AIM

ALLIANCE FOR INTEGRITY IN MEDICARE

Closing the Self-Referral Loophole and Preserving Medicare Integrity

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American Clinical Laboratory Association

ACR American College of Radiology

APTA American Physical Therapy Association

AQI Association for Quality Imaging

ASTRO

American Society for Clinical Pathology

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RBMA Building the Business of Radiology

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The *Ethics in Patient Referrals Act*, also known as the self-referral law, generally prohibits physicians from referring Medicare patients for "designated health services" (DHS) such as advanced diagnostic imaging services, anatomic pathology services, physical therapy, and radiation therapy, to entities in which they have a financial interest. The law seeks to ensure that medical decisions are made in the best interest of the patient on the basis of quality, diagnostic capability, turnaround time and cost without consideration of any financial gain that could be realized by the treating physician through self-referral. The in-office ancillary services (IOAS) exception to the law allows physicians to bill the Medicare program for self-referred DHS in many circumstances. Over the years, however, abuse of the IOAS exception has substantially diluted the self-referral law and its policy objectives, making it simple for physicians to avoid the law's prohibitions by structuring arrangements meeting the technical requirements, but circumventing the intent of the exception. Evidence shows that physician self-referral leads to increased utilization of ancillary services that may not be medically necessary, poses a potential risk of harm to patients, and costs the health care system millions of dollars each year. Indeed, a recent *New England Journal of Medicine* article recommends closing the loophole.

PROPOSED SOLUTION

The expansive use of the IOAS exception by physician groups in a manner not originally contemplated by the law, undercuts the purpose of the law and substantially increases costs to the Medicare program and its beneficiaries. AIM seeks to remove those health care services most susceptible to overutilization and abuse from the IOAS exception, while preserving the ability of robust, integrated, and collaborative multi-specialty group practices to offer these services. The body of evidence to support this solution is growing. The Medicare Payment Advisory Committee (**MedPAC**) has recognized the growing number of physicians expanding their practices into areas that are outside the scope of their respective specialties, but for which they control the stream of patient referrals. The Commission's June 2010 Report to Congress discusses how physician self-referral of services under the IOAS exception creates incentives for those physicians to increase their volume of procedures. MedPAC also noted the Congressional intent of the IOAS exception was for "quick turnaround" services, such as routine clinical lab tests or X-rays, provided during the same office visit, and acknowledged that many of these services offered under the IOAS exception are rarely completed during the same office visit.

A recent study in the April 2012 edition of ***Health Affairs*** focused on self-referral of anatomic pathology associated with prostate biopsies by urologists. It found that urologists involved in self-referral arrangements bill Medicare for 72% more specimen evaluations for patients with suspected prostate cancer than urologists who refer specimens to independent pathology providers. However, despite the increased billing by self-referring urologists, the study found that the per-patient cancer detection rate was significantly lower, specifically 57%.

Health Affairs also looked at the cost and effects of self-referral in diagnostic imaging in its December 2010 issue. The first study examined the association between self-referral, duration of illness episode, and three measures of cost for twenty common combinations of medical conditions and types of imaging. Self-referral was associated with significantly and substantially higher episode costs for most of the combinations of medical conditions and imaging. The second study refutes the claim that the practice of imaging self-referral offers patients convenient same-day, one-stop service and allows treatment to start sooner. The analysis of 2006 and 2007 Medicare data showed that self-referral provided same-day imaging for 74% of straightforward X-rays, but for only 15% of more advanced procedures such as CTs and MRIs. These findings indicate that except for X-rays, constraining the self-referral of imaging may be appropriate. Results from the third study show that physicians ordered substantially more scans once they began billing for MRI as opposed to when they referred those studies to a different facility. For example, the study cites that after orthopedists began billing for MRI, the number of MRI procedures used within thirty days of a first visit increased by about 38%.

The above studies are only a few of more than twelve studies in recent years in *Health Affairs* that have documented the conflict of interest created when physicians are permitted to self-refer.

In 2010, ***The Wall Street Journal*** investigated several group practices that have used the self-referral exception to purchase radiation therapy equipment and bill Medicare for intensity-modulated radiation therapy (IMRT services). The article found urology groups that offered radiation therapy had utilization rates well above national norms for IMRT treatment of prostate cancer. Moreover, the practice patterns for these groups showed dramatic utilization increases after they purchased the equipment. In addition, concerns were raised that patients were not informed of all of their treatment options.

A ***Baltimore Sun*** article in 2012 described how a Maryland urology clinic's prostate cancer referrals for IMRT tripled after they purchased a radiation therapy machine. As the article states, "The more patients the Baltimore-area urologists referred for that expensive therapy alternative, the more revenue and profits they would generate." The Maryland data is part of a forthcoming national study by Georgetown University. It is expected to show that urology practices across the country drastically increased IMRT referrals after they purchased a radiation therapy machine.

The **Government Accountability Office** is conducting a study to evaluate the clinical and economic impact of physician self-referral arrangements under Medicare. The report is expected Winter 2012.

HEALTH SERVICE AREA IMPACTS

Advanced diagnostic imaging services have evolved considerably since the creation of the self-referral law. As technology has progressed, many non-radiologist physicians have taken advantage of the IOAS exception to place advanced diagnostic imaging in their offices as the equipment has become smaller and cheaper. Although the equipment may now be contained in the office, these advanced diagnostic imaging services should not fall into the category of ancillary services as the vast majority of these procedures are not provided at the time of the initial office visit, but are provided at a later date because they require preparation and scheduling. A December 2010 *Health Affairs* study found that less than 10% of CT, MRI, and Nuclear Medicine scans take place on the same day as the initial patient office visit. In addition, numerous articles and studies also demonstrate that physicians who own their advanced diagnostic imaging equipment are more likely to refer their patients for procedures than those physicians who do not own their equipment. Most recently, a November 2011 study published in the *American Journal of Roentgenology* demonstrated a 49% increase in the odds of a patient receiving imaging among physicians who had acquired a financial interest in imaging equipment in comparison to physicians who had not.

Anatomic pathology services are specialized physician services in which pathologists prepare and analyze biopsied tissues to diagnose the presence, absence, extent and type of cancer or other disease in human tissues. Such services differ greatly from routine clinical laboratory tests that can reasonably be performed while the patient is in the office. Anatomic pathology does not fit within the intended purpose of the exception to assist the treating physician in rendering a diagnosis or making a treatment decision at the time of the patient's visit as these services generally cannot be performed at the time of the visit. In the past several years, there has been an explosion of arrangements under which specialty physician groups have utilized the IOAS exception to profit from self-referred pathology services performed on their own patients. Self-referral provides financial incentives to order more pathology services, potentially leading to increased surgical procedures that generate biopsies, and unnecessary laboratory testing in which the practice has a financial interest.

Physical therapy services provided in physician offices are provided subsequent to the initial visits. These services are not integral to the physician's initial diagnosis and do not improve patient convenience because patients must return for physical therapy treatments. According to MedPAC, in 2008, only 3% of outpatient therapy services were provided on the same day as an office visit, 9% within 7 days after a visit, and 14% within 14 days after a visit. MedPAC has also cited research that found physicians with a financial interest in physical therapy initiated therapy for patients with musculoskeletal injuries more frequently than other physicians and that physical therapy clinics with physician ownership provided more visits per patient than nonphysician-owned clinics.

Radiation therapy services are a primary cancer treatment that often occurs 5 days a week over the course of 6-8 weeks, and rarely occur on the same day as an initial office visit. The categorization of radiation therapy as an in-office ancillary service is inappropriate. Additionally, it has led to an increase in business arrangements that could compromise the quality of care and limit treatment options for patients. These arrangements can result in dramatic increases in utilization of the most costly form of radiation therapy for prostate cancer, while the use of other clinically equivalent and significantly less expensive treatments, such as radiation seed implants or active surveillance have declined. These arrangements incentivize treatment decisions that are inconsistent with prostate cancer clinical guidelines that emphasize patient preferences and an independent, unbiased discussion of the benefits and risks of each treatment option.