Via Courier

September 24, 2004

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
File Code: CMS-1429-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for calendar year 2005; Proposed Rule

Dear Dr. McClellan:

The American College of Radiology (ACR) represents over 32,000 Radiologists, Interventional Radiologists, Radiation Oncologists, Nuclear Medicine physicians and Medical Physicists. We appreciate the opportunity to comment on the August 5, 2004 proposed rule on revisions to payment policies under the physician fee schedule for calendar year 2005 (42 CFR 405, 410. 411 et. al.). Specifically, the ACR will comment on the following issues:

- Low Osmolar Contrast Media (LOCM)
- Professional Liability Insurance Relative Value Units (RVUs) (Malpractice RVUs)
- Payment for Initial Preventive Physical Examination, Malpractice RVUs (Section 611 and Malpractice RVUs)
- Coding Issues and the Change in Global Period for CPT Code 77427, Radiation Treatment Management, Five Treatments (Coding-Global Period)
- Coding for Brachytherapy Sources under Medicare Part B in the Physician Office and Freestanding Radiation Oncology Center
- Revisions to Reassignment Provisions (Section 952)
- Bone Marrow Aspiration (Coding-Bone Marrow)
- Venous Mapping for Hemodialysis
- Cardiovascular Screening Blood Tests (Section 612)
- Coverage for Routine Costs for Category A Clinical Trials (Section 731(b))
- Practice Expense
- Medicare Payment Update

Low Osmolar Contrast Media

The ACR applauds CMS’s proposal to eliminate the restrictive criteria for payment of low osmolar contrast media (LOCM). This decision will help to assure that all Medicare beneficiaries have access to this more efficient, higher quality and safer contrast material. The ACR greatly appreciates CMS’s time and attention to this important matter and strongly encourages CMS to finalize this proposal in its final rule.

Finalization of this important proposal will assure that effective January 1, 2005, separate payment for LOCM is established for all Medicare patients requiring enhanced images. It will further promote high quality care in the Medicare system and may help to assure consistency in Medicare payments across multiple clinical settings. The ACR also requests that CMS maintain the existing HCPCS codes used to bill for LOCM (i.e., A4644, A4645
and A4646) and ensure stabilization of payments as this expanded coverage is being introduced at the same time as expanded coverage of other types of drug as mandated by the MMA.

**Professional Liability Insurance Relative Value Units (RVUs)**

*Malpractice RVUs for Non-Physician Work Codes:*

In terms of methodology, the ACR is concerned by CMS’s approach to develop resource based malpractice RVUs. CMS proposes to use the physician work RVUs to adjust for risk-of-service and therefore creates an additional, non-physician work pool (NPWP) situation for those codes with no physician work (primarily technical components of diagnostic tests). **The ACR believes that this CMS proposed methodology is inappropriate and maintains that CMS should not apply a concept used in the practice expense methodology to the development of resource based malpractice RVUs.** The use of physician work RVUs to adjust for risk of service creates a NPWP situation and is not the best approach. One option to consider is the use of Physician Insurers Association of America (PIAA) data on the frequency of malpractice claims filed, settled and adjudicated, categorized by type of medical procedure involved, rather than using physician work alone. **The ACR respectfully requests that CMS re-evaluate this proposal and develop appropriate malpractice RVUs in a manner that does not apply the practice expense methodology.**

The ACR strongly encourages CMS to implement a solution for developing resource based malpractice RVUs for non-physician work codes during a public comment period and notice of proposed rule making process (NPRM). **The ACR requests that CMS not automatically implement a solution to this issue through publication of a final rule, even if the administration receives suggestions in response to this proposed rule.** As expressed by the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) comment letter, the overall malpractice RVU methodology is fraught with numerous problems. These overarching concerns must be resolved. This NPWP issue is a new dynamic in the overall methodology and specialty societies must have an opportunity to further consider this complex issue, discuss the implications and resolutions with CMS prior to any implementation of a permanent fix. **The ACR welcomes an opportunity to discuss this with CMS as part of our continued interaction on the overall NPWP issue.**

*Disproportionate Allocation of Malpractice RVUs:*

Of more fundamental concern are the conflicting messages and methodology that CMS applies when developing malpractice RVUs. Currently, there is an imbalance between the distribution of malpractice RVUs to the Professional Component (PC) and Technical Component (TC) of a service. The ACR has commented on this imbalance over the course of the 2004 rule making process as CMS’s rebasing and revising of the Medicare Economic Index (MEI) further exacerbated this problem. The rebasing and revising of the MEI initiated a redistribution of value from the physician work and practice expense (PE) RVUs to the malpractice RVUs. When this occurred, the majority of the malpractice value, and the increase in this value, took place on the TC side of a service at the expense of the PC side. As outlined in our previous comments on the Medicare physician fee schedule, the ACR strongly disagrees with this disproportionate distribution of malpractice reimbursement to the TC over the PC.

Evidence shows that physicians have been most affected (as opposed to hospitals) by their increase in professional liability rates. CMS reinforces this in the 2005 proposed rule when explaining the specialty-weighted approach for calculating malpractice RVUs for each code. Specifically, on page 47509 of the rule, CMS explains how the specialty-weighted malpractice RVU was multiplied by the procedure’s work RVUs to account for difference in risk-of-service. CMS explains their use of work RVUs since other acceptable data sources for determining risk of service were not available. **This**
47509, the ACR formally queries how CMS can justify diverging from this theory when allocating more malpractice reimbursement to the TC of a service, which includes no physician work, than to the PC of the same service. The ACR remains extremely concerned by the inappropriate allocation of malpractice reimbursement to the TC of a service as compared to the PC. As this is a complex methodology issue, the ACR requests ongoing dialogue and a meeting with CMS to further investigate, explain and discuss solutions for this troubling methodological inconsistency.

Rescaling for Budget Neutrality:
The ACR reiterates its request that CMS apply budget neutrality adjustments to the Conversion Factor (CF) rather than at the individual relative values at the code level to assure a true resource based system. Additional new money needs to be added into the Part B system in order to meet the goal of a truly resource based system that compensates physicians fairly and appropriately through higher values for the increased costs incurred in higher physician liability rates. In the instance, that new money will not appear in the system to fund this effort; the ACR recommends that the budget neutral adjustment take place in the conversion factor.

“Section 611” and “Malpractice RVUs”
Payment for Initial Preventive Physical Examination, Malpractice RVUs and Specific Concerns Related to Screening Mammography Malpractice RVUs

CMS proposes to establish a new G code for initial preventive examination and proposes to assign this G code 0.13 malpractice RVUs in the non facility setting based on the malpractice RVUs currently assigned to CPT code 99203 (0.10) and CPT code 93000 (0.03). In the facility setting, CMS is proposing malpractice RVU of 0.11 based on current malpractice RVUs assigned to CPT codes 99203 (0.10) and 93010 (0.01). The ACR would like to point out that the proposed malpractice RVU for this initial preventive screening exam is substantially higher than the malpractice RVU allocated to screening mammography, which is widely recognized as the highest-liability risk of all imaging procedures. The ACR requests that CMS provide for procedure specific consideration and re-evaluate the severely low malpractice RVUs assigned to screening mammography.

The professional component of screening mammography (CPT code 76092) has a malpractice RVU of .03 and the technical component of mammography has a malpractice RVU of .07. Mammography has significant professional liability and malpractice premiums associated with the service and should receive malpractice reimbursement at a rate at least comparable to that of the initial preventive screening exam. In addition, professional liability associated with screening mammography clearly places the expense, risk and onus on the physician so the PC malpractice reimbursement should appropriately reflect this.

The ACR raises this point to again demonstrate the clear issues with the current malpractice RVU methodology that does not allow for capturing specific high malpractice rates for individual procedures. This flawed methodology also results in inequities of malpractice reimbursement and disproportionate distribution of malpractice reimbursement to the TC over the PC. The ACR requests that CMS re-evaluate the malpractice RVU assigned to screening mammography and the redistribution of this RVU to the PC and the TC.

Please see an additional comment on mandated coverage of an initial preventive physical examination in the below section on the Sustainable Growth Rate (SGR).

Coding Issues and the Change in Global Period for CPT Code 77427, Radiation Treatment Management, Five Treatments
When first implemented in 2000, this procedure (CPT code 77427) was given an ‘xxx’ global period (i.e., no global period) designation. After five years of established Medicare policy and billing protocols associated with this CPT code based on the ‘xxx’ global period designation, CMS is now proposing to change the global period for this code from an ‘xxx’ global period to a global period of 90 days. The ACR acknowledges that follow up (evaluation and management) services for 90 days are included with a course of radiation therapy as per established CMS policy (Medicare Claims Processing Manual, Radiology Services and Other Diagnostic Procedures). Changing the global period, however, will result in code 77427 itself being denied. Since a course of radiation therapy consists of many weeks of treatments, with 77427 claims being submitted in series, a 90-day global period does not allow for, nor reflect, the process of care for radiation therapy.

The ACR is very concerned by this potential definition change for a code that affects the care provided to all patients undergoing radiation therapy. Any change in this global period will have significant ramifications for the process of care for radiation oncology and must be carefully considered before implementation.

The ACR requests that CMS maintain the ‘xxx’ designation for 77427 and further discuss any possible change to the global period for this code at the RUC prior to implementation of any change.

**Coding for Brachytherapy Sources under Medicare Part B in the Physician Office and Freestanding Radiation Oncology Center**

Physicians in the office/freestanding setting use CPT code 79900, provision of therapeutic radiopharmaceutical(s) to bill for brachytherapy sources. Unfortunately, rather than revising the descriptor of this code as was requested by the ACR, American Society for Therapeutic Radiology and Oncology (ASTRO) and the Society of Nuclear Medicine (SNM), the CPT Editorial Panel decided to delete this CPT code with an effective date of January 1, 2005 on the basis that supplies are more appropriately billed under a HCPCS Level II code.

Accordingly, the ACR requests that CMS reinstate and allow physicians in the free standing and/or physician office setting to bill HCPCS code Q3001 (radioelements for brachytherapy, any type, each) for brachytherapy sources. CMS should be aware that Q3001 is currently not active for use under the Medicare physician fee schedule and Medicare policy specific to the HCPCS code references code 79900 as the appropriate code for billing brachytherapy sources. Accordingly, CMS must activate this HCPCS code (Q3001) under the Medicare physician fee schedule, update its policy and educate its contractors appropriately. CMS should maintain current pricing and reimbursement for brachytherapy sources when providers bill this reinstated level II HCPCS code. Should CMS deviate from the current pricing structure, the ACR requests that CMS work with the ACR and ASTRO to assure appropriate reimbursement for brachytherapy sources.

The ACR requests that CMS encourage its Medicare Part B contractors to work with the ACR and the ACR Radiation Oncology Carrier Advisory Committee (CAC) Network to update the appropriate Local Coverage Decisions (LCDs) and educate the provider community.

**Section 952**

**Revisions to Reassignment Provisions**

Section 952 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) liberalized the reassignment of benefits rules. However, the ACR believes that CMS’s discussion of reassignment in this proposed rule is vague and requires further explanation.
As outlined in this proposed rule, prior to enactment of section 952 of the MMA, Medicare only allowed the reassignment of payments for services provided by an independent contractor physician or nonphysician practitioner if the services were performed on the premises of the facility or healthcare delivery system. Therefore, CMS did not permit reassignment of payments for services that were furnished offsite. In section 952, the Congress directed CMS to allow Medicare contractors to pay for claims submitted by billing companies or entities for services provided by independent contractor physicians or non-physician practitioners regardless of where they provided those services, thus the services may be provided on or off the premises of the entity receiving the reassigned payments. In its February 27, 2004 Transmittal 111 that implemented section 952 of MMA, CMS did not specifically address the methods of rendering off-site services. The ACR requests that CMS clarify its definition of on-site and off-site services.

In this section of the proposed rule, CMS also appears to reaffirm its statement in Phase I of the Stark self-referral regulation and reiterate the existing self-referral restrictions on providing services at the site where the study is obtained. The ACR understands that CMS does not wish independent contractor physicians or facilities to misuse the more flexible reassignment process and circumvent the Stark regulatory boundaries. The College supports CMS’s efforts to ensure program integrity through the self-referral regulations and further supports CMS’s caution that “parties should be mindful that contractual arrangements involving reassignment might not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals”.

However, the ACR requests that CMS further explain what “potential program vulnerabilities” the revised Medicare reassignment exceptions might create. ACR members and other physicians that are realigning contractual arrangements to meet those exceptions should understand the specific concerns that CMS has about reassignment and any additional program integrity safeguards it might develop. The ACR stands ready to work with CMS on this clarification.

Coding, Bone Marrow Aspiration (Coding-Bone Marrow)

In this rule, CMS proposes to create a new ‘add-on’ G code, G0XX1 (bone marrow aspiration performed with bone marrow biopsy through same incision on same date of service), to be used when a bone marrow aspiration and a bone marrow biopsy are performed on the same day through a single incision. Currently, such a scenario would be coded and reported with CPT codes 38220 (Bone marrow; aspiration only) and 38221 (Bone marrow; biopsy, needle or trocar). CPT codes 38220 and 38221 have physician work value of 1.08 and 1.37, respectively. When these two codes are performed on the same patient, by the same physician, and on the same day, the multiple procedure payment rules would apply so that the highest valued code (i.e., 38221) would be reimbursed at 100 percent and the lesser-valued code (i.e., 38220) at 50 percent. The ACR is concerned with CMS’s proposal to create a G-code to replace CPT code 38220 with a physician work value of 0.16. The ACR recommends that CMS not create a G code and use the existing CPT code 38220 to report this service. However, if CMS decides to create this G code for tracking purposes, the ACR recommends CMS to assign a physician work value to the G code that is consistent with reimbursement with code 38220.

Venous Mapping for Hemodialysis

CMS is proposing to create a new G code (GOXX3) for venous mapping for hemodialysis access placement. CMS indicates that this code should be used to report services performed by the operating surgeon for preoperative venous mapping prior to creation of a hemodialysis access conduit using an autogenous graft. CMS further indicates that creation of this code will enable distinction between CPT code 93971 (duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study) and GOXX3. The ACR requests clarification from CMS as to which code (i.e. 93971 or GOXX3) should be
direction to access the fistula for intervention. This proposed rule specifically states, “this G code would only be billed by the operating surgeon in conjunction with the following CPT codes: 36819, 36821, 36825 and 36832.”

If Radiologists are not permitted to use this G code, they must be allowed to use existing CPT codes to report and bill their services in this regard.

Section 612

Cardiovascular Screening Blood Tests:
Section 612 of the MMA provides Medicare coverage of cardiovascular screening blood tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease. The MMA also authorizes the Secretary to approve coverage of other screening tests for other indications associated with cardiovascular disease or an elevated risk for that disease. The CMS proceeds to invite comments about these types of tests from a variety of medical and specialty societies. The ACR requests that CMS include both the American College of Radiology and the Society for Interventional Radiology (SIR) on this list of physician organizations and consult with both the ACR and SIR when contemplating approval for coverage of other screening tests associated with cardiovascular disease.

Coverage for Routine Costs for Category A Clinical Trials (Section 731(b))

The ACR supports CMS’s efforts to implement section 731(b) of the MMA to allow coverage of routine care services related to a Category A (i.e., experimental/investigational devices) clinical trial. Please see an additional comment on this newly mandated coverage of routine care services related to clinical trials in the below section on the SGR.

Practice Expense

Supplemental Practice Expense Surveys:
The ACR is pleased that CMS has accepted, per The Lewin Group’s recommendation, the ACR’s radiology practice expense supplemental data collected this previous year. The ACR also appreciates CMS’s concurrence with our suggestion to defer implementation of the ACR data to allow time for the College to work with CMS to achieve a more stable and global solution that is workable for all specialties that are currently reimbursed from the NPWP.

The ACR appreciates CMS’s efforts to maintain the NPWP and all radiology and radiation oncology payments stable for 2005. The ACR supports CMS’s efforts in this regard, as it would not be appropriate for specialties and codes remaining in the NPWP to be reduced based on withdrawal of other codes from that pool when there is no data to indicate that the practice expenses of codes remaining in that pool have decreased due to the withdrawal of another specialty. The ACR submitted data does demonstrate a higher practice expense per physician hour value for radiology procedures and if necessary, we suggest that this hourly rate be used to keep the payments stable in the NPWP for 2005.

The ACR appreciates the recent opportunity to discuss the radiation oncology practice expense supplemental data with CMS. As this data was not accepted by CMS on methodology grounds including insufficient precision, the ACR will continue to work in conjunction with ASTRO and our contracted consultant, DOANE Marketing, to further evaluate the survey results, conduct follow up questions or data collection, and ultimately achieve acceptable data for CMS to utilize when resolving issues surrounding the NPWP. The ACR looks forward to continued discussions with CMS and The Lewin Group regarding this radiation oncology data and our additional attempts to refine it.
The ACR remains committed to actively engaging CMS in discussions regarding the NPWP and in developing a stable and global solution for this temporary pool. The ACR request that CMS continue a dialogue with the ACR on these issues and on the use of the radiology supplemental practice cost data in 2006.

**Parathyroid Imaging, Current Procedural Terminology (CPT®) code 78070:**
In our comments on the Medicare physician fee schedule for 2004 final rule, the ACR requested that CMS re-review the crosswalks used to determine the practice expense for CPT codes 78070 and 78804 (tumor imaging, whole body) to ensure that they properly reflected the number and length of the imaging sessions required to complete these procedures. The ACR appreciates CMS’s proposal in this notice of proposed rule making, to crosswalk CPT code 78070 to CPT code 78306 (bone and/or joint imaging, whole body) instead of CPT code 78804. The ACR encourages CMS to finalize this recommendation.

**Radiopharmaceutical Receiving Areas:**
In a methodology change, CMS will no longer use a “room” designation for radiopharmaceutical receiving areas, but rather will separately price each piece of equipment necessary for each procedure as individual line items since there is no standard configuration for such a room. The ACR concurs with this recommendation and will work in coordination with the SNM to assist CMS in collection of such cost information.

**Pricing for Seldinger Needle:**
The ACR concurs with the CMS proposed pricing of this supply item at $5.175. The ACR agrees with the reference to “Seldinger” needles, as this is the most common type of device used.

**Table 2: 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 2. The ACR wants to assure CMS receives correct and current pricing information and accordingly will continue to investigate and communicate with CMS in this area. Obtaining the cost, source and documentation information requested by CMS for each of these equipment items is a difficult and laborious task, as this information and more specifically, documentation on such pricing, is not readily available. The ACR will continue to work with CMS to obtain the correct pricing information for the items listed in Table 2 and requests an extension to allow additional time to collect and submit this information.

Enclosed in Attachment 1, please find new price information and documentation for the computer assisted detection (CAD) processor unit ($240,000), computer workstation for MRA post processing ($60,000), and mammography reporting software ($35,000).

In addition, in Attachment 2, please find new price and equipment information for the mammography room.

**Addendum C: Codes for which CMS received PEAC Recommendations on Practice Expense Direct Cost Inputs.**
The ACR appreciates CMS’s continued efforts to implement direct practice expense inputs as collected through the Practice Expense Advisory Committee Process (PEAC) and to assure CMS does so in an open and public process. Along these lines, the ACR would appreciate an explanation of the formula and methodology that will be utilized by CMS to incorporate these inputs into the practice expense...
reimbursements. In our review of CPT codes listed in Addendum C (i.e., codes for which CMS received PEAC recommendation on practice expense direct cost inputs), we have identified additional codes that are not included in this addendum, which however have gone through the PEAC process. The ACR recommends that these codes be added to this addendum. Please refer to Attachment 3 for the list of codes.

Addendum D: Proposed Changes to Practice Expense Equipment Description, Life, and Pricing. The ACR appreciates CMS sharing the proposed equipment costs for 2005. The ACR does not agree with the proposed room price for Magnetic Resonance Imaging (MRI) and Computed Tomography (CT). The ACR will continue to work with CMS to obtain the correct pricing information for these items and requests an extension to allow additional time to collect and submit this information.

Medicare Payment Update and the Sustainable Growth Rate Formula (SGR)

The Sustainable Growth Rate (SGR) formula takes into account four different variables including: the number of Medicare beneficiaries, physician services, the Gross Domestic Product (GDP) and changes in law and regulations. As indicated in the proposed rule, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) mandated coverage of an initial preventive physical examination under Part B for new Medicare beneficiaries. This is a much-needed new benefit for the United States elderly population, and is a clear change in law and regulation, which will result in additional expenditures for physician services. Accordingly, this change in coverage, brought about by the MMA of 2003, must be assessed and accounted for in the SGR formula to avoid inequitable impacts on the physicians who provide care to Medicare beneficiaries.

Similarly, Section 731(b) of the MMA mandated coverage for the routine costs of care furnished to a Medicare beneficiary participating in a clinical trial of a Category A device. Accordingly, this newly mandated coverage benefit would also fall under a change in law and regulation and should also be assessed and accounted for in the SGR formula.

In addition, Section 614 of the MMA contained language-requiring CMS to remove diagnostic mammography, when performed in the outpatient hospital setting, from the outpatient prospective payment system (OPPS), and reimburses it instead under the Medicare fee schedule. The ACR understands that while the TC reimbursement for diagnostic mammography performed in the hospital outpatient setting will be reimbursed under the corresponding MFS payment rate, the funds for this service are obtained from the OPPS fund. In other words, the ACR understands the dollars required to reimburse the technical component of diagnostic mammography in a hospital outpatient setting will not come from the Medicare physician fee schedule Part B funds. The ACR requests confirmation from CMS that this understanding is correct and therefore this change would not impact the SGR formula.

With an aging Medicare population, these services will increase the volume of physician visits over time. The increase in volume of services can cause a decrease in the SGR, which could lead to lower Medicare physician updates and thus, lower reimbursement. It is critical that CMS recognize the effect of these new screening services covered under MMA, assure that they are not subject to budget neutrality (i.e., as they are a change related to the MMA), and allocate additional money to Part B in order to accommodate this additional coverage and corresponding increase in the volume of services. Doing so will ensure that these new services do not have a negative impact on the SGR.

The ACR is very much interested in the SGR formula and its effects on the update and will continue to work with CMS and policy makers to come up with a long-term solution in this area.
Thank you for the opportunity to comment on this proposed rule. The ACR is always available to assist you or your staff on items mentioned within the context of this letter or with other issues/questions related to radiology and radiation oncology. Please contact Rachel Kramer at 1-800-227-5463 ext. 4559 or via email at rachek@acr.org with questions.

Respectfully Submitted,

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Chairman, Commission on Economics
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