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

Subject: **Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2010; Proposed Rule**

Dear Ms. Frizzera:

The American College of Radiology (ACR), representing more than 37,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, is pleased to submit comments on the notice of proposed rulemaking (NPRM) "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2010" published in the *Federal Register* on July 13, 2009. We will address the following issues: the equipment utilization rate; the Physician Practice Information Survey (PPIS); malpractice relative value units; potentially misvalued services under the physician fee schedule; physician self-referral; the physician fee schedule update for CY 2010; and the Physician Quality Reporting Initiative (PQRI).

Equipment Utilization Rate
The Centers for Medicare & Medicaid Services (CMS) proposes to change the equipment utilization rate from the current 50 percent to 90 percent for equipment priced over 1 million dollars. The ACR has significant concerns regarding this proposal.

General Comments
In the 2008 proposed rule published on July 12, 2007, CMS stated, "We do not believe that we have sufficient empirical evidence to justify an alternative proposal [to the 50 percent utilization assumption]." The ACR is concerned that CMS now proposes to implement a utilization assumption of 90 percent although there is no new or statistically valid data to support this change. Moreover, the abrupt adoption of a change of this magnitude risks doing grave harm to Medicare beneficiary access to high quality imaging services.

With respect to supporting data, the Balanced Budget Act of 1997 (BBA) requires CMS to use accurate data to make changes to the practice expense formula. The BBA of 1997 states, "(1) DEVELOPMENT- For purposes of section 1848(c)(2)(C)(ii) of the Social Security Act, the Secretary of Health and Human Services shall develop new resource-based relative value units. In developing such units the Secretary shall--

> (A) utilize, to the maximum extent practicable, generally accepted cost accounting principles which (i) recognize all staff, equipment, supplies, and expenses, not just those which can be tied to specific procedures, and (ii) *use actual data on equipment utilization and other key assumptions;"*

CMS' proposal is based on the Medicare Payment Advisory Commission (MedPAC) study that clearly does not meet the requirement of the BBA. Since CMS has stated in previous rules that it does not want to change the equipment utilization rate without valid data to support the correct equipment utilization percentage, the ACR asks that CMS maintain this position and continue to look for ways to gather such data.

MedPAC Study Lacks Validity

CMS is basing its decision to change the equipment utilization assumption on a MedPAC commissioned study conducted a number of years ago by the National Opinion Research Center (NORC). At the time it was initially presented, MedPAC commissioners were highly critical of the study stating that "the survey was not nationally representative, and it was not designed to determine equipment use rates." However, MedPAC agreed that this was a first step toward establishing a more accurate utilization rate assumption for diagnostic imaging equipment but that a valid survey should be undertaken. In the minutes of the April 19, 2006 MedPAC meeting, it was acknowledged that the MedPAC study on the equipment use rate cannot be considered valid as it included data from only six urban markets rather than a representative national sampling. Furthermore, the survey collected information only for CT and MRI. As such, it yielded no data to support the proposed higher utilization rates for radiation oncology, nuclear medicine (including PET) and interventional radiology equipment.

Moreover, the ACR believes that not all pertinent questions were asked on the survey. For example, a question asked about the hours of equipment usage, but not about the volume of studies. This distorts the results because a radiology practice may have responded that a CT or MRI scanner is in use or available even if there were no patients being scanned. Furthermore, there are problems associated with other questions asked on the survey such as Questions 4 and 6. These questions ask about the number of hours equipment is in operation each week. Some respondents likely interpreted that as actual scanning time, and others may have interpreted it as "available to be used." This is probably one of the sources of the wide variability in hours of operation reported. According to the NORC report, it states, "Responses to this question varied widely. For MRI scanners operated by physician groups, the number of hours that each machine was in operation ranged from a low of 8 hours to a high of 98 hours per week. Independent Diagnostic Testing Facilities (IDTFs) reported using each MRI machine from a low of 30 hours per week to a high of 100 hours per week." We believe this wide range in responses underscores

the lack of precision in the survey questions, and raises questions about the survey's validity. It is important to point out that since the MedPAC study was performed, the growth in utilization of imaging has declined. Other policy decisions such as the Deficit Reduction Act of 2005 (DRA) and the increasing use of preauthorization programs by private insurers may have changed the volume of many imaging centers.

Study design will be critical in obtaining an accurate measure of equipment utilization. There is no standard definition of a work day among medical practices. Some medical practices are open the standard 50 hours per week, but many others may be open longer or shorter hours. Those that are open longer hours may only be operating certain pieces of equipment on select days such as Mondays, Wednesdays and Fridays, making the hours of use less than 50 per week yet more than 50 percent of their available slots may be booked. Further, due to physician coverage issues, certain rural diagnostic imaging centers and radiation oncology practices may be open for business only a few days out of the week, again driving the denominator down such that the utilization percentage while open is high but not near a total of 40 or 45 hours per week. It is important that any study attempting to measure equipment usage take these issues into account.

Other Data Sources

The Radiology Business Management Association (RBMA) conducted a survey that shows imaging equipment in rural regions of the country is in use only 48 percent of the time an office is open, while equipment in non-rural areas is in use 56 percent of the time. The ACR believes that the RBMA survey is far more accurate and comprehensive for diagnostic imaging equipment than anything undertaken by MedPAC thus far and should be given very careful consideration by CMS. RBMA will be submitting more detailed information regarding its survey and the resulting data.

No Justification for Expanding the MedPAC Study to All High-Priced Equipment

CMS proposes to arbitrarily set a utilization rate of 90 percent for all higher priced equipment based on the premise that one would not purchase expensive equipment and then only use it about 50 percent of the time. There is no established relationship between the cost of medical equipment and its utilization; in fact there is abundant evidence to the contrary. For example, there are higher priced technologies, such as proton beam radiation therapy and positron emission tomography, which are highly beneficial to a select population but far from used at the proposed 90 percent capacity. In addition, unrealistic utilization assumptions would penalize rural and smaller urban locales, where it is particularly unlikely that the proposed high equipment utilization rates are being achieved.

Impact on Access to Care and Investment in Quality

The ACR is also gravely concerned that continued erosion of payment rates for imaging services would further negatively impact patient access to life saving imaging technology. The impact on access will be felt in already underserved areas of the country. Reduced access to diagnostic imaging will require rural patients to travel long distances for care and could lead to delayed diagnosis with adverse effects on beneficiaries and, consequently, increased costs. Reductions in

payments for imaging studies due to changes in the equipment usage assumption will further impact imaging services whose payment levels have already been dramatically reduced by previous policy changes that already threaten to disrupt access to patient care.

A recent survey of radiology practices conducted by the RBMA showed the potential impacts of these reductions as shown in the chart below. Even the 25 percent reduction in global payment rates will have a significant impact on radiology practices in various areas, to include: 1) Centers closing, 21.4 percent if 25 percent reduction in payment and 40 percent if 50 percent reduction in payment; 2) Centers reducing staff, 73.5 percent for 25 percent reduction in payment and 75.7 percent reduction if 50 percent reduction in payment; and 3) Centers delaying purchases of new imaging equipment, 85.5 percent if 25 percent reduction in payment and 78.3 percent if 50 percent reduction in payment. These impacts will be most pronounced in rural radiology practices.

	25% Reduction In Global Medicare Payment Rate		**50% Reduction In Global Medicare Payment Rate**	
	N	%	N	%
Reduce the number of staff	86	73.5%	87	75.7%
Reduce overhead	86	73.5%	87	75.7%
Drop out of Medicare	5	4.3%	29	25.2%
Limit access to Medicare beneficiaries	25	21.4%	41	35.7%
Forgo imaging technology upgrades	100	85.5%	90	78.3%
Forgo other technology upgrades	87	74.4%	89	77.4%
Reduce office hours	37	31.6%	49	42.6%
Consolidate sites of service	35	29.9%	46	40.0%
Close the imaging center	25	21.4%	46	40.0%
Number of respondents	117		115	

If the proposal of 90 percent equipment usage rate is finalized, while many radiology practices will be forced to close, nearly all of the existing practices report they will not be able to replace and/or upgrade their equipment. This is because radiology practices that are providing high quality advanced diagnostic imaging, especially those that invest in the most advanced equipment, have very high fixed-costs. The maintenance costs, Picture Archiving and Communicating System (PACS) software, information technology, etc. all play a part in the cost of providing high quality imaging services. With the significant reduction in payment rates, there will be no incentive for radiology practices to invest or upgrade their equipment, which will ultimately have a negative impact on the quality of treatment provided to patients. Ironically, those sites operating with more dated equipment and lower fixed-costs will fare better and

perhaps benefit from the fact that sites that have reinvested in the most advanced technology may close because they are no longer able to cover their fixed-costs.

Over the past two decades, a significant number of new technologies have been introduced that have advanced the field of imaging. Frank R. Lichtenberg published a study showing that over a 13-year period from 1991-2004, the average life expectancy in the U.S. increased by approximately 2.37 years but ranged from a low of around 0.19 years to a high of 4.5 years between states. Professor Lichtenberg analyzed how the higher performing states differed in their use of different medical resources and determined that medical imaging accounted for 0.62-0.71 years or 25-30 percent of the added life expectancy. If drastic cuts in imaging services cause many radiology practices with the most advanced equipment to close, this encouraging trend may be reversed causing unintended consequences in the quality of care provided to Medicare beneficiaries.

In conclusion, the ACR believes that there is inadequate data to support a change in the utilization assumption for advanced diagnostic imaging and other high cost equipment. As demonstrated in the flawed and unrepresentative MedPAC survey, it is difficult to collect accurate data on equipment utilization and a proper survey requires careful construction of the questions and selection of a representative sample of practices in both rural and urban markets. The ACR believes that the RBMA survey more accurately reflects the current equipment utilization for diagnostic imaging across a broad range of sites. Excluding the very small sample size for office-based interventional radiology equipment, the ACR supports the RBMA data and would support an expansion of that survey for additional data collection. Furthermore, the ACR rejects the premise that all high-cost equipment should be treated the same and arbitrary changes in the equipment usage assumption for radiation oncology, nuclear medicine and interventional radiology equipment without data is inappropriate. The ACR is willing and ready to work with CMS to ensure the appropriate equipment utilization rates are captured for the wide variety of equipment used in our field.

Physician Practice Information Survey (PPIS)
Quality of Data
CMS proposes to use new practice expense per hour (PE/HR) values from the PPIS for all Medicare recognized specialties that participated in the PPIS in determining Medicare payments for physicians' services furnished on or after January 1, 2010. The ACR is concerned about the quality of the data from the PPIS for diagnostic radiology, nuclear medicine and interventional radiology as compared to the more robust data from the diagnostic radiology ACR Socioeconomic Monitoring Survey (SMS) supplemental survey, which are currently being used to calculate practice expense payments for these specialties. The ACR believes that the data from the PPIS are not representative of practicing radiologists. This concern stems from the fact that the PPIS uses only 56 surveys to calculate the new PE/HR for radiology as compared to the 171 surveys used for the ACR SMS supplemental survey.

The low number of usable responses from the PPIS is in part due to the size of the survey, which is 50 percent longer than the ACR SMS supplemental survey. This not only may have decreased participation in general, but the survey is particularly onerous for office-based physicians, and thus many office-based physicians may have opted out, thereby skewing the results obtained to physicians with hospital-based practices and in teaching facilities where practice expense information is easier to gather. Furthermore, the ACR is disappointed that CMS is willing to accept the new survey data without the precision requirement that applied to the ACR SMS supplemental survey data. The ACR was able to meet the Balanced Budget Refinement Act (BBRA) precision requirements with the ACR SMS supplemental survey data indicating that the survey had a high likelihood of being representative of actual costs of radiology practices.

To underscore these points, out of 56 complete surveys in the PPIS, at least 66.9 percent of the responses were from radiologists who worked solely in the hospital setting, where they bill only the professional component (PC) and have no direct or indirect practice expense for the technical component (TC). This means that only 33 percent of surveys contained information about practice expense data for the direct practice expenses of office-based practices. The ACR is concerned that only 33 percent non-facility billing is not representative of the true practice of radiology and that the survey is inappropriately biased to hospital-based physicians causing the PE/HR to decrease. The ACR feels that this is a significant flaw in the PE/HR calculation methodology. A similar bias was noted for the subspecialties in radiology. For interventional radiology, 33 surveys were used to recalculate the PE/HR. Of those, 89.9 percent practice in teaching hospitals with no direct practice expense. This means that only 3 surveys had data that provided input for physician office practices. For nuclear medicine, only 16 surveys were used in the PE/HR calculation and again 77.7 percent of the physicians were hospital-based. Hence, no more than 3 surveys had any significant direct practice expense.

The ACR is extremely disappointed that CMS proposes to make the significant changes to payments for radiology and its subspecialties based on data that are not representative of the specialties and cannot possibly be statistically valid based on previous precision requirements. Data from the 2007 Medicare Physician/Supplier Procedure Summary (PSPS) file and internal ACR surveys about radiologist practice types indicate that nearly 50 percent of Medicare claims for radiology services come from the non-facility setting. However, the PPIS data for the three radiology specialties have shown that 77 percent of the sample is from hospital-based radiologists with a larger than expected representation from academic facilities. In those settings, practice expense costs would be even lower as many academic physicians are not responsible for their own billing and collections. As a result, many of the costs of the practice of radiology in the office setting are significantly underrepresented in the PPIS.

Lack of Precision of PPIS Data

While CMS has commented that it is not concerned about precision requirements in the PPIS since the survey was multispecialty, it should note that the percentage of academic practices and hospital-based practices is much higher for the radiology specialties than other specialties, suggesting that the bias in the survey away from office-based practices was unique to radiology.

In the PPIS, 77 percent of the radiologists, nuclear medicine specialists and interventional radiologists came from a hospital setting. While radiology and its subspecialties might have a higher percentage of hospital-based practices than other specialties, clearly radiology is an outlier within the PPIS. Accordingly, CMS should reconsider its proposal to accept the data without statistically validating that the data are representative of the true practice of radiology as captured in the supplemental survey.

The lack of precision of the data and the small number of data points indicate the PPIS is not representative of the true costs of radiology practices and should not simply replace the high quality data that was provided through the ACR SMS supplemental survey. In fact, we believe that the magnitude of the proposed reductions in PE/HR for diagnostic radiology, nuclear medicine and interventional radiology lacks facial validity. Even after implementation of budget neutrality adjustments for specialties whose PE/HR has increased, there is simply no logical theory or rationale to explain such a significant change in practice expenses over the four year period (2006 vs. 2002) that separates the PPIS and ACR SMS supplemental survey data other than the poor quality of the PPIS data for radiology and its subspecialties.

It may be possible to use the PPIS data by weighting the existing data to reflect the distribution of hospital-based and office-based radiology practices. Thus far the AMA, presumably with the support of CMS, has refused to release the source data from the PPIS so that the ACR or its CMS-approved independent contractor could analyze the data and determine whether an appropriate PE/HR value could be determined by weighting the survey data to accurately reflect the distribution of hospital-based and office-based radiology practices. Without the data from the PPIS, this could not be accomplished prior to the end of the comment period. As a result the ACR strongly believes that the AMA and CMS should release the data to, at minimum, an approved independent contractor and that implementation of the PPIS should be delayed until such time as a detailed analysis can be accomplished.

The ACR therefore recommends that CMS not use the PPIS data for radiology because it does not provide an accurate reflection of practice expenses incurred by radiologists. It does not make sense to discard practice cost data that met all of CMS precision requirements with a survey that has only 30 percent usable surveys and that obviously underrepresents office-based radiologists. However, if CMS insists on using the new PPIS data, the ACR requests that any implementation of the PPIS blend the PPIS data with the ACR SMS supplemental survey data.

PPIS not Representative of Radiology Practices
The ACR understands that CMS needs a comprehensive survey to cover all specialties that need practice expense valuation. However, there are many factors of the PPIS for radiology that still need to be refined in order to obtain representative data. The methodology of performing a physician level survey has always produced an overrepresentation of hospital-based radiologists who say they have little or no costs. Thus, the data tends to be populated with zeros. According to the Lewin Report, the original SMS also had the same problem. The SMS was also a physician level survey and the report pointed to the fact that SMS excluded imaging centers not

owned by physicians. Underrepresentation of global providers (whether physician or IDTF) was the principal reason that led to the performance, and CMS acceptance, of the supplemental survey.

With the summary data from the PPIS presented by the AMA, we see a similar trend and are extremely concerned that the PPIS has not achieved appropriate representation of the various practice types in radiology. The ACR SMS supplemental survey captured the hybrid nature of radiology practice. Most radiology practices have multiple hospital sites and multiple office sites and IDTFs. Some are even radiology/radiation oncology groups. The ACR SMS supplemental survey also used the RBMA membership of radiology practice administrators as their survey sample. This was a novel approach, but produced data that met all of CMS' precision requirements and accurately captured the costs of radiology practice.

Implementation and Transparency of the Data
Given the magnitude of the resulting payment changes as a result of the equipment utilization assumption and the PPIS, the ACR finds it difficult to understand why CMS did not propose to phase in the changes over a period of years, rather than in the abrupt manner actually proposed, especially since practice expense (PE) RVUs based on the new "bottom up" methodology are still being phased in. The ACR is disappointed that although each of four radiology and radiation oncology organizations paid $25,000 to contribute to the PPIS process, access to the raw data for further analysis had been denied throughout the comment period. The ACR has formally requested that the AMA allow its vendor, **dmr**kynetec, to have access to the raw data and be allowed to run analysis for the specialties that paid into the survey. The result of this request is unknown at this time and even if granted, there will be no time for meaningful analysis during the comment period. Transparency is of vital importance considering the magnitude of the changes being proposed. Furthermore, the ACR is extremely disappointed by the lack of transparency on the formulas and calculations used to arrive at the new PE/HR values and the failure to disclose the raw survey data for independent review and analysis. Due to the numerous changes being proposed for the 2010, it is not possible for a specialty to replicate how CMS arrived at the PE/HR and the proposed RVUs for 2010, especially when some key information has not been provided. For example, although the hours of practice information has an impact on the PE/HR calculation for each specialty, this information was not provided by the AMA or CMS for review. The ACR encourages CMS to provide further transparency in the calculation of the PE/HR to ensure the new data is valid and representative of the actual practice expense associated with running radiology and radiation oncology practices.

The ACR believes that CMS is obligated to provide this information under its statutory mandate for impact analysis that is "consistent with sound data practices" (Section 212, Pub. L. No. 106-113, Nov. 29, 1999). Consequently, CMS should defer its implementation of changes until societies have the opportunity to understand how the proposals are interacting with one another. The incomplete impact analysis provided by CMS in the proposed rule has required the ACR to hire outside consultants to attempt to analyze these moving parts and to try to determine the impacts of the various proposals. This has been quite difficult to accomplish in the short

comment period. However, our preliminary analysis has shown that many of the changes at the code level as a result of the various proposals (equipment utilization, PPIS, malpractice RVUs) are counterintuitive and point to a need for delay and/or phase in of the various proposals until societies have the opportunity to understand the impacts and develop comments based on data, not supposition. Studies like CT and MRI will experience as much as a 45 and 40 percent decrease in TC payment rates, respectively.

The ACR recommends that CMS delay implementation of a new PE/HR rate for radiology, nuclear medicine, interventional radiology and radiation oncology until an analysis of the details of the survey results can be completed and societies' comments addressed by CMS. If CMS insists on moving forward with the new PPIS data, the ACR strongly believes that the PPIS data for radiology, nuclear medicine and interventional radiology should be blended with the radiology supplemental survey data. Since most nuclear medicine and interventional radiology specialists practice as part of radiology groups, their costs were captured under the ACR SMS supplemental survey. The ACR is not aware of any formal request by any of the radiology specialties to break out the PE/HR into sub-specialized categories.

CMS has a long history of mitigating the impact of dramatic changes in practice expense payments by phasing in the changes over a four year period. CMS recognized a need to stabilize practice expense payments when it developed their proposal for eliminating the Non-physician Work Pool and acceptance of supplemental survey data submitted by specialty societies. In the 2006 MFS final rule, published on November 21, 2005, CMS stated, "We are concerned that, when combined with an expected negative update factor for CY 2006, the shifts in some of the PE RVUs resulting from our proposals could cause some measure of financial stress on medical practices. Therefore, we proposed to transition the proposed PE changes over a 4-year period. This would also give ample opportunity for us, as well as the medical specialties and the RUC, to identify any anomalies in the PE data, to make any further appropriate revisions, and to collect additional data, as needed prior to the full implementation of the proposed PE changes." The ACR is understandably disappointed that CMS intends to reverse this long-standing policy and implement the proposed changes without a phase in period, which will clearly cause considerable financial stress on many medical practices. The ACR requests that CMS be consistent with past rules and phase in changes to the practice expense values over four years.

In summary the ACR requests the following:

- CMS delay any implementation of the PPIS data for radiology PE/HR until a complete analysis of the survey result can be performed;
- CMS blend the final/revised PPIS result for radiology PE/HR with the ACR SMS supplemental survey data;
- CMS continue its policy of avoiding drastic changes to payment rates and phase in changes to PE RVUs over four years;

- CMS to place the relevant subspecialties of radiology in one practice expense category for the purposes of the practice expense cost surveys as many radiology practices provide a large spectrum of subspecialty care; and
- CMS to disclose all formulas that are used for calculating the PE/HR and revised PE RVUs to insure transparency in this significant effort.

Malpractice Relative Value Units

CMS proposes to update malpractice RVUs and to make several other related policy changes. In particular, CMS proposes to alter policies relating to the valuation of technical components, using premium data for medical physicists instead of historical allowed charges. We believe this change will produce inappropriately low malpractice payments for many radiology services. In the proposed rule, the malpractice values for the professional as well as the TC go to zero for certain procedures which is not logical as there is always some malpractice associated with both the professional and technical components of imaging services. The ACR does not believe that CMS has adequately accounted for this in its proposed methodology and we, therefore, recommend retention of the current methodology for determining malpractice values for the technical component because imaging centers bear the risk of lawsuits for adverse actions directly related to the liability of their employees in performing the TC.

Umbrella liability policies are typically purchased by the imaging centers to cover the center as well as its non-physician clinical personnel such as the radiologic technologists and nurses. This malpractice coverage is separate and distinct from a radiologist's professional liability insurance, represented by the PC malpractice RVUs. The costs of these liability policies are comparable to the cost of a radiologist's annual professional liability policy. In general, imaging technicians such as radiologic technologists and sonographers do not purchase their own liability insurance. On the other hand, medical physicists, whose work is reimbursed as part of the TC codes, frequently have individual policies. Imaging centers typically purchase an umbrella liability policy, under which coverage includes malpractice of non-physician clinical personnel.

The ACR strongly encourages CMS to use the malpractice information submitted by the RBMA for calculations of malpractice values. The information collected shows that the mean for the total annual liability premiums is $31,526. The ACR also recommends that CMS consult with the RBMA regarding liability policies and premiums paid by freestanding imaging centers.

Potentially Misvalued Services under the Physician Fee Schedule

Review of Services Often Billed Together

CMS plans to analyze codes that are billed together 75 percent of the time, excluding E/M services. After review of physician work and practice expense, CMS will consider expanding the multiple procedure payment reduction (MPPR) or bundling of services if duplications are found. Just as E/M services were designed to be separately reported from ancillary services performed on the same day, radiological supervision and interpretation codes *were designed* to be separately reportable along with the surgical code used to describe the image-guided

diagnostic study or intervention. In other words, their being "billed together" is inherent to their proper use within established coding conventions and there is no reason to think they would not be caught in a 75 percent threshold screen. The de facto assumption that there is duplicative work accounted for when these combinations of services are performed is erroneous.

The ACR continues to believe in the merits of the component coding system and is convinced that creating bundled codes describing all image-guided services is problematic and too complex to be done without careful consideration and involvement of the CPT® Editorial Panel and the Relative Value Update Committee (RUC). The volume and complexity of creating and valuing new bundled codes describing all possible procedures currently reported by component coding would be incredibly burdensome to the specialty societies. However, as the ACR has shown numerous times, we remain willing to work with these entities to address concerns as they arise.

The RUC five-year review workgroup has already created screens for services billed together 90 percent of the time and most of these services have been addressed through established CPT and RUC mechanisms. The ACR is pleased to assist in further identifying misvalued services, but urges caution in expanding this analysis to the 75 percent threshold as society resources could easily be stressed if this more relaxed screen results in new physician surveys for a large number of services. Multiple screens have been and continue to be utilized such as site of service anomalies, high intra-service per unit of time (IWPUT), and services with high volume growth. Further, review of the Harvard codes has been proposed as an ongoing screen and the statutorily mandated five-year review is to take place in 2010.

If further MPPRs are considered, the ACR urges CMS to recognize that a 25 percent reduction has already been applied to the TC of certain diagnostic imaging services. This has occurred in addition to the payment limit for advanced imaging services enacted as part of the DRA with the result being as much as a 40 percent reduction in Medicare payments for advanced diagnostic imaging studies. The recent report from the Government Accountability Office (GAO) shows a savings of $1.8 billion to the Medicare Program as a result of the DRA provision. In addition, Medicare's most recent utilization data show that volume growth for imaging services is equal to or less than that for other physician services. Hence, in the absence of continued growth, further reductions in payment seem unwarranted as recent actions have already yielded significant savings to the program. The ACR is concerned that further reductions could limit Medicare beneficiary access to imaging services, particularly in the rural settings, where geographic practice cost index (GPCI) reductions are also proposed.

Site of Service Anomalies

CMS proposes changes to codes for which the AMA RUC review process deleted or reallocated pre-service and post-service times, hospital days, office visits, and discharge day management services without the extraction of the associated RVUs. However, CMS' methodology of removing corresponding RVUs represents a "reverse building block" methodology and would produce negative (below zero) values for some services. Obviously, until this anomaly is corrected, this methodology should not be applied to any services. CMS should acknowledge

that site of service changes may lead to a decrease in some services while existing services may require a corresponding increase. Further, the intra-service times of these services may have been inappropriately low, having been adjusted to accommodate IWPUT and magnitude estimation. As such, we recommend that such services be evaluated in total through established RUC mechanisms which may require re-survey.

While CMS proposes to maintain RUC-recommended values until a methodology is developed to address codes that result in negative valuation when the CMS methodology is used, it proposes to adopt the agency's re-calculated values for other services. Instead, we believe that CMS should accept the RUC-recommended values and not make changes that risk disrupting the careful relative valuation of the affected services. Some of the values that CMS proposes to adopt are significantly lower than those recommended by the RUC, while others are higher than current values. In our view, a negative result is not the only indication of a problem with the CMS methodology. If CMS is unwilling to accept the RUC values, then we recommend that CMS simply retain the current values until the RUC has been given an opportunity to re-examine the values and perhaps develop a more complete and persuasive rationale for its recommendations.

Expert Panel

CMS seeks comments on the MedPAC recommendation to establish a panel of experts separate from the AMA RUC to review the relative values that have been assigned to services. The ACR opposes the creation of such a panel. Specifically, we believe that the composition of the panel would not be sufficiently representative of the entire spectrum of medical practice and this could lead to the inaccurate valuation of certain services. It is also unclear to us how such a body would interact with the AMA, CPT, RUC and other physician advisory panels. Instead of creating yet another panel, we believe that CMS should continue to work with the RUC on ways to enhance its consideration of potentially misvalued services, including potentially overvalued services. We believe this existing process has the greatest potential to address issues raised by MedPAC without leading to unintended consequences.

We believe that the RUC has amply demonstrated its value to CMS over the years. Moreover, the expert advice provided by the RUC to CMS comes without a significant cost to the government. Creation of an additional panel would be associated with increased cost to CMS and seems unnecessary given the resources available from the RUC. We look forward to working with CMS and our RUC partners to assure accurate valuation of all physicians' services.

Accreditation under MIPPA 2008

Please refer to a separate letter the ACR has submitted on accreditation matters.

Radiology Assistant (RAs) and Radiology Practitioner Assistants (RPAs)

CMS has requested a variety of information about radiology assistants (RAs) and radiology practitioner assistants (RPAs). This information is being provided in a separate letter submitted jointly by the ACR, American Society of Radiologic Technologists (ASRT) and American Registry of Radiologic Technologists (ARRT).

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Physician Self-Referral
The ACR is also extremely disappointed that CMS has not taken advantage of this year's rulemaking to address the issue of physician self-referral in the context of imaging and radiation therapy services. In particular, in past rulemaking, CMS has entertained the notion of making important changes to the current in-office ancillary services exception in order to close perceived loopholes allowing inappropriate physician self-referral (for example, for services provided at a site at some distance from the self-referring physician's office and on a day other than the one on which the patient was initially seen by the self-referring physician). As noted in MedPAC's June 2009 report, the use of imaging services was higher in episodes of care with a self-referring physician compared to episodes with no self-referring physician.

Moreover, MedPAC has shown that this greater use of imaging services was not offset by reductions in the use of other services. In fact, MedPAC found that the greater use of imaging services by self-referring physicians was associated with greater overall resource use for the type of episodes the commission examined, even after adjusting for patient severity and other factors. We find it especially troubling that CMS is proposing policy changes that would have the effect of significantly reducing Medicare payments for individual imaging and radiation therapy services while failing to take actions that could address the volume of imaging and radiation therapy services.

"Stand in the Shoes"
The ACR supports CMS' proposal to clarify part of its "stand in the shoes" (SITS) provision in the Stark self-referral regulations by amending the second sentence of 42 CFR § 411.354(c)(3)(i).

The ACR commented to CMS on the CY 2008 proposed rule that it agreed with CMS' rationale for tightening the SITS rules. The ACR fundamentally believes in CMS' Congressional mandate to regulate certain referral arrangements that may attempt to circumvent Stark prohibitions. Such arrangements may risk causing patient abuse and jeopardize program integrity. Physician organizations commonly have arrangements with independent contractor physicians as well as member and employed physicians. The Stark rules should apply to financial relationships with any physician in the health care delivery system regardless of their employment status.

However, the ACR agrees that as a practical matter, physicians who have SITS arrangements with their physician organizations for imaging and radiation therapy services should be able to rely on the organization's designated contract signatory to sign for them. Physicians need to communicate routinely with their physician organization stakeholders and know who is authorized to sign a contract for the organization with an entity furnishing designated health services (DHS). Therefore, the ACR agrees with CMS' proposal to simplify the second sentence of the SITS language - radiation oncologists and diagnostic radiologists alike should benefit from the change. Furthermore, the ACR concurs that the proposed language appropriately balances safeguarding against the potential for abuse with minimizing administrative burdens on

physicians. Yet CMS properly cautions parties to evaluate the entire spectrum of arrangements within a physician organization, not only referrals or other business that the physicians who stand in its shoes may generate. The Stark regulations should not permit any loopholes that DHS entities and group practices might exploit to the detriment of patients and the Medicare program.

Physician Fee Schedule Update for CY 2010
CMS proposes to remove physician-administered drugs from the definition of physicians' services for purposes of sustainable growth rate (SGR) calculations. The ACR applauds the Administration for taking this step, which the physician community has been urging for quite some time. We especially support CMS' decision to remove drugs from the calculation of allowed and actual expenditures for all prior years. We believe that these actions will help address at least one of the flaws inherent in the existing SGR methodology, even though they will not provide immediate relief to physicians.

Section 131(b) Physician Payment, Efficiency, and Quality Improvements - Physician Quality Reporting Initiative (PQRI)
In this section our comments will address group practice reporting, registry-based reporting mechanism, 2010 measure selection, measure suggestions, National Quality Forum (NQF) endorsement and public reporting of PQRI data.

Registry-Based Reporting Mechanism
The ACR agrees with CMS that reducing reliance on claims-based reporting of PQRI data will allow more sophisticated and timely reporting of data and will reduce the burden of reporting. However, even if there are a sufficient number of qualified registries by 2011, CMS should not totally discontinue claims-based reporting for several reasons. A common radiologist practice pattern is to practice at numerous locations where the data is controlled by the institutions, not the group or individual. Having access to the data to send to a registry may be problematic. Additionally, the cost to utilize a registry is another factor physician groups will need to consider as far as use of their practice resources. Lastly, because many radiologists specialize their practice by modality or body system, many can still only report one or two measures, making them ineligible for registry reporting. The ACR feels that CMS desires increased participation in the PQRI program, and has made numerous changes to support that. However, actions such as removing two oncology measures, 143: Oncology: Medical and Radiation – Pain Intensity Quantified and measure 144: Oncology: Medical and Radiation - Plan of Care for Pain from the 2010 program for being "analytically challenging" is a step backward from increasing participation. With that change, many radiation oncologists also may not be able to report 3 measures; with registry-only submission they would be precluded from PQRI participation as well.

2010 Measure Selection
NQF Endorsement
The ACR recognizes the statutory requirement that new measures in the PQRI program must be NQF endorsed. The proposed rule makes allowance for measures used in 2009 PQRI that have

not been endorsed by NQF by July 1, 2009, but were previously approved by the AQA. It is also noted that an exception to that endorsement may be made if there is an area or medical topic for which a practical and feasible NQF endorsed measure is not available. The MFS proposed rule goes on to state that measures specifically declined for endorsement by NQF are not proposed for inclusion in 2010 PQRI. The ACR believes that NQF endorsement should be a requirement for new measures, not only under PQRI but also under the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). We recognize that the underlying statutes for both reporting programs differ but we also believe that CMS has the discretion to adopt a consistent policy with respect to NQF endorsement, and we urge the agency to do so in order to avoid creating confusion and mistrust within the physician and hospital communities. We discuss this matter further in our comments on the CY 2010 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

2010 Individual Measure Selection

The ACR is pleased that CMS has proposed inclusion of Stenosis Measurement in Carotid Imaging Reporting as a replacement for Carotid Imaging Reporting (Measure #11). The revised measure allows greater participation by radiologists because of the expanded patient population; the benefits gained through compliance with the measure will also be extended to a broader population.

Group Practice Reporting

In response to MIPPA requirements, CMS has proposed a new PQRI reporting option for group practices. This option allows for the PQRI incentive to be paid to self-nominated groups with at least 200 individuals billing under the same Taxpayer Identification Number (TIN). Although the CMS proposed group reporting option is basically only available to primary care practices, in the future, group practice reporting may also lend itself to other specialties and conditions or care processes. In group practice reporting, the aggregation of data at a practice level (with resulting higher volumes) may overcome the lack of validity influenced by low frequency.

Public Reporting of PQRI Data

CMS proposes to post “enhanced” information related to PQRI reporting on the Medicare Physician Directory, e.g. names of professionals who 1) submitted data on PQRI quality measures; 2) met satisfactory reporting criteria for 2010 PQRI; and 3) qualified to earn a PQRI incentive payment for services in the 2010 reporting period.

The ACR encourages CMS to be specific and clear in posting the information that successful reporting is just that – successful reporting – and does not necessarily indicate higher quality care was or will be provided by those individuals who earned PQRI incentive payments.

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Conclusion

Thank you for the opportunity to comment on this proposed rule. If you have any questions about our comments or need more information, please contact Angela Kim at 800-227-5463 ext. 4556 or via email at akim@acr.org.

Respectfully Submitted,

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