Greetings:
The American Urological Association (AUA), representing over 90% of the practicing urologists in the U.S., welcomes this opportunity to comment on the MedPAC presentation and discussion of services provided under the in-office ancillary exception to the Stark laws at the Commission meeting on January 15, 2010. 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, with an estimated annual impact of eleven billion dollars. We appreciate your attention to the concerns of America's urologists.

The rationale for continuing MedPAC attention to services provided under the in-office ancillary exception seems to be that physician investment in ancillary services could lead to higher volume through financial incentives for physicians to order unnecessary services. MedPAC has concluded from several studies that physician self-referral is associated with higher volume of services. However, it is not known if additional services are appropriate or contribute to improved care and outcomes.

The AUA acknowledges, again, that imaging utilization has been increasing and some component of this use may be unnecessary. We note, however, that since implementation of the Deficit Reduction Act in 2007, growth in imaging has slowed significantly. We also acknowledge that the use of imaging may be higher among physicians who own imaging equipment, although we question some of the data used to support this conclusion and the magnitude of the use. The AUA repeats its vigorous objection to implications that physicians knowingly subject patients to imaging and potentially dangerous radiation for financial gain.
Volume growth may be caused by a number of legitimate factors beyond the self-interested physician ordering alleged. These factors include:

- Technological innovation and new clinical applications for imaging
- Defensive medicine
- Consumer demand
- Lack of research on the impact of imaging on clinical decision-making and outcomes
  - Lack of appropriateness criteria and/or inconsistent dissemination of existing criteria.

MedPAC staff performed an analysis to determine the frequency with which diagnostic imaging and other in-office ancillaries are performed on the same day that clinically-related evaluation and management or consultation services are provided. One rationale for the in-office ancillary exception is that physicians need immediate access to lab and imaging on the date of the visit to expedite diagnosis and treatment. Staff found fairly low rates of performance of ancillaries on the date of the visit for some modalities and more robust rates for others, such as standard imaging. Staff also examined rates of completing the studies within 7 and 14 days of the date of the visit and found fairly high rates of completion. MedPAC may view these data as undercutting the value of in-office ancillaries to patient care, but we would disagree with such a conclusion.

The data MedPAC examined included self-referred and non-self-referred services. Ancillaries not owned by the referring physician might not be as accessible to patients and could explain a portion of the ancillaries not performed on the date of the visit. Furthermore, the data examined did not include ancillary services provided in Hospital Outpatient Departments (HOPDs). It is very likely that the proportion of ancillary services delivered in the HOPD on the date of the ordering physician visit is lower than the proportion found in the MedPAC analysis. The proportion completed within 7 and 14 days of the visit also would be expected to be lower in the HOPD. It is quite possible that beneficiaries underwent imaging more expeditiously even if the imaging was not provided on the date of the visit when the imaging was provided in the physician’s office as opposed to another site or the HOPD. Patients are more familiar with their physician’s offices and undoubtedly find them more accessible than large HOPDs. Ordering physicians are also more likely to follow-up with patients to assure that studies are completed when patients are expected to return to the physician’s office to have the study performed. MedPAC staff did note that physicians who owned machines and could order imaging were more likely to perform services on the same day as the visit.

Urologists strive to provide imaging on the same day as the visit when there is
an acute need for imaging, such as for kidney stones, possible obstructions, and possible prostate cancer. Same-day imaging cannot always be achieved due to clinical obstacles or patient convenience factors. Clinically, patients may need preliminary testing, such as for kidney function, before undergoing a study. Patients may need to stop medication, such as warfarin, before a study. They may need to fast or undergo other preparation, such as an enema. Relative to patient convenience, patients may be unable to remain in the office for the study due to transportation issues or conflicting appointments. When a patient cannot receive the necessary imaging study on the date of the visit, the urologist tries to get the patient back into the office as soon as possible to complete the study. Even when a patient does not receive a scan on the date of the visit, obtaining the scan from the treating physician is optimal for a number of reasons.

- The ordering physician can control the scanning protocol relevant to his specialty and suspected problem
- The physician has direct access to the image
- The physician can track patient compliance with the order more readily and will follow-up aggressively
- The physician who orders the scan or test is often the most appropriate professional to read the result or scan and act on the results since he or she knows the patient and the suspected condition the best
- Poor coordination and communication often mark relationships between providers of imaging services and ordering physicians. This can result in duplicate testing and poor follow-up.

Some use of ancillary services under the in-office ancillary exception may be inappropriate. MedPAC should not seek to limit or modify the exception to address potential inappropriate use of imaging and other ancillaries. Rather, appropriateness should be promoted directly and assured in ways that do not increase patient waiting times to receive services or interfere with patient care. Examination of patterns of care, development of meaningful, specialtiespecific appropriateness criteria, dissemination of criteria, and physician prior notification of appropriateness concerns are rational approaches to concerns about appropriate use. Self-referral of patients for in-office ancillary services should not be targeted unless the referrals are inappropriate.

Thank you for your consideration of our concerns.

Sincerely,

Steven M. Schlossberg, MD, MBA
Chair, Health Policy Council