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To: Medicare Payment Advisory Commission
From: Matthew Schulze, American Society for Clinical Pathology
Date: October 15, 2009
RE: October 8th Session on In Office Ancillary Exceptions to Stark Self Referral Law

The American Society for Clinical Pathology (ASCP) would like to thank the Medicare Payment Advisory Commission (MedPAC) for convening its recent session on the physician self-referral law's in-office ancillary services exception (IOASE). We appreciate the Commission's attention to the issue of physician self referral, which we believe is timely and very deserving of increased scrutiny. In addition to these comments, we are providing as an attachment [ASCP's policy statement on Self-Referral, Markups, Fee Splitting and Related Practices](#).

As the Administration and congressional leaders have worked toward health care reform, they have repeatedly said that cost containment is at least as, if not more, important than extending coverage to all Americans. ASCP believes both are important goals. However, we do not believe that meaningful control of health care expenditures can be achieved without stronger safeguards against physician self-referral. The loopholes in the Stark law, such as the in-office ancillary services exception, must be closed.

While much of the focus on self referral has been focused on imaging services and physician-owned hospitals, the problem of self-referral knows no boundaries; it is also a serious problem affecting anatomic pathology (AP). ASCP is very concerned about self-referral of anatomic pathology services. For a number of years, a variety of arrangements have been used to enable clinicians to profit on their patient referrals for anatomic pathology services.

Clinicians who rely heavily on anatomic pathology services (biopsies, special stains) are increasingly restructuring their business practices so that they can capture the reimbursement for the AP, clinical laboratory and other medical services provided to their patients. In a 2005 article, the *Wall Street Journal* reported on the growing practice of clinicians marking up the cost of AP and clinical laboratory services by utilizing "pod lab" and/or client billing arrangements. Recently, many of these physician group practices, in response to efforts aimed at discouraging markups of AP services have begun bringing these services in house by establishing in-office labs where the technical component and possibly the professional component can be performed. These arrangements typically involve more AP services per patient than non-self-referring physicians, and may also involve the markup of purchased tests—tests perform outside the physician's office by another provider or laboratory.

The literature on the costs associated with self-referral is extensive and clear. Allowing physicians to profit on their referrals results in increased utilization of health care services and increased health care

costs. Self-referral arrangements present an inherent conflict of interest that exploits patients for personal gain. Such arrangements distort rational medical decisions and cause unfair competition by freezing out competitors unwilling to engage in such practices. These practices can adversely affect patient care and undermine patient trust in the medical profession.

In June 2007, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Service released the results of a series of three audits of urology physician group practices that had entered into arrangements to capture the reimbursement for pathology services. The OIG audits revealed that each practice increased their utilizing of AP services, by 699%, 230%, and 26%, respectively, and that the audited physician groups billed significantly more biopsies than the carriers paid on average to other urology groups—124%, 65% and 58%, respectively.

This data helped CMS revise its anti-markup rule to deter the exploitation of pathology and clinical laboratory services by self-referring physicians. Unfortunately, due to technical flaws with CMS' approach, the changes have not had their desired effect and abusive billing practices by physicians seeking to profit on their referrals for AP services continues to increase. Between 2002 and 2007, allowed charges for CPT code 88305 (biopsy) has increase 41 percent to \$1.13 billion.

The rationale for certain medical services being placed on the in-office ancillary services exceptions list is to improve patient care by allowing for certain medical services to be performed while the patient is physically present in the physician's office. In reality, however, many of the services provided by self-referring physicians run counter to the goals of patient convenience or enhanced care. This is particularly true in the case of anatomic pathology.

There is a patient care rationale for allowing certain *clinical laboratory tests*, such as a glucose test, for a patient who is diabetic. Performing the service while the patient waits allows the physician to alter the patient's treatment, if necessary. In contrast, however, *AP services* cannot be performed properly during the course of a patient visit. AP services, particularly the analysis of a patient biopsy specimen, are complex medical services. It takes time for a patient's biopsy to be properly processed, stained, mounted, etc. before it can be reviewed by a pathologist. Typically, the turnaround time for the pathologist to analyze the biopsy once it arrives in the laboratory is several days.

Moreover, few physician group practices with in-office histology or pathology laboratories have full-time staff to perform these services. Usually, these physician practices utilize independent contractors that come in once every one to two weeks. As a result, the turn-around time at these laboratories can take far longer, resulting in increased inconvenience, increased mental anguish and delayed treatments for the patient. Thus, from our perspective, there is no rationale for anatomic pathology being in the in-office ancillary service exception. The sole purpose of anatomic pathology being on the IOAS list is to enable the clinician to profit financially from their patient referrals.

A constant refrain from health care researchers is that self-referral is driving increased and often unnecessary spending. Because of the fact that there is no clinical benefit for anatomic pathology being on the IOAS list, ASCP believes that it should be removed from the list. If the federal government is serious about trying to control unnecessary health care spending, there may be no better place to start than reforming the Stark self-referral law.

In closing, ASCP appreciates this opportunity to provide comments on this issue. If you have any questions about our comments, please do not hesitate to contact me at (202) 347-4450 or by email at matthew.schulze@ascp.org.