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October 15, 2009

Medicare Payment Advisory Commission
Posted on-line at www.medpac.gov

Re: MedPAC Discussion of the In-Office Ancillary Exception to the Stark Laws on October 8, 2009

Greetings:

The American Urological Association (AUA), representing over 90% of the practicing urologists in the U.S., is pleased to have the opportunity to comment on the MedPAC presentation and discussion of the in-office ancillary exception to the Stark laws at the Commission meeting on October 8, 2009. 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. 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, 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 MedPAC staff presentation on the in-office ancillary exception to the Stark laws addressed imaging almost exclusively while acknowledging that other diagnostic and therapeutic services are subject to the exception. Imaging has been a MedPAC focus for a number of years due to significant growth in the volume of imaging services and increased physician investment in imaging equipment. Although the staff presentation and subsequent MedPAC discussion touched on multiple causes of for the increase in imaging use, physician ownership and self-referral were the targets. The guiding assumption of the presentation was that physician ownership creates irresistible financial incentives for physicians to refer patients for imaging.

Headquarters

Michael T. Sheppard, CPA, CAE
Executive Director

1000 Corporate Boulevard
Linthicum, MD 21090

U.S. Toll Free: **1-888-RING-AUA**
(1-888-746-4282)

Phone: 410-689-3700

Fax: 410-689-3800

E-mail: AUA@AUAnet.org

Web sites: www.AUAnet.org

www.UrologyHealth.org

www.urologichistory.museum



Annual Meeting
29 May - 3 June 2010
San Francisco, CA USA

www.AUA2010.org

The AUA acknowledges that imaging utilization has been increasing and some component of this use may be unnecessary. 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. However, the AUA strenuously objects to any implication that physicians knowingly subject patients to imaging and potentially dangerous radiation just for financial gain.

One recent research analysis shows evidence for the lack of impact self-referral has on imaging utilization. A peer-reviewed empirical article published in *Health Affairs* (Smith-Bindman, Miglioretti, & Larson, 2008) examined 377,048 patients who underwent diagnostic testing from 1997 through 2006. This study examined patients enrolled in Group Health Cooperative, a large nonprofit, managed healthcare system providing integrated care and coverage to approximately 10 percent of Washington state residents. Group Health provides care through its own facilities, including 28 primary care or family medical centers, five specialty medical centers, and two hospitals. The critical finding from this research is that **even in an environment with no opportunity to profit from self-referral, the researchers found a dramatic rise in the use of advanced imaging procedures in every imaging modality (e.g., CT, MRI, ultrasound). The researchers concluded that “legislative efforts that focus entirely on self-referral are likely not sufficient to limit the drivers of imaging.”**

As MedPAC well knows, multiple factors are driving increased use of imaging. These factors include:

- Technological innovation and new clinical applications for imaging
- Defensive medicine
- Consumer demand
- Lack of research on the impact of clinical decision-making and outcomes
- Lack of appropriateness criteria and/or inconsistent dissemination and adherence to existing criteria
- Incentives in the Medicare fee schedule and

Several of these drivers merit elaboration. Advanced imaging is clearly replacing invasive, riskier procedures such as open biopsies, exploratory surgery, and angiograms. Advanced imaging also enables more limited, targeted surgeries. Substitution of imaging for invasive (or more invasive) procedures reduces exposure to infection and other adverse events as well as pain and recovery time. Because advanced imaging modalities are more accurate and often quicker than older approaches to diagnosis, they are used in instances where no imaging procedure would have had value in the past. CT has become the gold standard for kidney stone diagnosis due to its high accuracy, very rapid completion and ability to painlessly detect almost all types of kidney stones. Prior to CT, [intravenous pyelogram \(IVP\)](#) was used for stone diagnosis, but IVP requires intravenous contrast

dye and serial X-rays over a period of 20 to 60 minutes. The accuracy and safety of renal mass biopsy has improved substantially due to refinements in CT- and MRI-guided techniques. The contribution of improvements in technology to higher use is significant and appropriate.

Another driver of higher use may be lack of data on appropriate surveillance and follow-up intervals. The absence of appropriateness standards may contribute to imaging use that is higher than clinically necessary. In addition, consumer demand and defensive medicine contribute to overuse. Further research is needed to inform appropriateness criteria and clinical guidelines. These criteria should be developed and disseminated to practicing physicians and professional organizations should play a key role in their development and promotion. To address one need for standards on imaging use, the AUA is currently conducting an evidence-based study that compares the effectiveness of different imaging modalities for diagnosis and management of a specific urologic condition, ureteral stones. The method used to produce this evidence-based document is modeled after our successful and scientifically rigorous guidelines process. The completed document will provide guidance to urology, primary care and related specialties on the most appropriate use of imaging for stones.

With respect to therapeutic modalities, lack of comparative evidence on the effectiveness of alternative modalities and of studies that elucidate patterns of care for new cancers may lead to over reliance on the in-house option. The AUA has identified the need for a comparative effectiveness analysis of treatments for prostate cancer and would be happy to collaborate with funders and researchers on such an initiative. The AUA would also be interested in looking at patterns of care for prostate cancer through analysis of clinical information that could be reported by urologists.

Physician ownership of imaging (and other) equipment may increase use due to greater ease of patient access and convenience. However, it is not known how much of this higher utilization is appropriate and effective. Patients who use more imaging because it is easier for them to obtain the tests their physicians order may experience quicker diagnosis and treatment, reduced periods of discomfort and anxiety, and improved outcomes. The cost of their care may ultimately be reduced. Little evidence has been reported to date demonstrating that patients who get in-office imaging receive higher quality of care or have better outcomes. That is because little research has been conducted on these questions. This important issue requires study before Medicare acts to limit payment for in-office ancillary services. It should also be noted that elimination of self-referral would not promote the delivery of coordinated care. The physician who orders the imaging test is frequently the most appropriate professional to read the test and act on the results as he or she knows the patient's history best. Additionally, there is often poor coordination and communication between providers of imaging services and ordering physicians which results in duplicate testing and/or poor follow-up.

Anyone who has had to miss an additional day of work to take an elderly parent in for a CT scan that could have been provided immediately after the visit to the ordering physician recognizes the importance and value of in-office imaging. This value is magnified many times for the patient who could not make that additional trip and would never receive the necessary scan if the ordering physician did not own a scanner.

MedPAC is focusing on physician ownership and self-referral because these factors are susceptible to the blunt instrument of Medicare payment policy, not because they are known to be key drivers of inappropriate use. We urge MedPAC to strongly consider recommendations that do not limit the in-office ancillary exception to address potential inappropriate use of imaging and other ancillaries. Examining patterns of care and development of appropriateness review criteria and comparative effectiveness analyses could play an important role in defining and addressing the issue. The AUA stands ready to be a resource and partner in these efforts.

Sincerely,

Steven Schlossberg, MD
Chair
Health Policy Council
American Urological Association

Given the unique patient-to-patient variability of brachytherapy sources, the use of prospectively-set average reimbursement runs the risk of creating significant barriers to access for individual cancer patients and places financial pressure on hospitals to take shortcuts in the use of brachytherapy sources. This problem is accentuated by the ongoing issues with CMS data for brachytherapy devices. Maintaining patient access to brachytherapy is critical because, in many instances, brachytherapy sources provide the safest and most effective treatment for prostate and other forms of cancer.

The current payment approach for brachytherapy is more accurate than the proposed prospective payment method and has been tested over time. The current system should be retained.

AMBULATORY SURGICAL CENTER ACCESS

Ambulatory surgical centers (ASCs) provide Medicare beneficiaries with a high-quality, convenient and less expensive option for their surgery. ASCs have succeeded in moving surgical services into less costly but clinically appropriate settings. ASCs were paid 86.5 percent of hospital outpatient department (HOPD) rates, on average, in 2004. However, a multi-year payment freeze, new payment

formula, and additional cuts have reduced ASC payments to 58 percent of HOPD rates in 2009 for the *same* procedures. The growth in the ASC industry has slowed considerably in response to payment freezes. The gap between HOPD and ASC payments will continue to grow if CMS does not act to change its policies. ASC payments were set as a percentage of outpatient prospective payment system rates in 2008. The AUA believes the relationship between ASC and HOPD rates should remain constant and not shift over time.

Failure to modify certain CMS policies could further lower ASC payments to 52 percent of HOPD rates within the next few years. This reduction would threaten the economic viability of performing many procedures in an ASC setting. Patients will be harmed if access to ASC services is reduced by these payment policies. Patients would pay substantially more in co-payments for the same procedure performed in the HOPD if access to ASC becomes more limited. They would also experience more inconvenience. Two CMS policies have a direct impact on the relationship between ASC and HOPD payments.

- CMS has adopted a secondary “rescaling” calculation, which reduces ASC payments when volume increases at ASCs.
- CMS is proposing to update ACS payments by employing the Consumer Price Index for urban consumers. The CPI-U represents inflation in the cost of items purchased by consumers, not by hospitals and other health care providers. Inflation for HOPDs and every other provider in Medicare is based on health care input costs. Updates for ASCs should be based on the same inflation index used for HOPDs. There is no logical rationale for doing otherwise. Using the CPI-U for ASC updates increases the gap between ASC and HOPD rates.

Secondary Rescaling

Payment for a service should not increase in one setting and decrease in another solely on the basis of the scaling factor, as is the case for many ASC services. In the first three years under the revised payment system, changes to the OPPS relative weights would have (2008), and did (2009 and 2010) result in the application of an ASC scaling factor that reduces ASC payments relative to the OPPS rates. CMS should use the authority granted it in by the statute and codified in regulations to suspend application of the scaling factor in 2010 to prevent a further divergence in payment between the two systems. Rescaling results in ASC payments that do not keep pace with rising costs. In this year and in future years, rescaling will further erode ASC payments and increase the gap between ASC and OPPS rates. Further, altering the ASC weights is contrary to the intent of using the cost-based OPPS measurements to determine the relative payments for the same procedures in the ASC.

Inflation through the CPI-U

The AUA welcomes the first inflation increase to ASC payment in six years. However, we question the appropriateness of using the CPI-U to calculate this increase. CMS is not required by statute to use the CPI-U for inflation of ASC rates.

The CPI-U does not accurately represent the cost pressures to which ASCs are subject. The CPI-U was developed to reflect household spending, not health care provider spending. The divergence between the CPI-U and the hospital market basket will add to the gap between ASC payment and HOPD payment.

AUA also asks CMS to use the hospital market basket to measure ASC inflationary cost increases rather than the CPI-U. We reiterate that the CPI-U does not reflect health care cost inputs and is reactive to economic factors that have no relationship to surgical care.

Failure to align the ASC and HOPD payment mechanisms may result in limiting the access of Medicare beneficiaries to efficient, high quality surgery options in ASCs.

PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES

The AUA requests that CMS add the following procedures to the ASC list of covered surgical procedures for 2010. The AUA's Quality Improvement and Patient Safety Committee (QIPS) reviewed these codes in 2009 based on CMS' requirements that "covered procedures performed in an ASC would not be expected to pose a significant risk to beneficiary safety and the procedures would not be expected to require active medical monitoring and care at midnight following the procedure (overnight stay)." The QIPS reviewed these codes and determined that these procedures can be performed safely in ASC settings and would not require an overnight stay if performed in an ASC.

- 50593 *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy*
- 57310 *Closure of a urethrovaginal fistula;*
- 52649 *Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed).*

CPT code 50593 *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy* is another modality to treat renal tumor(s). Currently, 50592 *Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency* is on the ASC list. This is a similar procedure to the 50593 but instead uses radiofrequency instead of cryoablation to ablate a renal tumor. The AUA requests that this CPT code be added to the ASC list as it can be performed safely in an ASC setting and the patient does not require an overnight stay.

CPT code 57310 *Closure of a urethrovaginal fistula* should be added to the ASC list. CPT Code 57320 *Closure of a vesicovaginal fistula, vaginal approach* is currently on the ASC list; however, 57310 is not. CPT code 57310 is a less complicated procedure than CPT Code 57320. The procedure described by CPT Code 57320 is utilized to close an opening between the bladder and the vagina,

while the procedure described by CPT code 57310 closes an opening between the urethral and the vagina in the female patient. Because these procedures are substantially similar, and can both be performed safely in an ASC setting, CPT code 57310 should be added to the ASC list.

CPT code 52649 *Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)* was available for reporting this procedure in January 2008. Similar BPH treatment CPT Code 52647 *Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)* and CPT Code 52648 *Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)* are now included on the ASC list. As with these procedures, CPT Code 52649 does not require an overnight stay and can be safely performed in the ASC setting.

Thank you for your attention to the concerns of America's urologists. We would be happy to answer any questions you may have on our comments. Please contact Stephanie Stinchcomb (410.689.3786 ssinchcomb@auanet.org) for further discussion.

Sincerely,



Anton Bueschen, MD
President
American Urological Association