PHYSICIAN SELF-REFERRAL AND ANATOMIC PATHOLOGY
MYTH VS. FACT

MYTH: In-office tests and procedures promote patient convenience and offer a "quick turnaround" of services.

FACT: Performing some tests and procedures during an office visit makes sense for patients, like urinalyses, blood work, or rapid strep tests, to help providers diagnose and treat patients during an office visit. Narrowing the Stark law in-office ancillary services (IOAS) exception by removing anatomic pathology services **would not** affect a provider's ability to perform these simple laboratory tests in their offices. Only anatomic pathology services that can almost never be completed with results available at the time of the patient's visit would be excluded.

Currently, the in-office ancillary services exception allows providers to order complex medical tests like anatomic pathology services in which providers have an ownership or other financial interest to receive payments for them. These services are not being performed while the patient is in the waiting room for a quick turnaround of diagnosis or treatment, as was originally intended by the exception, but rather results can only be provided in follow-up visits.

Anatomic pathology results are almost never available at the time of the patient visit because they involve careful analysis of patient tissue by a pathologist. Once the biopsy or other surgical procedures has been performed by the referring clinician to obtain the tissue, the resulting sample requires rigorous and strictly controlled preparation by the laboratory in order to be properly studied. The multiple, detailed steps required to preserve, mount, stain, and examine the specimen routinely take many hours to complete, making it generally impossible that these tests could be finished while the patient remains in the waiting room.

MYTH: The CAP wants to eliminate all physician self-referral.

FACT: The CAP does not want to eliminate all physician self-referral. The CAP seeks to eliminate abusive self-referral arrangements that do not improve patient convenience and therefore, do not conform with the intent of the Stark law. In determining which laboratory services would continue to be permitted under the IOAS exception, the College distinguishes between clinical laboratory services such as urinalyses, blood work, and rapid stress tests and anatomic pathology. The CAP does not object to the inclusion of clinical laboratory services continuing to be allowed under the exception. In fact, the Stark law specifies that clinical laboratory services are designated health services that can only be provided if an exception under the Stark law applies, not anatomic pathology. In this context, the CMS has interpreted clinical laboratory services

that can be performed at the time of the visit to include the more complex anatomic pathology that cannot be completed at the time of the visit. This interpretation does not conform with the express intent under the Stark law to afford patient convenience.

MYTH: Integrated practices will be negatively affected by this change.

FACT: This change would limit the use of the exception so that only robust, integrated and truly collaborative multi-specialty practices could offer these services through the exception. Further, many integrated group practices would not be affected by this change because they utilize other Stark law exceptions and not the IOAS exception to refer services within their health systems. The CAP supports the ability of truly integrated multi-specialty group practices to refer patients within their systems and seeks to preserve that option, while closing the loophole for those practices that are merely opportunistic and taking advantage of the existing IOAS exemption for the revenue.

MYTH: Quality of care will suffer and care will not be coordinated well if the in-office ancillary services exception is narrowed, because the referring physician has less oversight.

FACT: High quality, well-coordinated care is rendered every day by clinicians who do not receive referrals through the in-office ancillary services exemption. To imply that only providers who self-refer can properly supervise and coordinate care is absurd.

Not only is there no basis for asserting self-referral facilitates care coordination, but in fact, the reverse is true. Tangible steps backward from integrated coordinated multi-disciplinary care creating silos of clinical care and barriers that did not exist prior to the implementation of self-referral arrangements have resulted due to anatomic pathology self-referral. In most instances, the pathologists in self-referring arrangements are part-timers and often read slides after the ordering physicians' office is closed, with slide storage and reporting systems isolated to the physicians' practice, and thus unavailable to the hospital where treatment may ultimately be provided. This does not achieve a greater nexus between the pathologist and ordering physician nor greater integration or coordination of care that would benefit the entire delivery system. In fact, coordination already occurs in non-self-referral arrangements with pathologists conferring with one another in their practices and with ordering physicians, and with the slides and reports in a central laboratory repository, available for reference in the management of the patient's care.

Although in theory ACOs remove the incentive to overutilize, while ACOs have grown significantly, they do not cover the majority of Medicare patients nor will they for quite some time, if ever.

Those involved in self-referral arrangements have argued that since they are in the same physical space they can easily seek each other out for direct communication. In reality, when the pathologists is only present a few days a week and is otherwise miles away from the practice, communication and coordination is not furthered. In other pathology practices, pathologists maintain a full-time presence in the same hospital where their ordering physicians perform procedures. They also often participate in a regularly scheduled multi-disciplinary conferences and have access to the patient's entire electronic medical lab. To say that an in-office lab staffed by non-local pathologists creates a "nexus" of clinician-pathologist interaction is naïve at best, but more aptly inaccurate.

Certain cancer centers have conveyed to our non-self-referring pathologists that self-referral arrangements are a step backward for integrated care resulting in a greater degree of fractured care delivery. Self-referral arrangements have been said to perpetuate the practice of silo medicine where one provider may not know what the other is doing or has done. Within office arrangements, the pathology report may not automatically be included in the hospital medical record. When not incorporated as is the generally accepted and established policy, slides from in office laboratories must be reviewed to review the case introducing an unnecessary step into the process and slowing review.

MYTH: The CMS and the entities that advise Congress on Medicare do not view self-referral as a problem.

FACT: The CMS and MedPAC have both identified self-referral as a problem. In July 2007, CMS solicited comments on whether "services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services" should no longer qualify for the IOAS exception. In October 2009, Herb Kuhn, then MedPAC commissioner, also suggested exploring a "time-based rationale" permitting only those services under the IOAS exception that can be completed at the time of the patient visit noting the purpose for the exception as convenience and seeing a lot of services that do not meet this qualification. MedPAC remained concerned about the expansion of physician investment in their practices, the potential for self-referral to lead to higher volume, and inappropriate use; however, its June 2011 report to Congress identified only clinical pathology. It did not mention anatomic pathology or distinguish it from clinical laboratory services. Despite mounting evidence, neither the CMS nor MedPAC has recently revisited self-referral.

In the meantime, noted third parties such as the Kaiser Foundation, Simpson-Bowles Commission, and the Bi-Partisan Policy Commission have recommended that anatomic pathology and other designated health services be excluded from the in office ancillary services exception.

MYTH: Rural patients will be negatively affected by this change.

FACT: The Stark law provides an exception for rural areas of the country to be able to self-refer. The CAP does not propose to alter or limit that rural exception in any way. Given the nature of anatomic pathology services and inability to perform them on the date of the patient visit, in rural areas, practices would still be able to perform clinical laboratory services to inform diagnosis and treatment at the time of business and would still be able to collect specimens and access the services of a laboratory performing anatomic pathology laboratory that undoubtedly includes extensive courier service and no negative effect on patient convenience or receipt of results.

MYTH: Self-referral affects some ordering physicians and specialties and not others.

FACT: The perverse incentive that underlies self-referral arrangements increases cost and utilization universally. The first GAO report on advanced imaging found increases in cost and utilization in self-referral arrangement involving those services. The GAO looked at the self-referral of anatomic pathology by dermatologists, gastroenterologists, and urologists and found those specialties to represent 90% of all anatomic pathology self-referral. It found similar effects of self-referral of these services. The GAO found this without including arrangements that involve the self-referral of the professional component only so the GAO's numbers, while compelling are understated. The GAO's study was nationwide in scope relying on Medicare data and corroborated the previous anatomic pathology self-referral performed by Dr. Jean Mitchell of Georgetown University published in the peer-reviewed leading health policy journal, *Health Affairs* in April 2012. That study focused on the self-referral of anatomic pathology services associated with prostate biopsies.