



# American Urological Association

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April 6, 2011

Glenn M. Hackbarth, J.D.  
Chairman  
Medicare Payment Advisory Commission  
601 New Jersey Avenue, NW  
Suite 9000  
Washington, D.C. 20001

Dear Chairman Hackbarth:

The American Urological Association (AUA), representing over 90% of the practicing urologists in the U.S., is writing to communicate our concerns with the discussion of use of ancillary services at the MedPAC meeting on February 23, 2011, and with some of the proposed recommendations to Congress.

The long-standing mission of the AUA is to promote the highest standards of clinical urological care through education, research, and formulation of health care policy. The public health burden of urological disease in the U.S. is large and growing. Urologists are the specialists who most often diagnose and treat prostate cancer, the second leading cause of cancer deaths among men in the U.S. In addition, urologists diagnose and manage the care for kidney stones, bladder cancer, urinary incontinence, urinary tract infections, benign prostatic hyperplasia, and other diseases prevalent among Medicare beneficiaries. We appreciate your attention to the concerns of America's urologists.

The AUA has been closely following MedPAC's ongoing discussion of services provided under the in-office ancillary exception to the Stark laws. We submitted written comments to MedPAC on this topic four times in 2009 and 2010 and provided oral public comment in September of 2010.

We present here two distinct sets of comments on: 1) four MedPAC draft recommendations; and 2) in-office ancillary use.

### Section I. Comments on MedPAC draft recommendations

1) Elimination of duplicate services and payment that may be furnished when services are provided together. MedPAC would call on the Secretary of Health and Human Services (HHS) to request that the American Medical Association (AMA) /Specialty Society Relative Value Scale Update Committee (RUC) and the Current Procedural Terminology (CPT) Advisory Panel accelerate and expand their efforts to combine discrete services into comprehensive codes

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and to bundle services that include multiple ambulatory services furnished during an episode of care.

While MedPAC staff acknowledges that the AMA-RUC and CPT Advisory Panel have developed a process to review multiple services that are commonly billed together, it charges that the process is too time-consuming. However, in contrast to such assertions by MedPAC, the RUC process is proceeding apace with the very sorts of activities MedPAC recommends. In fact, the RUC is now focusing on a larger volume of services that are provided together 75 percent of the time. Further, the RUC process routinely includes a careful evaluation of pre-service, intra-service, and post-service inputs of physician effort to identify any potential duplication of services.

- 2) Congress extend the multiple procedure payment reduction (MPPR) to the professional component of two or more diagnostic imaging services provided in a single session, aligning the policies for the technical and professional components.

Although details were not provided on which imaging procedures would be targeted by this recommendation, we assume they would be the same procedures subject to the existing MPPR regulation. The current MPPR policy imposes a 50 percent reduction to the technical component of the second CT, MRI, nuclear medicine, or ultrasound procedure conducted during one session. That would mean this policy would apply to two or more imaging procedures in one session, not limited to contiguous body parts or to one modality. MedPAC staff asserted that such a policy would remove duplicate pre-service and post-service activities from the physician payment rate. The only potential for duplication of physician services in the pre-service period lies in review of the reason for the exam and review of prior imaging studies. This is only one element of pre-service work for a typical CT scan such as 74160 (abdominal CT with contrast) and the full pre-service component is only a small proportion of the procedure. Post-service time includes review and discussion of the findings with the referring physician. Although reporting time does not double for a second or subsequent scan, it does increase. A 50 reduction in the work values for pre- and post-service time is clearly not justified on the basis of actual time saving. The 2009 Government Accounting Office report on efficiencies achieved when services are provided together did not reference imaging for non-contiguous body parts or multiple modalities.

The RUC process assesses each component of physician work for the procedures in question and does not impose across-the-board arbitrary reductions in physician payment for diagnostic imaging services; thus making targeted reductions where they are actually needed. We feel this recommendation should be dropped in favor of the first recommendation that emphasizes reliance on the current RUC process. We also strongly endorse the application of any proposed payment cuts to the professional component for second and subsequent imaging procedures to imaging performed in all settings, including hospital outpatient departments (HOPDs) and independent diagnostic testing facilities (IDTFs).

- 3) Reduction in the professional component for imaging and other diagnostic tests that are ordered and interpreted by the same physician.

The rationale for this recommendation is that the physician who refers to himself will spend less time reviewing the chart in the pre-service period and will spend less time following-up with the referring physician in the post-service period (since the referring physician will be the interpreting physician). However, this is not exactly correct. Sometimes physicians must review a patient's medical history after they receive the results of the first image before they perform the second image test. Although the interpreting physician will not need to follow-up with himself about a self-referred patient, he will need to generate and review a report for inclusion in the medical record for each image test and for payers. The option to extend this cut to tests ordered, performed and interpreted by the same practice was also considered. If this recommendation is applied to all physicians in one practice, any remnant of a logical rationale for reducing the professional component will be lost.

In light of the above, the AUA believes that this recommendation constitutes an arbitrary reduction to physician payment for imaging, and strongly objects to any such recommendations. Physician payment for imaging has declined significantly since implementation of the Deficit Reduction Act caps in 2006, introduction and increase in the MPPR for the technical component, increase in the equipment utilization rate, and adoption in 2007 and 2010 in changes to calculation of practice expense. Further reductions in payment for imaging could threaten access for Medicare beneficiaries, particularly in rural and underserved areas.

Furthermore, the proposed penalty for self-referred imaging and testing could limit ordering and performance of tests by physicians in their offices. This would lead to less coordinated care, greater inconvenience for patients, and higher payments by Medicare beneficiaries and the Medicare program to higher priced hospital outpatient departments. MedPAC data indicate that 42 percent of office-based standard imaging and 42 percent of office-based echography (i.e. ultrasound) are ordered and performed by the same physician. There is no question that the majority of these procedures are used immediately to support the diagnosis and treatment of the patient. That is certainly the case with ultrasound which is used by a urologist as a stethoscope is used by a primary care physician. Most urologists perform and interpret their own ultrasound examinations so that patients can benefit from immediate decisions without the need for additional visits. Research shows additional visits and time gaps contribute to a decrease in compliance, particularly for male patients. Medicare payment for interpretation of such ultrasounds is fairly low already. Reducing payment further could drive patients to hospital outpatient departments and more costly and potentially risky imaging procedures, such as CT. We urge MedPAC to carefully consider the unintended consequences of recommendations directed at self-referral on integration of services. In addition, the role of radiologists in suggesting additional studies and of physicians employed by hospitals in referring imaging to their institutions should always be included when self-referral is addressed

- 4) Institution of prior authorization or prior notification of advanced imaging ordered by physicians who are outliers. This recommendation would apply to self-referred and non-self-referred imaging and should apply to imaging performed in all sites of care.

It is possible that *prior notification* could be a useful option to educate physicians about evidence-based and physician derived appropriateness criteria without hampering the provision of needed care. However, mandatory *prior-authorization* will be burdensome to physician practices and to CMS which must administer the program. Data show such programs lose

impact on use after the first year and no reliable studies have demonstrated long-term impact. Prior-authorization will also slow the delivery of needed care and increase physician practice expense in an environment already buffeted by threats of SGR cuts and other payment reductions.

Determination of appropriate use of imaging is critical, since at present, the true extent of overuse is not clear and policies are enacted to reduce presumed overuse without adequate empirical evidence of its existence in many instances. The AUA is actively engaged in the production of evidence-based imaging guidance to accompany our rigorous clinical guidelines to help physicians implement the latest knowledge into their practice. Such a step may go a long way to reduce whatever current proportion of imaging may be attributable to overuse. Studying the effect of implementation of such guidance for specific procedures in contrast to comparable situations where guidance is unavailable for those same procedures (and controlling for referral status for example) could help us to understand the independent effect of appropriate guidance on practice patterns and to distinguish inappropriate from appropriate use.

MedPAC staff has provided evidence that some diagnostic imaging services ordered by physicians are not clinically appropriate. However, the inappropriate use cited is not linked to self-referral and occurs in all settings and under all financial arrangements. The data cited demonstrates high levels of inappropriate use and referring among primary care physicians and a meaningful, but lower level of inappropriateness use among specialist physicians who self-refer.

We support any other such options that promote appropriateness directly without impeding the efficient delivery of care. We would like to see physician use of appropriateness criteria rewarded through the Physician Quality Reporting System (PQRS) and through reduced malpractice insurance premiums and development of malpractice safe-harbors for physicians who rely on guidelines and appropriateness criteria.

## Section II. In-office ancillary use

The AUA continues to be concerned about MedPAC's assertions that "the volume of ancillary services provided in physicians' offices, particularly imaging, has been growing rapidly and contributes to Medicare's growing financial burden on taxpayers and beneficiaries." While self-referral is at the center of the in-office ancillary policy debate, it is only one of many factors that drive imaging utilization. A June 2009 MedPAC report notes that several factors contribute to increases in imaging utilization besides physician ownership and ancillary revenue incentives. These factors include:

- technological innovation and new clinical applications for imaging;
- incentives in Medicare's fee-for-service (FFS) payment systems;
- defensive medicine;
- consumer demand for diagnostic tests;
- lack of research on the impact of imaging on clinical decision making and patient outcomes; and inconsistent adherence to clinical guidelines.

Thus, the exclusive focus on self-referral and financial incentives does not address the complexity of the current level of utilization in diagnostic imaging. Throughout its meetings in 2010, MedPAC proposed various modifications to the exception in order to address the alleged effect of financial gain upon increased utilization. However, moving forward with a healthcare policy that bans or limits self-referral for imaging services without adequate evidence demonstrating that the increase in imaging use is primarily caused by financial gain reflects more of a skewed and ill-informed political agenda rather than a concern for quality of patient care.

The AUA also objects to MedPAC's assumption that physician investment in ancillary services leads to higher volume through greater "capacity and financial incentives for physicians to order additional services." MedPAC has not provided evidence that physicians knowingly subject patients to potentially dangerous radiation purely for financial gain and without medical necessity.

MedPAC staff has cited studies that show an association between physician self-referral and higher use of imaging. These studies are correlational and not causal but MedPAC's interpretation ignores this critical distinction and treats self-referral as a main driver of utilization. For example, there may be significant infrastructure and accompanying care delivery differences between some practices that own and those that do not: higher use in these studies may be driven by improved access, greater patient convenience, and patient expectations/demand. Furthermore, the empirical findings linking self-referral and imaging utilization are at best inconclusive. A recent study published in *The Journal of Urology* demonstrates that physician ownership of imaging equipment did not increase utilization in a large urology group practice. This study examined physician ordering of imaging for two calendar years prior to purchase of imaging equipment and two years after purchase. The study found no difference in imaging ordering and utilization in the two periods (Knapp, P.I, Suh, R., and Beltz, H., 2010. Urologist ownership of imaging does not impact utilization, *The Journal of Urology*, 183, (4), Supplement, e106). Other studies have documented increases in imaging use where no physician ownership applies (e.g., Smith-Bindman, R., Miglioretti, D.L., & Larson, E. B. 2008. "Rising use of diagnostic medical imaging in a large integrated health system," *Health Affairs*, 27, 1491-1502). Thus, existing evidence does not conclusively demonstrate that self-referral drives imaging utilization.

Another factor important to assessment of current imaging utilization trends has been virtually ignored to date. Introduction of new technologies or procedures is often accompanied by a phasing out of less efficient methods over time. However, we find that there are few analyses that examine these in juxtaposition, overlooking which services decline in tandem with those that grow. Thus, growth of certain services is often wrongly examined in complete isolation and conclusions drawn are skewed. For example, the use of newer imaging technologies, such as CT, has replaced the use of older technologies, such as the intravenous pyelogram (IVP) for detection of kidney stones. Data from the Medicare Physician Supplier Procedure Summary Master File shows that in 2003, urologists performed more IVPs than CTs of the abdomen with and without dye. In 2004, the use of CT caught up with the use of IVP. Beginning in 2005, urologists' use of CT was inversely related to the use of IVP. In other words, as CT use rose rapidly, IVP use declined rapidly. These trends over time illustrate that the use of advanced diagnostic imaging may be driven by a change in practice from using an older, less advanced procedure to a more accurate and patient-friendly technology.



In a related vein, hospital outpatient imaging utilization rates are never examined in juxtaposition to physicians' in-office utilization rates, and thus many studies give a biased picture of overall Medicare expenditures in this area.

### Section III. Conclusion

The AUA opposes further reductions to payment for diagnostic imaging that are not based on actual time and effort spent in rendering the services. We also oppose cuts in payment for services simply because they are self-referred. We oppose mandatory prior authorization that will burden physicians and regulators alike, hamper patient access to needed imaging services, and result in sparse savings. Finally, we encourage MedPAC to recommend that any funds generated by cuts to physician payment remain in the pool that funds services under the Medicare Physician Fee Schedule be budget neutral.

We question the discussion of clinical appropriateness of imaging which wrongly suggests that imaging provided in physician offices is less appropriate than imaging provided in other settings. While we are pleased that MedPAC is not simply recommending the elimination of the in-office ancillary exception but rather examining constructive ways to address perceived problems with ancillary use, nonetheless these recommendations seem to concentrate more on reducing payment than promoting clinical appropriateness. Both payment accuracy and appropriate ordering and performance of imaging studies should be promoted.

The AUA is committed to finding solutions to the practice and payment challenges with which MedPAC and the broader federal government struggle. Indeed, as noted in this comment letter, we are actively engaged in two separate efforts that we believe will yield data and information that can shed light and hopefully contribute to potential new solutions to these problems: 1) the development of evidence-based imaging guidance to accompany new and existing clinical guidelines so that the appropriate use of imaging for specific urologic procedures can be disseminated to the wider clinical community; and 2) empirical examination of the range of factors that can contribute to imaging use and the role of self-referral in relation to other possible factors, through the careful statistical analysis of Medicare claims data and other public and private sources that can yield much needed information on this important topic.

We are extremely interested in sharing our insights and engaging in a data-driven dialogue with MedPAC from these endeavors as we progress. We appreciate the opportunity to comment and hope that the Commission finds these comments useful in its further deliberations.

Sincerely,

Steven M. Schlossberg, MD, MBA  
Health Policy Chair