The in-office ancillary services (IOAS) exception to the federal Stark Law was back in the news again recently when AARP added its voice to a growing chorus advocating for closing the so-called loophole.

The White House has voiced support for excluding certain services from the IOAS exception, estimating that it would save $6.1 billion over 10 years. Some professional societies and other groups have made it a top legislative priority to end the exception, expressing concerns that it has been exploited by certain physicians and has resulted in increased costs to the Medicare program.

Supporters of preserving the exception argue that it promotes better coordination of care and that its demise actually will increase costs to the health care system. This article explains the basic provisions of the IOAS exception in the context of the Stark Law, the historical impact of the exception and the potential implications of ending it.

Background on the Exception

There are a number of exceptions to the physician self-referral law, commonly referred to as the Stark Law. [42 U.S.C. § 1395nn.] One of these is the IOAS exception, which states that Stark restrictions do not apply to physicians ordering certain health care services within their own practices.

These services must pass three tests in order to fit within the exception. These tests relate to the practitioner delivering the service, the location where the service is provided, and how the service is billed.

Generally, the exception protects services that are provided or supervised by the referring physician or his/her group, are provided either in the same building as the referring physician’s practice or a centralized building operated by the practice, and billed by the physician (or the physician’s group) performing the service. [42 C.F.R. § 411.355(b).]

For example, chemotherapy infusion drugs typically are protected under the exception because they are administered in the physician’s office. Imaging services also generally are protected under the exception, although the Patient Protection and Affordable Care Act (PPACA) added a provision stating that, in certain circumstances, physicians must inform a patient in writing at the time of a referral that the patient may obtain these services from other suppliers and provide a list of suppliers within 25 miles of the office. [PPACA § 6003(a).]
Physical therapy services also generally are protected under the exception as long as they are billed for by the practice that employs the physical therapist and not billed independently by the physical therapist. [42 CFR § 411.355(b).]

**Evidence Regarding the Impact of the IOAS Exception**

Critics of the IOAS exception generally argue that it creates incentives for physicians to refer patients for services that may not be medically necessary but from which physicians gain financially. These incentives, they argue, have resulted in over-use of certain health care services and, ultimately, higher costs for payers and patients. Some studies conducted by the Government Accountability Office (GAO), the Medicare Payment Advisory Commission (MedPAC), and private researchers bolster these arguments.

In 2009, MedPAC found a higher proportion of imaging services within episodes of care when there was a self-referring physician when compared with episodes with no self-referring physician. In addition, episodes with a self-referring physician had higher ratios of observed-to-expected imaging costs compared with episodes with no self-referring physician. [See MedPAC, Report to the Congress: Impact of physician self-referral on use of imaging services within an episode, Ch. 4, June 2009, available at http://medpac.gov/documents/reports/fun09_Ch04.pdf?sfvrsn=0.]

In October 2014, MedPAC found a higher proportion of imaging services within episodes of care when there was a self-referring physician when compared with episodes with no self-referring physician. In addition, episodes with a self-referring physician had higher ratios of observed-to-expected imaging costs compared with episodes with no self-referring physician. [See MedPAC, Report to the Congress: Impact of physician self-referral on use of imaging services within an episode, Ch. 4, June 2009, available at http://medpac.gov/documents/reports/fun09_Ch04.pdf?sfvrsn=0.]

**Episodes with a self-referring physician had higher ratios of observed-to-expected imaging costs compared with episodes with no self-referring physician.**


Some argue that the IOAS exception also may affect clinical quality. A *New England Journal of Medicine* article found that the cancer detection rate was higher for men treated by urologists who did not self-refer, suggesting that financial incentives caused self-referring urologists to perform prostate biopsies on men who were unlikely to have cancer. [See Jean Mitchell, “Urologists’ Use of Intensity-Modulated Radiation Therapy for Prostate Cancer,” 369 *New Eng J Med*, at 1629, October 2013, available at http://www.nejm.org/doi/pdf/10.1056/NEJMsA1201141.]

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Proponents of the IOAS exception argue that it is a critical component of patient-centered coordinated care, and that this increasingly has become important in light of payment reform and non-fee-for-service payment arrangements such as accountable care organizations (ACOs), bundled payments, and shared savings programs. Although the GAO and MedPAC have conducted numerous studies and investigations related to the IOAS exception, neither as yet has recommended restricting or eliminating it.

**In October 2014, The Wall Street Journal published an article describing how a large Florida urology practice that owned its own laboratory protected under the IOAS exception encouraged its physicians to order certain high-cost tests from the laboratory in return for a portion of the lab revenues.**

While critics have attributed shifts in volume to self-referring physicians, proponents cite a variety of studies demonstrating that overall use of common ancillary services, such as physical therapy, imaging, and pathology, has
been flat or decreasing. For example, a report by the American College of Radiology (ACR) showed that use of medical imaging among Medicare patients was 4.5 percent lower in 2010 than in 2006. [ACR, “Medical Imaging: Is the Growth Boom Over?,” October 2012, available at http://www.acr.org/~/media/ACR/Documents/PDF/Research/Brief%2001/PolicyBriefHPI092012.pdf.]

In fact, proponents of the exception often cite the same GAO reports promoted by the exception’s critics, acknowledging the shifts toward self-referrals but noting a relatively flat overall use trend for certain services such as radiation therapy. [See GAO, “Higher Use of Costly Prostate Cancer Treatment by Providers Who Self Refer Warrants Scrutiny,” Rep. No. 13-525, July 2013, available at http://www.gao.gov/assets/660/656026.pdf.] While this finding suggests a shift away from hospital outpatient departments and non-self-referring groups and toward self-referring groups, some proponents of the exception have argued that this shift may be beneficial because data suggest that some services provided in hospitals actually cost payers and patients more than if performed in a physician office.


**Implications of Limiting or Ending the IOAS Exception**

Several prominent medical societies, including the American Society of Radiation Oncology (ASTRO), have long advocated for narrowing the scope of or eliminating the IOAS exception. The White House added its support beginning in 2013 and has included it in recent budgets, estimating Medicare savings of $6 billion over 10 years through reduced use.

The largest and most vocal constituencies that support either limiting or ending the IOAS exception are pathologists, radiologists, some radiation oncologists and physical therapists. The GAO has published several reports that estimate that limiting or ending the exception relative to these constituencies could result in tens or even hundreds of millions of dollars in savings to the Medicare program. Doing so, they argue, essentially would level the economic playing field among providers so that particular groups that own equipment, labs, or other services would not be able to gain additional revenue from services they do not personally provide.

For radiologists, the issue has become more important as diagnostic imaging technology has evolved over the past two decades. As advanced imaging equipment has become smaller and more affordable, non-radiologist physicians have been able to install this equipment in their offices. While one of the intentions of the exception was to allow for procedures such as imaging to be done at the time of an office visit, the American College of Radiology contends that most advanced imaging procedures, in fact, are not done at the time of the visit, mostly due to preparation and scheduling requirements. Therefore, they argue, the purpose of maintaining in-office equipment is to generate revenue from referrals that may not be appropriate.

Indeed, the GAO concluded that “financial incentives for self-referring providers were likely a major factor driving the increase in referrals” for advanced imaging such as magnetic resonance imaging (MRI) and computed tomography (CT). The GAO estimated the fiscal impact...
of these referrals to be more than $100 million in 2010. [See July 2013 GAO Report at 2.]

The College of American Pathologists (CAP) argues that anatomic pathology services are complex and, unlike routine laboratory tests, cannot reasonably be performed while the patient is in the office. Therefore, they argue that these services do not align with the primary intended purpose of the exception to assist physicians in making diagnosis or treatment decisions at the time of a patient’s visit.

CAP contends that specialty physician groups increasingly have purchased laboratory equipment in order to exploit the IOAS exception and profit from self-referred pathology services. In turn, they believe that this has created a cycle of increased services and costs as these physicians order more pathology services, potentially leading to increased surgical procedures that generate biopsies. CAP points to the GAO’s estimate that the higher rate of procedures and higher number of services per biopsy by self-referrers cost Medicare $69 million in one year (2010), and that these dollars could be saved by ending the exception for anatomic pathology. [Id. at 22.]

Similar to anatomic pathology, proponents (such as ASTRO) of ending the exception for radiation therapy services, and specifically intensity modulated radiation therapy (IMRT), contend that these services rarely are provided on the same day as an initial office visit. Thus, the categorization of radiation therapy as an in-office ancillary service is inappropriate.

As with other types of services, there has been a documented increase in the number of physician groups that own specialized radiation equipment. ASTRO and others contend that this could compromise quality of care and limit treatment options for patients, although there is little data to support this. Nevertheless, the GAO found that the number of prostate cancer-related IMRT services performed by self-referring groups increased 46 percent from 2006 to 2010. [See July 2013 GAO Report at 10.]

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The American Physical Therapy Association (APTA) argues that physical therapy services almost always are provided on a date subsequent to an office visit, not on the same day, and, therefore, should not be protected under the exception. In addition, the group believes that these services do not facilitate a physician’s initial diagnosis nor improve patient convenience as patients must return for physical therapy treatments.

MedPAC used Medicare claims data to analyze the frequency of services covered by the IOAS exception being provided on the same day as an office visit and found that outpatient therapy services such as physical and occupational therapy rarely were provided on the same day as an office visit. MedPAC also found that fewer than half of advanced imaging, ultrasound, and clinical laboratory and pathology services were performed on the same day as an office visit.

When the White House made its proposal to limit the IOAS exception last year, a number of groups sent letters to members of Congress voicing their opposition, stating that it would impede care coordination, decrease efficiency and interfere with the physician-patient relationship.

MedPAC concluded “[t]he finding that many ancillary services are not usually provided during an office visit raises questions about a key rationale for the IOAS exception—that it enables physicians to provide ancillary services during a patient’s visit.” [MedPAC, Report to the Congress, Ch. 8 Addressing the growth of ancillary services in physicians’ offices, June 2010, available at http://www.medpac.gov/documents/reports/Jun10_Ch08.pdf?sfvrsn=0.]

On the other side of the exception argument are groups such as the American Medical Association (AMA), which argue that the path to payment innovation is built upon coordination of care, a goal that would become more difficult if the exception were eliminated. When the White House made its proposal to limit the IOAS exception last year, a number of groups
sent letters to members of Congress voicing their opposition, stating that it would impede care coordination, decrease efficiency and interfere with the physician-patient relationship.

MedPAC said in a June 2011 report to Congress that “limiting the IOAS exception could have unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice. In addition, it could be difficult to craft a more limited IOAS exception that distinguishes between group practices that improve quality and coordination and those that use additional services of marginal clinical value. Therefore, we do not currently recommend that the exception be changed.” [MedPAC, Report to the Congress: Improving payment accuracy and appropriate use of ancillary services, Ch. 2, June 2011, available at http://www.medpac.gov/documents/reports/June11_Ch02.pdf?sfvrsn=0.]

As reimbursement reform gains momentum and more payers and providers enter into arrangements that do not pay fee-for-service, the financial incentives that some argue are driven by the IOAS exception would diminish. MedPAC has said that, “under a model in which providers receive a fixed payment in advance for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services.” [MedPAC, Report to the Congress, Ch. 8, at 220, June 2010.]

In addition, the other major argument for preserving the exception comes from community-based providers feeling financial pressure from decreased reimbursement and increasing practice expenses. These providers feel that elimination of the exception could be the last straw, forcing them to be acquired by hospitals, which they contend will be more expensive and less convenient for patients.

In a March 18, 2014, letter to the chairman of the House Energy and Commerce Committee, more than 30 specialty physician groups as well as the AMA stated their vehement objections to eliminating the exception, stating that it would “result in further centralizing of care around a few dominant hospital systems, which will undermine competition and in turn raise costs to the entire health care system over the long-term.”

**Conclusion**

What happens now? The original bill introduced in 2011 never gained broad support, although the voices of ASTRO, CAP, APTA, and others who are pushing for ending the exception have grown louder over the past few years.

Nevertheless, opposition also has been intense, backed by the muscle of the AMA, the American College of Surgeons, and the American Urological Association. These organizations continue to remind lawmakers that MedPAC has not recommended limiting the exception.

The American Hospital Association has not weighed in on the matter, but it continues to promote the value of payment innovation through provider integration. If past history is any indication, the exception is likely to remain in place for the foreseeable future, especially as a Republican Congress has taken over in 2015.

Ultimately, Congress must weigh the potential cost savings for the Medicare program versus political fallout, which it has not been willing to do up to this point. In the meantime, advocates for and against the exception will no doubt continue to press lawmakers on this issue.

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**About the Author**

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