions to payment locality structures. We look forward to future dialogue with the agency as this issue progresses.

Review of Potentially Misvalued Services under the Medicare Physician Fee Schedule

SCCT continues to support the role of the AMA RUC and its efforts to ensure accurate valuation of services under the Resource-Based Relative Value Scale (RBRVS). As CMS acknowledges in the proposed rule, the RUC has taken significant steps to refine and enhance the accuracy of the RBRVS, including the "rolling" 5-Year Review process that focuses on identification and review of potentially misvalued services.

The AMA RUC draws on the expertise of medical specialty societies and other health care professional societies in order to conduct extensive reviews to examine appropriate valuation of codes in the RBRVS system. Top CMS officials participate in the discussions at the RUC and Practice Expense Review Committee (PERC) before a valuation is recommended by the RUC and presented to CMS for vetting prior to publication in the proposed physician fee schedule for the following calendar year.

While the RUC process may benefit from some revisions, the creation of another advisory body to CMS would not appear to offer anything different than currently exists under the RUC structure or that could be available to CMS through the Practicing Physician's Advisory Council (PPAC). It appears that under the PPAC charter, the Secretary has the authority to define the services that PPAC shall consider in an advisory capacity to CMS. We encourage you to explore this mechanism as a meaningful and less duplicative way of gaining further review and assistance on potentially misvalued services.

The Medicare Payment Advisory Commission (MedPAC) acknowledged that an independent expert review panel would "increase demands on CMS and [we] urge the Congress to provide the agency with the financial resources and administrative flexibility to undertake them." SCCT does not believe that allocating scarce public financial resources to the creation of an independent "oversight group" to debate and/or duplicate the work already performed by the RUC is a prudent use of limited health care dollars.

Requirements for Accrediting Agencies

SCCT fully supports the ongoing implementation of the accreditation requirement for suppliers furnishing the technical component of advanced diagnostic imaging services, as mandated by the Medicare Improvements for Patients and Providers Act. Accreditation by independent entities, appropriate to the field of practice, is an important component of continuous quality improvement for all providers of diagnostic imaging services.

Accrediting Organization Criteria / Knowledge and Experience

SCCT encourages CMS to ensure that designated accrediting organizations document adequate experience in the accreditation of facilities providing advanced diagnostic imaging services. The agency might consider a minimum floor of experience that is required of potential designated accrediting organizations.

In addition, it is necessary for CMS to ensure that designated accrediting organizations utilize surveyors, clinical personnel, contractors and leadership with documented training and experience in the specific modality under review.

Evaluation of Image Quality

SCCT encourages CMS to require designated accrediting organizations to evaluate imaging quality as part of the accreditation process. Accreditation organization personnel must possess expertise specific to image acquisition, and interpretation for the imaging modality under review.

CMS Audits of Imaging Suppliers

CMS audits of imaging suppliers should be conducted by individuals with training and experience in the imaging modality under review. Agency auditors should also have a working knowledge of the designated accrediting organization's policies and processes, including but not limited to application for accreditation, audits, and site visits.

If CMS audits reveal deficiencies with an imaging services supplier, we encourage the agency to establish a mechanism for constructive dialogue with the designated accrediting organization in order to address problems and develop corrective action plans for the imaging services supplier and/or the designated accrediting agency.

SCCT appreciates the opportunity to provide comment to CMS on the provisions of the 2010 proposed physician fee schedule. We look forward to working together with CMS regarding the valuation of cardiac computed tomography and other diagnostic services under the Medicare Physician Fee Schedule. If SCCT may be of assistance as CMS continues to consider and review the 2010 Medicare Physician Fee Schedule, please do not hesitate to contact either Denise Garris at dgarris@scct.org or Carrie Kovar at ckovar@scct.org.

Thank you for your consideration,



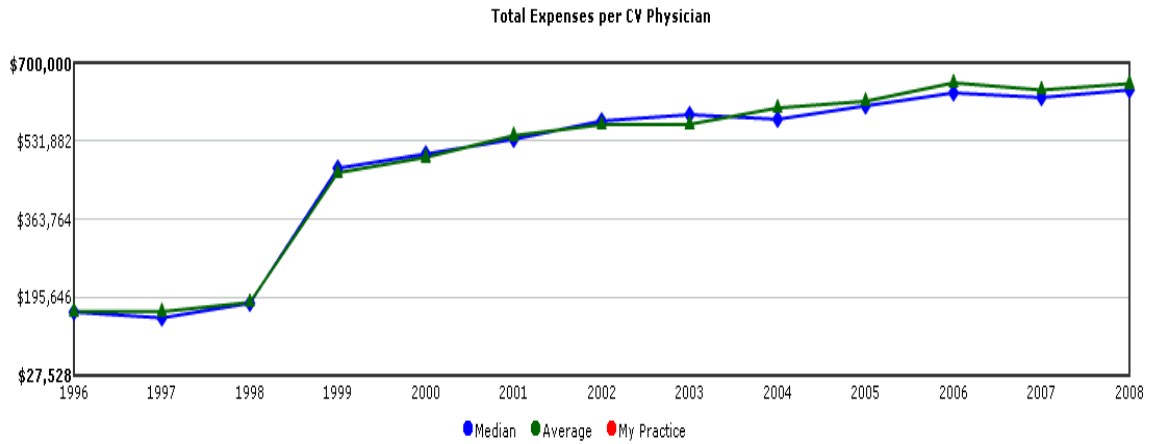
Jack A. Ziffer, PhD, MD
President
Society of Cardiovascular Computed Tomography

Attachment A – MedAxiom Benchmarking Data

cc: Ken Simon, MD, CMS
Rick Ensor, CMS
Pamela West, CMS
Ken Marselek, CMS
Cathleen Scally, CMS
Diane Milstead, CMS
Gaysha Brooks, CMS

an emergent specialty society with limited to no access to the American Medical Association's Relative Value Update Committee (RUC) processes. The PPIS survey was a joint project developed at the request of CMS by the AMA. This effort was developed

Attachment A MedAxiom Data



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
My Practice										
Average	\$462,698	\$496,254	\$542,942	\$566,914	\$567,672	\$602,463	\$616,923	\$656,974	\$641,236	\$655,313
Median	\$473,280	\$503,498	\$535,010	\$574,567	\$587,776	\$578,019	\$606,705	\$634,631	\$624,880	\$641,802

MedAxiom data shows total expenses have increased steadily since 1996 with the minor exception of a slight decrease (2 percent) from 2006 to 2007. Using the PPIS standard of 2,571 hours worked per cardiologist per year, the MedAxiom expense per hour in 2006 was \$247 at the Median and \$256 at the mean.