



September 29, 2005

Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1502-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule**

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, submits comments on the following areas of the "Revisions to Payment Policies Under the Physician Fee Schedule" published in the Federal Register on August 8, 2005.

- Multiple Procedure Reduction
- Nuclear Medicine Services
- Implementation of Practice Expense Data and Change in Methodology
- Malpractice RVUs
- Low Osmolar and High Osmolar Contrast Media
- NCS Timeframes

### **Multiple Procedure Reduction**

The American College of Radiology has reviewed the Centers for Medicare and Medicaid Services (CMS) proposal to extend the multiple procedure reduction to the technical component of diagnostic imaging procedures when more than one procedure is performed in the same session on multiple contiguous body areas. The ACR appreciates and agrees with CMS not proposing to apply a multiple procedure reduction to PC services because physician work is not affected for multiple procedures.

After lengthy review and careful consideration of this proposal, the ACR ***requests that CMS delay implementation of this multiple procedure reduction*** until this issue can be more thoroughly evaluated in several different areas. The ACR firmly believes that the issue is far too important to justify a hasty implementation for 2006. Not only is this concept novel and not fully vetted, but it will create a precedent for a methodology that

can be applied to any number of multiple procedure scenarios where economies in practice expense exist and as such may not be exclusive to imaging. Following are specific comments on the various elements of this proposal and the questions and the complexities it poses.

*Effects of the Implementation of the PEAC and Supplemental Survey Data*

The ACR is very concerned that the payment reductions that CMS proposes are based on inputs developed by the Practice Expense Advisory Committee (PEAC) which are just now being implemented. As James Borgstede, M. D., Chairman of the ACR's Board of Chancellors expressed to Congresswoman Nancy Johnson in his testimony before the House, Ways and Means Committee March 17, 2005, **implementing any multiple procedure reduction should be delayed until the resource-based practice expense inputs have been fully implemented and clearly defined.** The ACR has submitted both SMS-like supplemental data and code specific direct practice expense inputs (clinical time, supplies and equipment) for this process. Given that the 2006 Medicare Physician Fee Schedule will be the first year of a proposed four-year phase-in of this data and that CMS has now changed its methodology, the ACR firmly believes that code specific practice expense refinement issues must be resolved and implemented before the practice expense values can be considered for discounting.

*Same Session Versus Separate Sessions*

The ACR recommends that **CMS clarify how it will be able to determine when two diagnostic imaging procedures are done in the "same session" versus separate sessions.** In the eleven families in which CMS proposed to apply multiple procedure reductions, many examples exist which demonstrate that two procedures in the same family may be done on the same day but in separate sessions. In these instances, there are absolutely no economies in performance of these procedures. For example, a patient may have a breast ultrasound performed in the mammography center and later have a pelvic ultrasound in a different location in the same imaging center, where general ultrasound is performed. In these instances the patient has had two separate procedures in essentially two different sites but on the same day and same visit.

Likewise it is conceivable that the result of a possible aneurysm from a magnetic resonance imaging (MRI) of the brain may cause an emergent recall of the patient to return later in the day for an MRA of the head - again, the same day but a separate session. If "same date of service" is not used to define "in the same session", what parameter will be used and how will CMS and its contractors apply that parameter to electronic claims submission? If there is no mechanism to electronically distinguish claims for examinations performed at separate sessions versus those performed in the same session, **the ACR is concerned that physician payment will be unfairly discounted when no economies have occurred.**

*Fifty Percent Reduction*

The ACR agrees with CMS that there are some efficiencies in some of the procedures that CMS presented in the eleven families. However, after reviewing the direct practice expense (PE) input data for the clinical labor activities specified in the proposal, the ACR does not agree that all of those clinical labor activities are not performed twice when two procedures in a given “family” are performed. We therefore cannot agree that excluding those practice expense inputs is appropriate or provides support for a 50% reduction in the payment for the TC of subsequent procedures.

The ACR agrees that the clinical labor activities of greeting and escorting the patient, providing education, obtaining consent, setting up the IV and cleaning the room are not repeated for subsequent same session procedures. **The ACR disagrees with the assumption that, for all families and procedures listed, there is no duplication of clinical labor activities in retrieving prior exams, preparing the equipment, entering the patient data and positioning the patient.**

In all families, particularly those involving computed tomography (CT), MRI and magnetic resonance angiography (MRA), the number of diagnostic images required for review of prior exams has increased significantly. Therefore, the clinical labor time involved in retrieving, organizing and reviewing multiple prior exams is additive to the time involved for a single prior exam and, due to increased image volume, may involve more than twice the effort. Preparing the equipment, entering patient data and positioning the patient are also all repeated in performance of multiple procedures in the same session for most of the families.

Within Family 5, for example, when a brain MRI and neck MRA are performed in the same session on a Medicare beneficiary with a stroke, it is necessary to change from a head coil to a neurovascular coil before performing the MRA. This requires removing the patient from the magnet to physically change the coils. The coil must also be re-tuned, multiple new scan parameters must be entered into the scanner, the patient must be re-positioned in the magnet and an entire new set of pulse sequences must be run, occupying the equipment for at least as long as for the initial procedure. Many times, patients want to take a break and this also adds time to the procedure essentially simulating two entirely separate patients. Likewise, MRI of both extremities requires similar duplication of clinical labor and equipment time.

In Family 1, a patient who has a complete pelvic ultrasound, followed by a transvaginal ultrasound must be taken off the examining table, escorted to the toilet to empty her bladder and then repositioned on the examining table. The transabdominal probe must be detached and the transvaginal probe must then be prepared and inserted, often requiring an additional chaperone in the room, again simulating two separate patient exams. This total duplication of effort has been recently recognized by CMS in the restructuring of the OB ultrasound and pelvic ultrasound CPT codes. Also, in Family 1, in many practices,

breast ultrasound is not performed in the same location as pelvic ultrasound or by the same physicians. In those settings, all components of the procedure are duplicated.

As the above two general examples demonstrate, there is sufficient reason to question the validity of assumptions made by CMS in this proposed rule. The following discussion will provide some specific examples of the type of refinement that would be necessary before the proposal could be implemented.

- We agree with the CMS proposal for *some* reduction in the technical component for the following procedures:
  - All of the procedures in Families 2, 9 and 11
  - CTA of the head and CTA of the neck (CPT codes 70496 and 70498) in Family 3

Although bridging two families, we believe that MR angiography of the abdomen, MR angiography of the pelvis and MR angiography of the lower extremities (CPT codes 72198, 74185, 73725) would be associated with some efficiencies when performed together and as such we would endorse some payment reduction for the second or third procedure when performed together,

- other such family realignment may be necessary prior to implementation and the ACR would like to have some time to work with CMS on this realignment.
- We disagree with a 50% reduction in Family 1 for the reasons stated above.
- We disagree with a 50% reduction for most of the procedures in Family 3.
  - In contrast to Family 2, for each procedure in Family 3, patient positioning has to be changed and parameters for image acquisition must be changed as outlined in the example of MRI brain and MRA neck.
- We disagree with a 50% reduction for most of the procedures in Family 4.
  - For services in Family 4 there would typically be repositioning and changing the position of the body array coil, most of which are not large enough to cover multiple body areas.
- We disagree with a 50% reduction for most of the procedures in Family 5 but its clinical labor savings may be more than Family 4.
  - There is some duplication of clinical labor in the intra-service period for the following procedures because the same receiver coil is employed:
    - MRI orbits/face/neck (CPT codes 70540 – 70543)
    - MRI brain (CPT codes 70551 – 70553)
    - MRA head (CPT codes 70554 – 70546)
  - We would like the opportunity to discuss the level of reduction because it should not be as great as those in Family 2.

- We do not believe there are significant reductions in the clinical labor time for positioning for MRA neck (CPT codes 70547 – 70548) because this would typically require that the receiver coil be changed between examinations.
- There is some efficiency of clinical labor in the intra-service period for some of the services in Family 6 because the same coil is typically used for each examination; however, we disagree with a 50% reduction.
  - We would like the opportunity to discuss the level of reduction because it should not be as great as those in Family 2 but perhaps more than Family 4.
- There is some efficiency of clinical labor in the intra-service period for some of the services in Family 7 because the patient is not repositioned for each examination; however, we disagree with a 50% reduction.
  - We would like the opportunity to discuss the level of reduction because it should not be as great as those in Family 2 but perhaps more than Family 4.
- There is some efficiency of clinical labor in the intra-service period for some of the services in Family 8 and Family 10; however, we disagree with a 50% reduction.
  - Occasionally the same coil can be used for these examinations but most often different coils must be used to achieve the desired degree of coverage.
  - We would like the opportunity to discuss the level of reduction because it should not be as great as those in Family 2 and similar to Family 4.

*MedPac recognized that different modalities and different body areas would likely result in different levels of reduction for payment of the second and subsequent examinations within a family. The ACR also supports the MedPAC statements that: "The percentage reductions in payment for the second and third procedures may vary by modality because different modalities produce different efficiencies when done contiguously." and, "CMS should encourage physicians to review and comment on the edits before they are finalized, as the agency does with its CCI edits." We strongly agree with these statements and recognize that developing an accurate multiple procedure discount for imaging services requires more work than can be accomplished in the comment period for the proposed rule. We would like an opportunity to work with CMS and the PEAC data to better define the families and the appropriate level of reduction within each family.*

In conclusion, while the ACR agrees that there are some efficiencies in clinical labor activity when multiple imaging procedures are performed in the same session, we do not

agree that these efficiencies are uniform across all families nor do we agree that these efficiencies support a payment reduction as large as 50% in any of the families.

**The ACR recommends that CMS delay implementation of its proposal for Multiple Procedure Reduction to allow further analysis of the validity and impact of this complex and precedent-setting proposal; and, that CMS work closely with ACR and other stakeholders in the process of further analysis.**

### **Nuclear Medicine Services**

The American College of Radiology appreciates and supports CMS' proposal to amend § 411.351 to include diagnostic nuclear medicine services including PET and therapeutic nuclear medicine services as "designated health services" (DHS). We agree that this proposal is consistent with the intent of the Congress to prevent over-utilization of health care services covered by Medicare and to prohibit physicians from selecting treatment modalities based on financial incentives. We are pleased that CMS has recognized diagnostic and therapeutic nuclear medicine services within the DHS categories of "Radiology and Certain Other Imaging Services" and "Radiation Therapy Services and Supplies". Radiologists certified by the American Board of Radiology (ABR) perform and interpret the vast majority of nuclear medicine studies done in the United States. These physicians acquire competency in the practice of nuclear radiology within the standard diagnostic radiology training program with a federal regulation defining the minimum number of hours of basic science and clinical training. The written and oral ABR examinations, which represent the fundamental competency-based tests for radiologists, have an integral section dedicated to nuclear medicine.

**The ACR also supports the CMS statement that physician-investors in nuclear medicine equipment (including PET scanners) will be required to divest their ownership or investment interests in joint ventures that involve nuclear medicine DHS referred by physician-owners that do not meet a Stark II exception.** The ACR believes this statement to be consistent with CMS' long-standing position that immediate divesting by physician-investors is required for any services identified as DHS. Since many of these arrangements have been in place for years, in order to minimize the impact on physicians who are currently parties to such arrangements, **the ACR recommends an effective date of January 1, 2006 with a one-year grace period prior to enforcement. The ACR does not support grandfathering because it would essentially negate the intent of this proposal.**

### **Implementation of Practice Expense Data and Change in Methodology**

The ACR appreciates CMS' careful consideration of the issues surrounding the potential instability of the TC values in the non-physician work pool and its attempt to find an acceptable method to permanently settle these codes into the MPFS using the PEAC data.

Using the bottom-up methodology certainly seems to be a simpler and easier way to make the transition with minimal impact. However, there are a few areas of this proposal that need clarification.

***Practice Expense Per Hour Figures***

The ACR appreciates CMS’ printed correction of the overall hourly rate and specific rates for the six cost pools for the radiology and radiation oncology supplemental data in the September 1, 2005 Federal Register. The ACR requests a detailed explanation, in the final rule, of the methodology which resulted in a significant discrepancy between the Lewin Group report PE/hr and the CMS proposed PE/hr for some specialties and not for others. CMS has apparently agreed with the Lewin report data for Urology, Dermatology Allergy/Immunology and Gastroenterology but has reduced the Lewin report PE/hr for Radiology, and Radiation Oncology by approximately 14%. The table below outlines the comparative data in question.

**PRACTICE EXPENSE PER HOUR FIGURES**

Specialty	CMS Clinical staff	Lewin report	CMS Admin. Staff	Lewin report	CMS Office expense	Lewin report	CMS Medical supplies	Lewin report	CMS Medical equipment	Lewin report	CMS Other	Lewin report	CMS Total	Lewin report
Radiology	22.8	26.57	29.7	34.63	18.8	21.94	8.8	10.28	21.4	24.96	35.2	41.04	136.7	159.41
Cardiology	46.7	44.38	41.8	40.67	41.3	52.96	20.3	18.81	14.6	13.96	19.6	19.52	184.3	190.30
Radiation Oncology	39.0	45.47	20.4	23.82	31.1	36.32	3.8	4.42	21.7	25.32	22.0	25.73	138.0	161.08
Urology	26.3	same	39.9	same	50.7	same	13.6	same	10.6	same	22.1	same	163.2	same
Dermatology	38.3	same	48.5	same	74.3	same	14.5	same	10.4	same	26.6	same	212.5	same
Allergy/Immunology	62.1	same	53.1	same	62.1	same	21.2	same	5.9	same	29.3	same	233.7	same
Gastroenterology	27.6	same	36.2	same	44.3	same	7.5	same	5.4	same	12.2	same	133.2	same

When ACR’s contractor calculated radiology’s expenses in 2002 dollars, it estimated \$195 per physician hour (the average sum of six). When a deflator of 18% is applied to this figure it reduces the amount by \$35 to a total of \$160. While the \$136 is better than the \$96 in the original table 14, it is still lower than what ACR’s contractor calculated, and lower than Lewin’s recommended \$159.41. The ACR would like clarification on how CMS applied the deflators to the practice expense per hour figures and to confirm that CMS did not blend this new data with the old SMS data. The ACR would like to ensure fairness that all data is being evaluated and scaled uniformly.

*Budget Neutrality*

The ACR requests that once the PE RVUs are established and fully implemented that any further budget neutral adjustments be made in the formula for the conversion factor. Adjustments to direct practice expense inputs should not be adjusted for budget neutrality within the specialty pool since direct practice expense is being converted to a “bottom up” methodology across all of medicine.

*Proposed 2009 Fully Transitioned Practice Expense Values*

The American Medical Association (AMA) circulated the proposed 2009 transitioned practice expense values received from CMS to RUC participants. The ACR compared the technical component of radiology CPT® codes between the 2005 values and the proposed 2009 transitioned values. The calculations show a wide range of reductions and increases for radiology codes. Fully transitioned RVUs proposed for 2009 range from a -81% RVU reduction for peripheral CT bone density code 76071-TC to a +198% increase in RVUs for CT scan for localization code 76355-TC. The new practice expense methodology should provide more consistent RVU assignment across all radiology procedure codes. **The ACR is very concerned with this wide range of variability in practice expense values in all modalities and seeks explanation and additional information from CMS on how the fully transitioned values were calculated. The ACR appreciates and strongly supports the four year transition period.**

**While we acknowledge that the methodology for the charge based PE calculations for radiology PE in the past were dated and difficult to verify in a resource based environment, we also believe that the relativity between codes was thoughtfully developed. We encourage CMS to look at the outliers, such as those but not limited to those described above, with scrutiny so that rank order anomalies are not created in a process whose goal is to refine relativity to a cost based system. The ACR will provide comments on a code by code basis to address these potential anomalies and is hopeful that CMS will be cooperative in supplying information on how the new values were calculated.**

**Miscellaneous Practice Expense**

*Tumor Image PET and PET/CT Codes*

In Transmittal 475 published on February 11, 2005 CMS assigned non facility practice expense values to the -26 line of the MPFS to the PET and PET/CT codes 78811, 78812, 78813, 78814, 78815, 78816, 78491, 78492, 78608, and 78609. In the 2006 proposed rule, CMS assigned zero non facility practice expense values for these codes. Clearly there is practice expense for performing these exams in the “non-facility” setting. **The ACR recommends that CMS reassign the non facility practice expense values to these codes.**

*Practice Expense Recommendations for Codes 76975 and 78350*

In the proposed rule, CMS states that PERC/RUC recommended no inputs be assigned to codes 76975 in the office setting. The ACR agrees with this recommendation and recommends that CMS accept PERC/RUC recommendations to not price code 76975 in the office setting as virtually all of the exams are performed in a facility setting. However, for code 78350, the ACR recommends that CMS not accept PERC/RUC's recommendation as there is practice expense in the office setting. The ACR will work with CMS to provide appropriate practice expense for code 78350.

*Table 19: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions*

The ACR appreciates CMS's effort to obtain correct pricing information for the medical equipment listed in Table 19. CMS requested detailed description, source, and current pricing information for the densitometry unit, whole body, SPA. The ACR wants to assure CMS receives correct and current pricing information and has checked with various manufacturers on this item. We found that this equipment item is no longer being built and accordingly, there is no additional information to submit at this time.

*Equipment Cost Calculations*

The ACR strongly supports SIR's recommendations that CMS' equipment cost calculations for interventional radiology 74XXX and 75XXX CPT codes reflect total procedure room time, not just pre- and post- procedure room time.

The ACR believes that the application of all direct inputs be consistent with RUC/PEAC actions with respect to direct inputs for other procedures especially under the newly proposed bottom-up methodology.

*Imaging Rooms*

The ACR appreciates CMS willingness to work with the College to ensure that appropriate cost and equipment items are assigned to various imaging rooms. In the mammography room, the ACR listed mammography cassettes as one of the items found in the room. A mammogram cannot be performed without using multiple cassettes. **Accordingly, the ACR recommends that CMS recognize mammography cassettes in a standard mammography room although they do not meet the \$500 threshold that exists for individual items.**

**Malpractice RVUs**

In the proposed rule, CMS states, “we are concerned that the malpractice RVUs could be inappropriately inflated or deflated due to aberrant data based upon incorrectly reported specialty classifications. CMS proposes to use the 5 percent threshold to eliminate specialty performing less than 5 percent of the procedure in calculating the malpractice RVU. The ACR is concerned that this 5 percent threshold will inappropriately remove some specialties performing radiology codes, especially interventional radiology services. The ACR supports SIR’s recommendation for CMS to calculate the malpractice RVUs based on 1 percent and not the 5 percent threshold.

### **Low Osmolar and High Osmolar Contrast Media**

The ACR appreciates CMS’s decision to pay separately for high osmolar contrast and agrees to the removal of the contrast agents only from the practice expense inputs that were presented to the PEAC and approved by the RUC.

### **PET/CT Coding**

In the interest of insuring accurate payments when PET/CT and a diagnostic CT(s) are performed for a patient on the same day, we look forward to having a more substantive conversation with CMS after the comment period is over.

### **NCD Timeframes**

CMS proposes to implement a 30-day comment period and eliminate the reference to the 90-day implementation for the national coverage process time-line. The ACR supports CMS decision to implement a 30-day comment period prior to implementation of any national coverage decisions.

### **Conclusion**

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or regarding radiology and radiation oncology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at [achoe@acr.org](mailto:achoe@acr.org).

Respectfully Submitted,

[Endorsed Copy to Follow]

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