Client Alert
The Stark Law's In-Office Ancillary Services Exception: Changes Ahead?

Many of our physician practice clients have expressed concern about a Congressional proposal to limit the scope of the "in-office ancillary services" exception to the Stark law. This email alert provides a brief update on the status of that proposal as well as recent commentary opposing the proposal.

By way of background, the Stark law's "in-office ancillary services" exception enables physicians to "refer" patients for Stark-defined "designated health services," including advanced imaging, pathology, and physical therapy services, provided in their offices and reimbursable by Medicare, as long as the requirements of the exception are met. Many physicians believe that the in-office ancillary services exception is important to the prompt, efficient delivery of care within their offices. Certain members of Congress, however, are concerned about the financial incentives for physicians to self-refer patients for ancillary services that are not medically necessary and the commensurate cost to the Medicare program. They also have expressed doubts about whether the in-office provision of services sufficiently enhances efficiency and coordination of care to offset the perceived risk of over-referral. Accordingly, in August 2013, a bill titled "Promoting Integrity in Medicare Act of 2013" was proposed in the U.S. House of Representatives. The bill seeks to amend the in-office ancillary services exception by removing specified services, including advanced imaging services, anatomic pathology services, radiation therapy services and supplies, and physical therapy services, from its protection. If the legislation is enacted as written, there are concerns that, for example, specialists will no longer be able to refer Medicare-covered patients for in-office imaging such as CT and MRI.

As proposed, the bill would not affect routine clinical laboratory services or simple imaging services such as x-rays and ultrasounds that are provided during a patient's initial office visit. The bill also would not alter the Stark law's exclusion of services recommended by pathologists, diagnostic radiologists, and radiation oncologists pursuant to a "consultation" from another physician from the definition of prohibited referrals. (Note, however, that this exclusion does not protect the physician who orders the consultation, who will generally be deemed to refer the patient receiving the ancillary service.)

The legislation has recently garnered increased attention, thanks to the efforts of four U.S. Senators, all medical practitioners. Those Senators wrote the attached letter to Senate leadership, arguing in support of preserving the exception. Among other concerns, the Senators explained that limiting the exception would introduce additional cost and time barriers to patient care, thereby frustrating the provision of comprehensive and integrated care.

The Promoting Integrity in Medicare Act of 2013 has 11 co-sponsors and has been referred to two House Committees for further review. There is currently no companion bill in the Senate. President Obama's budget for fiscal year 2014 also addresses the issue. The budget proposes to repeal the in-office ancillary services exception for radiation therapy, advanced imaging, and physical therapy services, but makes exceptions for practices that meet certain accountability standards.

We will continue to monitor this bill and will update you with any key developments on the matter. In the meantime, please feel free to contact us with any questions or concerns.

Jeremy A. Ball	Samuel C. Haisley	Sara H. Heisler
804-775-3870	804-775-3885	804-775-3861
jball@lawmh.com	shaisley@lawmh.com	sheisler@lawmh.com
Jennifer L. Ligon	Dominic P. Madigan	Jamie Baskerville Martin
804-775-3842	804-775-3858	804-775-7216
jligon@lawmh.com	dmadigan@lawmh.com	jmartin@lawmh.com
Thomas W. McCandlish	Samantha S. Otero	Alana M. Ritenour
804-775-3838	804-775-3868	804-775-3886
tmccandlish@lawmh.com	sotero@lawmh.com	aritenour@lawmh.com

McCandlish Holton, PC
1111 E. Main St. Suite 1500 | Richmond,Virginia 23219
(804) 775-3870 | Fax (804) 775-7286
www.lawmh.com

United States Senate
WASHINGTON, D.C.

December 3, 2013

The Honorable Harry Reid
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Mitch McConnell
Republican Leader
United States Senate
Washington, DC 20510

Dear Majority Leader Reid and Republican Leader McConnell:

As we work together to strengthen Medicare and reform physician payments, we would like to express our strong support for preserving the "in-office ancillary services exception" (IOASE) to federal physician self-referral regulations (the "Stark" law). This provision permits physician practices to provide critical services –including radiation therapy, diagnostic imaging, pathology, and physical therapy –in an integrated and coordinated fashion within their respective practices.

While President Obama's budget proposes to repeal this provision for radiation, advanced imaging, and physical therapy, we have strong concerns with that approach. As medical practitioners with decades of combined experience in treating patients, we believe these changes would effectively force more patients to receive these services in hospital settings, thereby increasing costs to patients in private and public programs. Given the number of individuals enrolled in Medicare, Medicaid, and other federal health care programs, a significant portion of these increased costs will also burden taxpayers whose tax dollars fund these public programs.

From a medical perspective, the full range of ancillary services are used on a daily basis by physician practices to provide comprehensive services to patients. Integration of these medical services facilitates the development of coordinated clinical pathways, improves communication between specialists, offers better quality control of ancillary services, and enhances data collection – all of which can improve patient care while maximizing economic efficiencies.

We are concerned that limiting the IOASE would introduce additional cost and time barriers to patients receiving medically-appropriate screenings and treatments. In fact, MedPAC, in its June 2011 report to Congress, recommended *against* limiting the Stark law exception for ancillary services, citing the dangers of "unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice."

As practitioners, we believe that the vast majority of physicians practice medicine for the right reasons; that is, they work with their patients to provide the best, most appropriate care they can. On the whole, profit considerations do not drive the clinical decisions that physicians make every single day. However, in our desire to allay any lingering concerns about the optics of this issue, we recognize the suggestion made in the joint discussion draft of the Senate Finance and House Ways and Means Committees on SGR reform that physicians adhere to Appropriate Use Criteria (AUC) at the time that a test is ordered.

We applaud the development, adoption and use of physician-developed, peer-reviewed AUC. We believe that if AUC are adopted –with flexibility given to providers based on clinical judgment—the questions related to financial incentives or the need for third party authorization are helpfully laid aside.

Another serious concern we have with changes to the IOASE that reducing the use of these services in the outpatient setting could not only drive the services to a higher cost inpatient setting, but could accelerate current trends in provider consolidation and further increase system costs over the long term. Reducing the viability of the full spectrum of care being delivered in an independent, outpatient setting will most likely centralize the delivery of health care around a few dominant health hospital systems, which in turn will reduce consumer choice and ultimately drive up cost. As a 2012 report by the Catalyst for Payment Reform warns, a historical review of the available data suggests that increasing providers' purchasing power in certain markets "could lead to higher prices with either a neutral or negative effect on quality market power."[i]

Current trends are very concerning. Over the past several years, hospitals have consolidated their market control in many communities. For example, the American College of Cardiology reports that since 2007, the number of hospital-employed cardiologists has more than tripled, while the number in private practice has fallen 23 percent. For many procedures, Medicare reimbursement to hospitals is much greater (in some cases two to three times the amount) than that to physician offices for precisely the same service – typically hospitals *mandate* that employed physicians use hospital services. This trend will likely only increase with the rollout of hospital-based Accountable Care Organizations.

Repeal of the IOASE would literally make it *illegal* for physician practices to integrate these ancillary services that would be *legally* integrated in an inpatient setting. We believe as an issue of basic fairness, the federal government should not disproportionately favor one care setting over another, especially when such a change will increase costs to taxpayer-backed federal health programs. Moreover, we find it highly ironic that some industry actors who have raised concerns IOASE are the same entities that stand to gain the most financially if the IOASE is terminated and care moves to a higher cost setting.

What is most perplexing about the desire by some to end the IOASE is that the utilization of ancillary services has actually decreased in recent years. Below are examples of data regarding utilization of certain ancillary services:

- Growth in the volume of imaging services, especially advanced imaging, has seen a sharp decline since 2007, with no growth per enrollee in 2011.

- The volume of advanced imaging services has slowed significantly, from 13.4 percent growth in 2006 to 5.4 percent in 2007, with an estimated growth of only 2 percent in 2011.

- More than three-quarters of advanced medical imaging is now provided in the hospital[ii], where costs are, by statute, equal or greater than the physician office.[iii] Prohibiting integrated physician practices from providing these services would result in much of this care being provided in the more expensive hospital setting.

- Data from the Medicare 100 percent data sample demonstrated that overall, there was a 5.9 percent *decrease* in utilization of Intensity Modulated Radiation Therapy between 2011 and 2012 in the physician office setting. And due to simultaneous reimbursement changes, Medicare expenditures for IMRT in the physician's office actually decreased by 16.9 percent, or over $128 million.

- From 2007 to 2011, despite a nearly 160 percent increase in the number of urologists in practices with ownership of IMRT (468 to 1202), IMRT utilization to treat prostate cancer during this period increased by only 2.2 percent.[iv]

- In its July Report, the Government Accountability Office (GAO) noted that: *"[a]fter 2007, the rapid increase in prostate-cancer related IMRT services performed by self-referring groups coincided with declines in these services within hospital outpatient departments and among non-self-referring groups.*

Overall utilization of prostate cancer-related IMRT services therefore remained relatively flat across these settings after 2007, indicating a shift away from hospital outpatient departments and non-self-referring groups and toward self-referring groups."[v]

- A recent study on in-house pathology utilization of prostate biopsies that reviewed over 4.2 million specimens between 2005 and 2011 demonstrated no significant difference in both positive biopsy rate and utilization trends between physician owned laboratories and a national reference lab. Therefore, there can be no savings from prohibiting physician incorporation of these services.[vi]

- MedPAC analysis of 2011 claims data showed that spending for outpatient therapy services (physical, occupational, and speech-language pathology) furnished in physician and non-physician private practice comprised only 4 percent of total therapy spending. Medicare expenditures for outpatient therapy in physician offices actually *decreased* from 9 percent of total outpatient therapy spending in 2002 to just 4 percent in 2011.

We applaud bipartisan efforts to strengthen Medicare and reform physician payments. However, we hope you will agree to reject the unwise policy if closing the IOASE, since that approach would increase costs to consumers and taxpayers, reduce competition, increase inefficiency, and potentially further erode the quality of care that we believe is essential to America's patients and taxpayers alike.

Sincerely,

Tom Coburn, M.D.
U.S. Senator

John Barrasso, M.D.
U.S. Senator

Rand Paul, M.D.
U.S. Senator

John Boozman, O.D.
U.S. Senator

---

[i] Provider Market Power in the U.S. Health Care Industry: Assessing its Impact and Looking Ahead http://www.catalyzepaymentreform.org/images/documents/Market_Power.pdf
[ii] GAO-12-966, p. 8
[iii] P.L. 109-171, Section 5102(b)
[iv] Kapoor DA, Olsson CA. Urology Ownership and Utilization of Intensity Modulated Radiation Therapy to Treat Prostate Cancer in the Medicare Population, 2006-10. Manuscript in preparation; personal communication with authors
[v] GAO Report 13-525 p. 11
[vi] Kapoor DA, Bostwick, DG, Mendrinos SE, et al. Utilization trends and positive biopsy rates for prostate biopsies in the United States, 2005-2011. Rev Urol. In press.