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Latest Round of CMS Stark Law Rules Highlights Statute's Greatest Uncertainties

It used to be the anti-kickback statute that gave health care providers sleepless nights, criminalizing what in many industries is considered routine business practice. Then came the Stark Law, a strict liability statute that also imposes prohibitions largely absent in business arrangements outside of health care. Both present attorneys with some of the greatest uncertainties in all of health care law, according to John T. Brennan Jr. with Crowell & Moring LLP in Washington D.C.

Perhaps to help reduce the difficulties, the Centers for Medicare & Medicaid Services finalized regulations in July 2004 (the Stark II, Phase II regs) that contained an exception for instances of temporary and inadvertent noncompliance.

Before the exception existed, the Stark law's Draconian penalties led many health law attorneys ''to bend over backwards to make a distinction between technical and substantive violations,'' Brennan told BNA Feb. 17. ''People looked at the enormous penalties for what appeared to be relatively minor oversights and concluded, 'Congress couldn't possibly have meant to subject a hospital to millions of dollars in fines because an otherwise unobjectionable lease was not in writing for six months.' So the rationalization was that 'technical' Stark violations almost didn't count because you could fix them and get back in compliance.''

Line in the Sand. Then the Stark II regulations became effective and turned out to contain a sleeping tiger. The exception that initially seemed to ease the regulatory burden was in fact ''a line drawn in the sand,'' Brennan said. ''This was the CMS and HHS Office of Inspector General saying, 'We know a previously compliant relationship can fall out of compliance for a limited time, so we'll give you 90 days to get it back in place.' '' But the bright line clearly meant that anything not excepted was unprotected, Brennan said.

The fallout was predicted by former chief of the OIG Industry Guidance Branch Kevin McAnaney in Washington, D.C., who told BNA that because CMS ''focused the statute and omitted a lot of the underbrush,'' its disproportional penalties and lack of prosecutorial discretion would become more apparent.

Health law attorneys tell BNA concern about Stark violations has risen, spurred by the large payouts seen in cases such as the $22.5 million Tenet/Northridge Stark settlement, the $40 million Erlanger Medical Center settlement, and the prospect of more to come as whistleblower cases alleging False Claims Act (FCA) violations premised on improper referrals make their way through the courts.

Since the Stark law makes illegal any claim made for services referred in violation of Stark, FCA cases bootstrapped onto Stark violations are ''tremendously problematic'' for hospitals, McAnaney told BNA. ''You can pay a physician $1,000 and then discover the payment doesn't fit into any exception. If that physician happens to be your heart surgeon, you can find you've received millions of dollars in overpayments.'' Given that the OIG also can impose civil monetary penalties of up to $15,000 per violation or $100,000 per arrangement, the penalty for violation is ''grossly disproportionate,'' McAnaney said.

Beth McClain with Fried, Frank, Harris, Shriver & Jacobson LLP in Washington D.C. agreed. ''If anyone had envisioned that Stark would be enforced this way, as a strict liability statute that was then piggy-backed or bootstrapped onto the False Claims Act, I think there would have been a huge outcry in the provider community when Congress was considering Stark.''

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GREGG BLOCHE, GEORGETOWN UNIVERSITY LAW CENTER

Instead, health care lawyers find themselves spending more and more time dealing with potential Stark problems than they do with the anti-kickback statute with its high burden of proof. "Ironically, it's the no-intent Stark statute that poses more danger to providers right now than the criminal statute," Brennan said. "The Stark violation is more certain and more likely to lead to significant penalties."

Seeking Every Exit. The first thing savvy attorneys do when they discover a potential Stark violation is to examine the business arrangement to uncover any "credible and responsible basis that might exist for legitimately concluding that no Stark violation occurred or that a violation may not have occurred," according to Patricia T. Meador with Kennedy Covington in Research Triangle Park, N.C. For example, if the required writing is not found in the file as a neat contract dated and signed, it may be constituted from meeting notes, e-mail exchanges, invoices, endorsed checks, or draft agreements, she told attendees at an American Health Lawyers Association teleconference in January.

State law may sometimes offer a refuge. One element of the temporary noncompliance exception is that the financial arrangement must have been fully compliant for 180 days immediately preceding the date on which it became noncompliant. Then the entity has 90 days to rectify the situation. If an entity discovers a relationship that satisfied all of the requisite requirements except for being out of compliance for more than 90 days prior, "Is it an irredeemable violation because once the term lapsed there was no longer an effective writing?" asked David E. Matyas with Epstein Becker & Green PC in Washington, D.C. "It is possible that, under state law, the written agreement might still be considered valid and that the arrangement never has fallen out of compliance," he told BNA.

However, when nothing can be discovered or devised to make a potential Stark violation go away, attorneys must determine whether the law requires a refund to be made to CMS or if the violation otherwise must be disclosed to the government under, for example, a corporate integrity agreement, compliance plan, or the Sarbanes Oxley Act. Disclosure has its advantages, even if not mandated, Brennan told AHLA teleconference participants. Voluntary disclosure can minimize whistleblower opportunities, reduce False Claims Act damages, avoid criminal exposure, and perhaps lead to more favorable administrative sanctions. It also can help a provider "maintain control of events by reducing the risk of subpoenas, employee interviews or depositions, and other formal discovery; reduce or eliminate surprise; maintain a measure of client serenity; and send correct signals about company priorities and values to employees and staff and to the government, customers, competitors, and the media," he said.

'Monster in the Closet.' During the teleconference, Brennan analyzed some of the statutes and regulations governing the disclosure question, including 42 U.S.C. § 1320a-7b(a)(3), an obscure statute criminalizing failure to disclose that health law attorney Sanford V. Teplitzky of Ober Kaler Grimes & Shriver in Baltimore has called "the monster in the closet."

"Brennan was pretty aggressively saying that there are not necessarily the kinds of affirmative obligations to refund or disclose or de facto violations that the government would have you believe there are," McClain said. "It was definitely defense-oriented, but I think it was a fair interpretation of the law."

Fair it may be, but it is certainly not the government's position, defense attorneys told BNA. At least that is not its official position, they said. One attorney explained that, in fact, when a Stark violation is only technical (e.g., agreement not in writing) as distinct from substantive (e.g. not fair market value), the sense is that the government actually does not want it to be reported "because they don't know what to do with it," not wanting to penalize hospitals unduly but also not wanting to be seen as ignoring the law.

Law as Russian Roulette

Telling a client that "the government is not interested in technical violations" is a risky business for both client and counsel, Crowell & Morings' John T. Brennan Jr. said. "If no disclosure is made and the client is then sued, perhaps by a whistleblower, will the client come after the attorney for malpractice?"

While it is difficult to disclose and face a penalty, it is equally difficult to tell a client, "you'd be crazy to disclose because no one else does and the government would prefer that you do not." Why should people be left to this uncertainty when the risks of guessing wrong are so high?

The truth is there needs to be some formal recognition of this, and a way developed to waive all penalties where the evil targeted by the Stark Law—biased physician decision-making based upon financial interest— is just not present, Brennan said.

Georgetown University law professor Gregg Bloche, a visiting fellow at Brookings Institution, told BNA the government will not willingly make public any deviation from the black-letter law. "If I'm a regulator, I want uncertainty and risk aversion to help extend the deterrent power of my enforcement efforts."

This, however, makes people see the law as something to manage and get around rather than a moral force, Bloche said. To survive, health care providers need "an insider's sense of the unwritten rules, the unstated probabilities of any action. You are not going to get that if you are a hospital or medical practice. You need a law firm with practitioners in regular communication with the agencies, who also keep their ear to the ground with respect to what the political appointees want and even what congressional oversight is doing."

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Bargaining in Shadow of Law. The result is what happens ''whenever you have a law that gives only black and white answers when in real life there are only shades of gray,'' Bloche said. ''Everyone bargains in the shadow of the law; the actors figure out their own solutions in the interstices. The regulators know that if they start using the full literal power of the law, the industry is going to engage all the mechanisms of political accountability, including rushing to Congress.''

The comment that the OIG does not want to know about ''iffy violations'' rings true, Bloche said. ''The fewer options the law provides for managing intermediate problems in a pragmatic fashion the more regulators look for escapes from the black and white choices.'' In a September 2005 speech in Baltimore, for example, CMS's Donald Romano suggested that technical violations involving small dollar amounts sometimes can get ''lost'' as they pass for collection from OIG to the Office of Financial Management, where they may not get high priority. Also, because reopening old claims always is discretionary, the agency may let some recoveries fall by the wayside.

But the uncertainties leave some providers with a Hobson's choice of settling government allegations with multi-million dollar checks or ''bet-the-company'' litigation. The latter is a scary option. ''I don't want to be the one to advise my client on taking this fight to court,'' one attorney said.

McClain said, ''I think anyone challenging this statute in a litigation context could raise very legitimate constitutional challenges—Eighth Amendment excessive fines issues, due process challenges—there are outer limits on what the government can do under Stark. But what people are concluding when they agree to pay $40 million like Erlanger did is that the risk of losing is too great, including the possibility of exclusion and all the other collateral consequences that can follow.''

At the same time, McClain said she thinks the government, too, realizes that if they ''push too hard or the relators get too greedy, it is just going to create a huge backlash and could lead to new legislation.

''I think both sides have a healthy dose of realism,'' she said.

By Susan Carhart