Foot-dragging on Stark reform leaves APMs at risk, slows growth of program

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Congressional foot-dragging on reform of Stark and other fraud-and-abuse laws may leave providers in alternative payment models (APMs) subject to penalties even if they're acting in good faith — which may be making the program too difficult for all but the richest entrants to attempt.

Those laws came back into provider focus with a March 21 hearing of the House Ways and Means Committee at which members of Congress questioned CMS officials about the Medicare Access and CHIP Reauthorization Act (MACRA). Rep. Kenny Marchant, R-Texas, brought up Stark, claiming doctors' and medical groups' "big complaint is they say that the Stark laws are creating real barriers to their coordination."

Marchant mentioned his bill — H.R. 4206, the Medicare Care Coordination Improvement Act — which has been before the House since 2017, that would essentially give the same exceptions to Stark and other such laws currently enjoyed by accountable care organizations (ACOs) to APMs — the experimental cost-sharing organizations that, when designated by CMS as "advanced APMs," provide an alternative to the merit-based incentive payment system (MIPS).

"Stark has a really big impact on how relationships are structured in the health care space," acknowledged CMS Principal Deputy Administrator Demetrios L. Kouzoukas. He mentioned President Donald Trump's January budget proposal, which contained a plan to "reform physician self-referral law to better support and align with alternative payment models and to address overutilization." However, that proposal was not addressed in the budget bill that became law last month (*PBN blog 2/9/18*).

Stark law is known to providers mainly for its prohibitions against self-referral — usually by means of referral to a party in which they have a financial interest — of designated health services (DHS). Unless such a referral is specifically excepted by Stark, as with the in-office ancillary service exception, it's usually against the law to give it.

No intent needed for Stark violation

With Stark, it doesn't matter whether the provider is willfully trying to cheat or just trying to do the right thing when he or she runs afoul of the law, says Darrell Armer, a partner in Gray Reed & McGraw's health law section in Dallas. While other such laws — for example, the anti-kickback statute (AKS) — are intent-based so the intention of the provider in performing the act can be taken into account, "you simply do not have that flexibility with the Stark law," says Armer.

Stark law is made up of "essentially strict liability provisions in which the very act of making a prohibited referral is illegal, and the service rendered cannot be billed to Medicare," as Joel Dziengielewski, director of Navigant Consulting in New York, and Margaret J. Davino, an attorney with Kaufman Borgeest & Ryan LLP in New York, described it in their 2015 report, "Mergers and Acquisitions in Healthcare on the Rise: Legal and Compliance Issues." And because prohibited referrals should not be made under Medicare, any claim thus made would be a potential violation of the False Claims Act as well.

This makes Stark a landmine even for honest providers. "There may be no harm to public [treasury], no issue of fair market value — but if a hospital has an agreement with a physician that's supposed to be signed but isn't signed, for example, it is a violation," says Kathy H. Butler, officer and attorney in the Health Care Practice Group at Greensfelder, Hemker & Gale, P.C., in St. Louis. "So on that basis, a hospital whose arrangements were otherwise compliant but not appropriately signed may have to give CMS back all the money they got from that physician's referrals." Without Stark changes, even mere technical errors in an APM's arrangements could be in violation.

ACOs protected — not APMs

Stark laws are part of a constellation of fraud-and-abuse laws such as the False Claims Act and the Civil Monetary Penalties Law (CMP), the latter of which prohibits provider gainsharing and has traditionally been considered an issue between hospitals and practices. In gainsharing, hospitals pay physicians to induce them to reduce or limit Medicare or Medicaid services, with the two parties sharing the savings (*PBN 10/27/14*).

As that is literally the model for Shared Savings and other Medicare ACO programs, in 2010 the Affordable Care Act created exceptions for them. But no such exceptions exist for APMs — not in MACRA or anywhere else. That's a potential problem.

"Stark law is geared toward FFS [fee for service]," says Baker. "They're concerned about providers getting paid based on the volume or value of referrals under FFS — which is a mismatch with the APM program, which is geared toward quality and efficient use of resources." Nonetheless Stark still applies.

And the fact that CMS approves APMs does not create a legal defense for their Stark-liable features. "CMS is not the DOJ [Department of Justice] or OIG [Office of Inspector General]," says Baker, "so even if CMS approves of an arrangement under the Stark law, there is no guarantee that the exact same arrangement might not be viewed as a violation under the CMP law or AKS."

Do waivers help?

While CMS can't amend Stark laws — only Congress can do that — it, HHS and the OIG have authority to regulate based on the laws. HHS, based on its interpretation, can issue waivers to some features of Stark and other statutes. For example, CMS says it's "requesting fraud-and-abuse waivers" from HHS for its Bundled Payments for Care Improvement (BPCI) Advanced Payment Model (*PBN 2/9/18*). "CMS gets its authority from the statute, and the secretary of HHS by statute has been delegated the authority to formally enact regulatory exceptions consistent with the statutory prohibitions in the Stark law," says Baker.

But getting waivers is a cumbersome bureaucratic process that is far from automatic. Also, "a Stark law waiver absent waivers of other similar penalties, like AKS and CMP laws, would not be effective in promoting alternate payment mechanisms as it would leave open the chance of potential liability from HHS, OIG and DOJ," says Baker.

APMs aren't the only Quality Payment Program features left vulnerable to these laws; referrals among members of virtual groups, a designation for otherwise unrelated practices to report MIPS measures as a group, will not be covered by the in-office ancillary exception (*PBN 7/31/17*).

Stark effect on APMs

All this makes it tougher to get an APM off the ground.

"As they're looking to have APM proposals approved, lawyers have to think about whether it could violate Stark," says Baker. "ACOs have waivers in place, but not APMs, and compensation terms have to be carefully constructed to ensure their compensation models comply with the regulatory requirements."

Neal Shore, M.D., president of the Large Urology Group Practice Association (LUGPA), has been trying to get approval for his group's localized prostate cancer APM, discussing it with HHS and the Center for Medicare and Medicaid Innovation and presenting to the Physician-Focused Payment Model Technical Advisory Committee. They've spent two years and countless hours on it, and they're naturally worried that the unreformed Stark laws "put providers in legal jeopardy for self-referral," says Shore.

"There's no doubt that any APM, like any health care model, has to have guardrails and oversight of abusive behavior," Shore says. "But if lawmakers can't provide flexibility needed for APMs, then we'll have a real challenge evolving the model. Right now, the number of approved APMs is rather limited — few have even been proposed, and I think it's largely because of the complexity and challenges of the process." — *Roy Edroso (redroso@decisionhealth.com)*

Resources:
Ways & Means "Implementation of MACRA's Physician Payment Policies" hearing:
https://waysandmeans.house.gov/event/hearing-implementation-macras-physician-payment-policies/
"Mergers and Acquisitions in Healthcare on the Rise: Legal and Compliance Issues," Joel Dziengielewski and Margaret J. Davino, 2015 [*Word doc*]: https://www.healthlawyers.org/find-a-resource/HealthLawHub/Documents/Compliance/FC15_davino_dziengielewski.docx

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