

November 16, 2004

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

Dear Mr. Hackbarth:

The undersigned organizations representing physicians and other health care organizations are concerned with the Medicare Payment Advisory Commission's (MedPAC's) recent deliberations regarding the growth in imaging services. While we are all acutely aware of the effect that the volume of imaging and other physician services are having on the Medicare physician payment formula, it is a complex situation that requires in-depth analysis and discussion.

**Charged with "seeking options for reducing growth of services paid under the [Medicare] physician fee schedule," we understand that MedPAC is examining the growth in imaging services. We suggest that MedPAC take a more analytical approach, beginning with a closer examination and analysis of all fee schedule data to explain why the growth in imaging services is occurring. With a complete analysis and input from the physician community, MedPAC can then, if necessary, offer recommendations about how the physician fee schedule can more accurately and appropriately account for shifts in the site of service; medical advances; changes in Medicare beneficiary demographics, including age and health status; and new coverage decisions by CMS.**

#### **Growth in Imaging Procedures**

The reasons for the growth in imaging services are multi-faceted and complex. However, by focusing just on physician payments, MedPAC is basing its deliberations about the growth in imaging on an incomplete picture. The costs to Medicare for imaging performed in both hospital and non-hospital settings are similar. However when the procedure is performed in a physician's office, all the equipment and staff costs are born by the physician and compensated by Medicare through the physician fee schedule. No hospital charges are submitted or paid. MedPAC's analysis of Medicare payments for imaging services takes note of growth that results from global reimbursements that include those equipment and staff costs for procedures done in physician offices, but it fails to account for an offsetting lack of hospital charges that would have been incurred if the procedure had been done in a hospital outpatient department. An accurate evaluation of the growth in imaging would either include the hospital costs in the base year or exclude the technical component charges in later years when these procedures are done in offices. For example, nuclear cardiology procedures have evolved from being performed in hospitals to physicians' offices. The ratio of nuclear cardiology procedures performed in hospitals and physicians offices was 65 percent to 35 percent, respectively, in 1996. By 2003, these numbers nearly reversed to 39 percent in hospitals to 61 percent in physician offices. By

reviewing only a portion of the imaging costs to Medicare, MedPAC overstates the growth in nuclear imaging by about one-third.

### ***Advances in Imaging Technology***

The volume of imaging studies is influenced by refinements in imaging technology and changes in standards of care that lead to a better quality of care and greater patient satisfaction. The Agency for Healthcare Research and Quality found in its Technology Assessment #43, published in 2001, entitled, “Making Healthcare Safer: A Critical Analysis of Patient Safety Practices” that “[r]eal-time [ultrasound] guidance for [central venous catheter] insertion...improves catheter insertion success rates...and the number of complications associated with catheter insertion.” In this case, an evolving standard of care results in increased usage of imaging. Yet savings to Medicare are realized when the complications associated with blind catheter placement such as pneumothorax and perforation of the carotid artery are averted.

**Migration to Less-Invasive Diagnostic Tools --** For example, the migration of imaging technology now allows image-guided breast biopsies to be performed in a physician’s office. In the past, women suspected of having breast cancer would automatically receive invasive biopsies. The use of in-office ultrasound now enables the use of minimally invasive techniques that are equally effective in diagnosing both cancerous and non-cancerous conditions, resulting in improved patient satisfaction due to shorter recovery times and less scarring, improved quality of care, and reduced costs overall.

In obstetrics and gynecology, the use of ultrasound imaging has almost eliminated “exploratory surgery.” The high negative predictive value of sonography for benign appearing adnexal masses or endometrial tissue in cases of abnormal uterine bleeding has caused a marked decrease in invasive diagnostic procedures. Furthermore, when pathology is significant, ultrasound assessment allows for appropriate operative triage (e.g., gynecologic oncologic availability for masses highly suggestive of cancer.)

In its March 2003 report, MedPAC acknowledged that new indications for existing technologies may be contributing to imaging growth rates and that decreases in some services may be the result of the substitution of one service for another. In cardiology, non-invasive imaging may be supplanting the use of hospital-based invasive cardiac catheterization. Non-invasive imaging can be done outside of hospitals, is less risky, and requires little or no recovery time for the patient. Furthermore, non-invasive imaging, such as echocardiograms can reveal other reasons for a patient’s symptoms and can help guide decisions for the use of invasive procedures. From 2001-2003, while the number of echocardiographic and nuclear cardiac imaging procedures increased 10.5 percent and 14.7 percent annually respectively, the number of diagnostic catheterizations declined 0.4 percent annually.

**Image-Guided Therapy --** Imaging is also increasingly being used for therapeutic uses, which can result in cost savings, fewer complications, shorter hospital stays, and better patient management. Take for example a patient, following surgery, who is referred by a colon surgeon to a urologist for a painful prostate mass. After performing a transrectal ultrasound, the urologist detects a prostatic abscess as a result of the surgery. Because the urologist could perform the ultrasound in the office, a quick intervention can occur by incising and draining the

abscess to prevent further spread of the infection and possible subsequent hospitalization and surgery.

Improvements in imaging modalities have also been incorporated into the practice of radiation oncology, which has led to the development of a new treatment called image-guided radiotherapy. This is radiotherapy that uses cross-sectional images of the patient's internal anatomy to better target the radiation dose in the tumor while reducing the radiation exposure to healthy organs. This image guidance leads to improved control of the tumor while simultaneously reducing the potential for acute side effects due to irradiation of healthy tissue surrounding the tumor. In the end, the patient may require fewer visits for radiation treatment, and avoid surgery or hospitalization. The practice of radiation oncology is one that greatly depends upon these latest technologies to treat cancer patients both curatively and with palliation.

### *Changing Demographics*

The changing demographics of the Medicare beneficiary population are also likely affecting imaging volume. For example, according to the Centers for Disease Control and Prevention, there has been a decrease in the number of heart disease-related deaths over the past three decades, during which time the prevalence of heart disease among Americans has also increased. As more people live longer with heart disease, they will require more health care services – including cardiac imaging. MedPAC needs to review and adjust for the impact of disease prevalence and longevity on any analysis regarding growth in Medicare services.

### **Imaging Ownership and Referral**

MedPAC is analyzing the feasibility of Medicare's implementing various purchasing strategies that the private sector is using in an attempt to control imaging volume growth. We welcome the discussion of how the medical community can work with both Medicare and private payers to improve the quality of patient care. We are not convinced, however, that there is, as described by one commissioner, a "problem of self referral" and therefore a need for Medicare to adopt various purchasing strategies, such as mandatory accreditation, privileging, preauthorization, and physician profiling.

Mr. Ariel Winter stated in his presentation, "we really don't know" the extent to which "self-referral" influences growth of imaging in Medicare. The purchasing strategies referenced in the June 2004 MedPAC report and presented at the October MedPAC meeting are being offered as a solution to control growth on the unsubstantiated premise that imaging performed by physicians in their offices is both inappropriate and of poor quality. In fact, not only is the vast majority of in-office imaging appropriate, but real benefits for patients are achieved when an appropriately trained physician selects the optimal study to perform, interprets the image, and is able to integrate the results with the full knowledge of the patient's clinical condition to establish an appropriate treatment plan.

**Before MedPAC can provide recommendations on strategies that would limit or restrict physician in-office imaging, we believe there must be a careful and thorough examination of whether or to what extent inappropriate self-referral is responsible for the increased utilization of diagnostic medical imaging services.**

**We are also concerned that MedPAC appears to be basing concerns about the safety and technical quality of in-office imaging on one questionable study.** Again, there is no credible national study that we are aware of that indicates that in-office diagnostic testing by physicians other than radiologists jeopardizes patient safety. The study cited in the June 2004 MedPAC report (page 108) is an informal survey that did not look at the actual quality of the images that were produced by the sites or the outcomes of the patients imaged. The study does not tell the reader how the sites were evaluated and what criteria were applied. Also, more than 40 percent of the radiology services included in that survey consisted of chiropractor and podiatry offices that generally provide services that are not even covered by Medicare. Furthermore, the chart fails to note that cardiology practices were surveyed and that no equipment problems were identified.

The Institute of Medicine has stated that all health care organizations and professionals should pursue quality through safe, effective, patient-centered, timely, efficient, and equitable practices. We believe in-office imaging by specialists allows for the important continuity of care in a cost- and time-efficient manner consistent with these goals.

### **Private Sector Purchasing Strategies**

Private payers are, in fact, exploring various strategies, such as accreditation and privileging, as cost containment mechanisms. What we have learned through the private payer experience is that quality must be linked to cost containment, most private sector strategies are not ready for large-scale application, none of the purchasing strategies being explored by MedPAC will solve the larger problems associated with the physician payment formula, and that the success of these tactics are inextricably linked to physician community input and support. Furthermore, we fear that, if adopted into the Medicare program, some of these tactics could ultimately restrict beneficiary access to in-office imaging services performed by well-trained and qualified specialists.

Among the strategies being considered is accreditation. Accreditation is a step that payers and physicians can consider when it comes to ensuring high quality imaging. While accreditation would present a barrier to any physician who was not deeply committed to providing imaging services to their patients, we are not sure that accreditation will actually result in significant cost savings over time. In fact, the costs to physicians, in both time and money, to complete certification and/or accreditation processes are significant. The rigor of any accreditation program is a key element in addressing quality.

Participation in accreditation programs should be voluntary. If mandatory, accreditation should be accompanied by clinical evidence that accreditation results in measurable and significant improvement in quality of care and compliance mandates should include sufficient time to allow providers to achieve accreditation. Furthermore, accreditation should not be limited to the standards of just one accrediting body. For example, for cardiovascular laboratories, accreditation bodies include the Intersocietal Accreditation Commission (IAC) and the American College of Radiology (ACR), and the differences between these programs must be considered. In obstetrics and gynecology accreditation is offered through the ACR and the American Institute

of Ultrasound in Medicine, which developed its standards through joint consultation with ACR and the American College of Obstetricians and Gynecologists.

Another strategy being discussed is privileging. Privileging is designed with the intent to limit who can provide certain services, and in many instances restricts imaging privileges only to radiologists. In some areas of the country where privileging has been implemented, the unfortunate consequence of an increased reliance on invasive procedures has resulted. For example, in Philadelphia where surgeons have been unable to receive credentials to perform ultrasound services in their offices, they are forced to perform all breast biopsies in the hospital outpatient setting, using the method of an open or excisional biopsy. This biopsy method is more expensive, more disfiguring, requires more time-off for the patient, and can lead to more side effects.

Although some in the medical community believe the use of imaging should be restricted to only radiologists, it seems unlikely that restricting imaging to only to radiologists will lead to a reduction in utilization. For example, some imaging technology, such as MRI and CT, have only recently moved to smaller, office-based settings as the technology has progressed. Since MRI and CT are predominantly performed by radiologists, the growth in volume is largely attributable to radiologists. In orthopaedics, from 2000-2003, the number of total spine and pelvis images (x-ray, CT, and MRI) performed by non-radiologists increased 18 percent compared to almost 50 percent for radiologists. Of the total number of spine and pelvis images taken in 2003, 80 percent were performed by radiologists (9.7 million) versus non-radiologists (2.5 million).

We agree that physicians who perform imaging studies should be properly trained and that any accreditation or credentialing should be based on the physician meeting the specific training requirements of their specialty organization and not include or exclude physicians in mass based on what two-digit specialty code appears on the claim. We believe training requirements can be effectively addressed through rigorous accreditation programs.

In many cases, non-radiologists are equally, if not more qualified, to perform certain imaging procedures. Nuclear cardiology is an example of this. Cardiologists must have 24 months in general cardiology training and anywhere from 4-6 months of nuclear cardiology training to practice nuclear cardiology. For radiologists, on the other hand, their training includes 4-6 months in general nuclear medicine, which includes a wide variety of scans/tests, not just cardiology. Furthermore, radiologists, unlike cardiologists, do not have the experience in clinical cardiology are therefore unable to place the nuclear study in the context of patient care.

For ultrasound-guided breast biopsies, the American Society of Breast Surgeons Ultrasound certification program has a requirement documentation of 20 interventional exams per year and 15 AMA category 1 CME credits. For radiology, the requirements for the interventional element of the procedure are three hands-on procedures and three category 1 CME credits.

Since 1985, ultrasound has been recognized as an essential element of training for obstetricians and gynecologists. Training in diagnostic imaging is a part of ob-gyn residencies and questions related to this field are a part of the certifying examinations of the American Board of Obstetrics and Gynecology.

In the field of cancer care, the radiation oncology residency training program includes a one-month rotation in medical imaging for each discipline such as medical, surgical, and radiation oncology. In addition to the one-month requirement for each discipline, it is also mandated that medical imaging implications be addressed for both pediatric and adult patients for one-hour per month for each discipline. Specifically, the didactic components of the program require that the resident be familiarized with diagnostic imaging through regularly scheduled lectures, case presentations, conferences, and discussions relevant to the practice of radiation oncology. For radiology, residents receive broad-based training in medical imaging implications as they relate to radiation oncology and specific requisites vary with each individual residency program.

Mr. Winter has pointed out, the “goals of privileging are to prevent poor quality studies that lead to inaccurate diagnoses or repeat tests.” Again, there is no credible evidence that in-office testing by non-radiologists results in more inaccurate diagnoses or repeat tests. Quite conversely, when a patient’s treating physician performs a diagnostic imaging test, the physician is also in position to quickly and accurately interpret the results of the test in the context of other relevant clinical information.

With respect to physician profiling, we believe the design challenges that have been laid out for MedPAC in this area are on target and are consistent with the challenges that have confronted the private sector in instituting physician profiling. We would add, however, that many in the physician community see profiling physicians as the complete antithesis of the quality improvement movement, which extols the benefits of a team-based approach to patient care.

Furthermore, we hope that MedPAC will not consider recommending repeal of the in-office ancillary exceptions allowed for under the Stark regulations. Advanced imaging technology has forever changed the landscape for patient care. The new plan of care paradigm incorporates imaging not only as a diagnostic tool, but also throughout treatment to guide minimally invasive procedures and to assess outcomes. Additional restrictions on self-referral would effectively disrupt the evolution of medicine that holds great promise for the diagnosis and treatment of disease; reduce patient access to timely, convenient testing; and fragment the important continuity of care.

Additionally, elimination of the Stark II in-office ancillary services exception will dramatically affect the manner in which multi-specialty medical groups function.<sup>1</sup> The in-office ancillary services exception permits medical group physicians to refer their patients for ancillary services provided within the medical group. These services include all designated health services as delineated in the Stark statute, not just imaging services. Elimination of this critical exception then would prohibit such referrals, making medical groups’ focus on care coordination, team building, practice integration, ect., effectively moot. Such a result contradicts the Institute of Medicine’s conclusions in its 2001 *Crossing the Quality Chasm* report that stressed these factors and others as means to creating a new health system for the 21<sup>st</sup> Century.

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<sup>1</sup> While other Stark II exceptions may be utilized by medical groups, such as the employee or prepaid plan exceptions, it is unknown how many medical groups’ physician compensation arrangements fall completely within these exceptions. Consequently, we believe, retention of the in-office ancillary exception is critical for a likely majority of medical groups.

## **Appropriateness**

One area that has not been a focus of MedPAC's discussions, which we believe warrants consideration, is the development and use of guidelines and appropriateness criteria (what to do, when to do it, and how often) to identify overuse, under use and misuse. Many in the physician community are already responding to the demands by the private sector for appropriateness criteria as a tool to respond to growing utilization in general. Developing appropriateness criteria can be very complex, and of course very divisive, but the physician community has a responsibility to ensure that every procedure ordered for a patient is backed by solid value-added care. Much of what exists in clinical guidelines does not answer the question of "what is appropriate." For example, American College of Cardiology (ACC) guidelines are developed around disease states and will not tell a payer how many tests for a patient are appropriate. The ACC is in the process of extrapolating appropriateness criteria from its guidelines – a process that will be both time consuming and costly. Any adoption of guidelines and appropriateness criteria must be done in consultation with the physician community and must incorporate valid and reliable measures.

We thank you in advance for your thoughtful consideration of the issues we have raised as you move forward in developing recommendations to Congress. We believe we are united in our common goal to efficiently provide high quality care to our nation's Medicare population and look forward to working with you in the months ahead.

Sincerely,

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cc: Mark Miller  
Ariel Winter