SUBTOPIC

What did the *New England Journal of Medicine* study, “Urologists Use of Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer,” published on October 24, 2013 reveal about self-referral?

The IMRT study by Dr. Jean Mitchell, who also conducted an anatomic pathology study published in *Health Affairs* in April 2012, provides further evidence to what is now a mountain of published research that the self-referral arrangements currently offered under the in-office ancillary services (IOAS) to the Stark Law cost the Medicare system billions without benefitting patients.

The study analyzed Medicare claims from 2005 through 2010 and constructed two samples—one comprised of 35 self-referring urology groups in private practice and a matched control group comprised of 35 non-self-referring urology groups in private practice, and the other comprising non-self-referring urologists employed at 11 National Comprehensive Cancer Network (NCCN) centers matched with 11 self-referring urology groups in private practice. The study compared the use of IMRT in the periods before and during ownership to evaluate changes in IMRT use according to self-referral status. Among the survey findings:

- **Increased Likelihood of Undergoing IMRT.** The report concludes that “men treated by self-referring urologists, as compared with men treated by non–self-referring urologists, are much more likely to undergo IMRT, a treatment with a high reimbursement rate, rather than less expensive options, despite evidence that all treatments yield similar outcomes.”

- **IMRT Utilization Among Self-Referring Urologists Increased Dramatically while Non- Self-Referring Groups Remained Nearly the Same.** IMRT utilization among self-referring groups increased from 13.1 percent to 32.3 percent, a 146 percent increase, once they became self-referrers. In contrast, IMRT utilization by non-self-referring urologists, who were peers practicing in the same community-based setting, was virtually unchanged with a modest increase of 1.3 percentage points. Additionally, IMRT utilization among a subset of 11 self-referring urology practices near NCCN centers increased from 9 percent to 42 percent, an increase of 33 percentage points, from the pre-ownership to the ownership period, compared to an insignificant increase of 0.4 percentage points at the NCCN centers.

- **Self-Referring Urologists Decreasingly Used Effective, Less Expensive Treatments.** Data showed a decrease in utilization of other effective, less expensive treatment options by self-referring urologists, while the study found “virtually no change in practice patterns” for non-self-referring urologists.

**What is physician self-referral and why does CAP oppose it?**

Physician self-referral is the practice by some physicians of referring patients for services in which the physician or a family member has a financial interest in providing. Generally prohibited under the Stark Law, an exception, called the IOAS exception, exists where physicians can offer certain services at the time of the office visit as long as those services meet specific requirements for patient convenience.
The CAP opposes self-referral because allowing physicians to bill for these services provides no added benefit to patients but needlessly adds billions to Medicare spending.

**What is the impact of physician self-referral on health care spending?**
There is a mountain of research documenting the huge cost to health care spending and Medicare from allowing physicians to self-refer certain medical services: over $6 billion, according to the White House’s 2014 budget proposal.

However, providing some of these services such as urinalyses or rapid strep tests during an office visit really does meet the exception’s intent as they help inform diagnosis and treatment at the time of the patient visit, increasing patient access to care by making care more convenient. In this scenario, the benefit to patients balances the added cost. The problem with including anatomic pathology and other services in the IOAS exception is that almost never are the results available during a patient office visit so there is no benefit to patients. It is truly a loophole that some physicians exploit to maximize profits.

**What are other impacts on patients?**
In addition to the obvious potential to be referred for unnecessary biopsies that bring inherent health risks, patients often wait longer for test results from self-referring physicians, and often their diagnoses are made by a single pathologist rather than having the benefit of a team of pathologists reviewing tests as one normally finds in a dedicated laboratory as compared to an in-office self-referral laboratory arrangement.

**Q5. What independent research has been done around self-referral and what have been the findings?**

**A5.** The Government Accountability Office (GAO) released the report, “Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny,” in early August 2013, which found significant increase in cost and utilization due to radiation therapy self-referral. The report found Medicare expenditures for IMRT services performed by self-referring groups increased rapidly from 2006 through 2010 by approximately $138 million, as compared to a $91 million decrease in the non-self-referring group. During the same time period, IMRT utilization among self-referring groups increased by 456 percent, while the number of IMRT services performed by non-self-referrers decreased by 5%. GAO could not attribute any of these findings to patient preferences, age, geographic location, or patient's health status.

Two other GAO reports on advanced diagnostic imaging and anatomic pathology have had similar findings on self-referral, including the study, “Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer,” which found that in 2010, providers who self-referred made an estimated 918,000 more referrals for anatomic pathology services than they likely would have if they were not self-referring. CMS estimated these additional referrals cost Medicare about $69 million in 2010.

The Office of the Inspector General of the U.S. Department of Health and Human Services, numerous peer-reviewed, published academic studies, including 12 studies from *Health Affairs* alone in recent years, as well as several bipartisan groups such as the Moment of Truth Project and the Bipartisan Policy Group, have all conducted independent research and have stated the need to narrow the IOAS exception under the Stark Law.
**Why did the Government Accountability Office conduct its own research on physician self-referral?**

Short answer: It was time for GAO to establish once and for all the cost of self-referral of anatomic pathology services to Medicare and American taxpayers. A bipartisan group of lawmakers from the House and Senate requested the GAO to issue a report because they were concerned about the effects of self-referral on Medicare cost and utilization and this is the result of that request. GAO will ultimately perform four self-referral studies. The first three reports on advanced imaging, anatomic pathology, and radiation therapy are complete (see above). The fourth study on physical therapy is forthcoming. The findings of all three studies to date have been consistent in demonstrating significant increases in cost and utilization due to self-referral of the studied services.

**Is it true that CAP asked Members of Congress to request the AP study?**

Yes, the CAP’s efforts to close the loophole have been frustrated because there was very little previous research on self-referral of anatomic pathology. We approached Members of Congress to help quantify the problem.

**Who sponsors the GAO studies?**

GAO’s report is funded by taxpayer dollars. It is a report to Congress from a government agency based on information attained from the Medicare system. CAP also funded research based on Medicare data, which yielded very similar results.

**Has CAP sponsored its own research on self-referral?**

Yes. CAP has sponsored research that was conducted independently by well-known Georgetown health policy researcher, Jean Mitchell, PhD, and published in the April 2012 edition of *Health Affairs*, the leading peer-reviewed health policy journal. It was the first research to focus exclusively on self-referral of anatomic pathology services, and helped draw policymakers’ attention to the problem. The article, "Urologists’ Self-Referral for Pathology of Biopsy Specimens Linked to Increased Use and Lower Prostate Cancer Detection," compared Medicare billing practices for anatomic pathology services related to prostate biopsies by self-referring and non-self-referring urologists, and using Medicare’s own data, showed that self-referring urologists billed Medicare for 72% more prostate biopsy specimens compared to non-self-referring physicians, with no increase in cancer detection. In fact, self-referring urologists had a 40% lower cancer detection rate than those who did not self refer despite billing for nearly twice as many specimens.

**What were GAO’s findings in its AP self-referral study and how do they compare to the research published by CAP in *Health Affairs*?**

The GAO study found that financial incentives for self-referring providers were likely “a major factor driving the increase in anatomic pathology referrals” and, in 2010, providers who self-referred made an estimated 918,000 more referrals for anatomic pathology services than they likely would have if they were not self referring. GAO estimated these additional referrals cost Medicare about $69 million in 2010. CAP believes the number is likely higher as GAO did not include other services provided in conjunction with biopsies.

It also did not capture professional component (PC) only arrangements, which represent a large portion of the self-referral arrangements. The CAP expressed this concern with GAO. GAO indicated it did not include PC only arrangements because it could not reliably determine whether they were performed in the physician office or independent laboratory. The Georgetown study, however, did capture PC only
arrangements. In addition, the Georgetown study, which focused on a single service, prostate biopsies, found that while self-referring urologists billed Medicare for more services, it found cancer at a markedly lower rate. This dispels the misleading assertion that more tests yield better cancer detection and raises questions about the medical necessity of the test ordered and need for biopsy performed. Unfortunately, the GAO study did not look at cancer detection rates.

If all of the peer-reviewed published research raises concerns about what happens when physicians are allowed to benefit from referring patients for medical services, why not outlaw it once and for all?
The CAP agrees. There is no good reason to continue allowing greed and self-interest to enter into medical decision-making and for the ongoing waste and abuse of Medicare dollars. Congress must act to remove anatomic pathology from the IOAS exception.

What needs to be done to resolve problems caused by physician self-referral?
A legislative fix is needed to eliminate the financial incentives to self-refer, principally eliminating anatomic pathology services from the in-office ancillary services exception currently in effect.

Why hasn’t Congress acted to close the loophole on self-referral of anatomic pathology yet?
The issue has been portrayed by the opposition as a fight between specialties, leaving lawmakers hesitant to become entangled in choosing winners and losers. Even now, self-referring physicians are misrepresenting recommendations to remove services from the IOAS exception, and sounding the alarm that all services, even those that improve access to care and patient convenience, are under fire. This is not true. The GAO report focused on anatomic pathology services called on Congress to act. CAP has faced this problem for years even after providing evidence via the Mitchell study of increased cost, utilization, yet lower cancer detection rates using Medicare data. We are encouraging Congress to take action to put an end to the egregious abuses and waste that has been permitted to continue for years while costing Medicare beneficiaries’ money and providing them with no benefit.