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## INSIGHT: Stark Law Reform Could Shift the Dynamics—And Maybe Even the Burden of Proof—in Future FCA Cases



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Recent developments relating to the physician self-referral law (Stark Law) suggest the possibility that meaningful reforms may be on the horizon. These reforms have the potential to provide additional relief to defendants by shifting the dynamics in False Claims Act (FCA) cases based on Stark Law violations, and possibly even shifting the burden of showing whether providers complied with the law back to the plaintiff.

### Background on Stark Law Reform

The Stark Law has long been the focus of criticism for its exceptional complexity and draconian penalties. Recent statements and action by officials within the Department of Health and Human Services (HHS) suggest the administration is poised to consider potentially meaningful reforms. In June, the Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI) soliciting input from stakeholders regarding potential changes to the Stark Law. As discussed in a recent article, the RFI is particularly focused on obtaining information from the health care industry on how the Stark Law frustrates efforts to implement value-based care models. Subsequent testimony before the House Ways and Means Committee from Eric Hargan, Deputy Secretary of HHS, made clear that HHS is “open-minded” with respect to potential changes to the Stark Law that may reduce the regulatory burden on providers.

Former Secretaries of HHS Kathleen Sebelius and Tommy Thompson recently described the Stark Law, along with the Anti-Kickback Statute (AKS), as a “remnant of the fee-for-service world” that “harm the very

patients they are supposed to protect by deterring more comprehensive patient-centered, coordinated care.”

These statements and the Stark Law RFI build on prior efforts to examine the law by the Senate Finance Committee in 2015, which resulted in a 2016 white paper, *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models*. In the white paper, the Committee concluded that, “[t]he Stark law was created to address a risk in an [fee-for-service] payment model” and “[t]he financial incentives that trigger overutilization concerns in an [fee-for-service] payment model are largely or entirely eliminated in alternative payment models.” Notably, the Committee observed that the Stark Law’s strict liability standard and significant penalties are viewed by health care companies as serious obstacles to implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and other alternative payment reforms.

Among the core challenges to implementation of value-based care models are the Stark Law’s requirements that compensation to physicians be consistent with fair market value and not take into account the volume or value of referrals. These standards are very poorly defined and, broadly construed, are implicated by many potential approaches to value-based payment models because of the alignment of physician incentives with care patterns.

The growing universe of FCA cases predicated on alleged Stark Law violations has only amplified concerns by parties who might otherwise embrace value-based care in response to policy and market pressures. Particularly vexing to defendants in such cases is that the burden of proof to demonstrate compliance with the Stark Law effectively falls to the defendant because ap-

plicability of a Stark Law exception has been characterized by most courts as an affirmative defense.

## The Stark Law and FCA

The Stark Law contains a two-part prohibition: (1) a physician may not make a referral to an entity for designated health services (DHS) if the physician (or an immediate family member) has a financial relationship with that entity, unless an exception applies; and (2) an entity may not submit a claim to Medicare for a DHS furnished pursuant to a prohibited referral. Violations of the Stark Law may result in penalties, exclusion, and an obligation to refund amounts received from Medicare. Stark Law violations may also form the basis of an FCA action, on the premise that a claim submitted in violation of the Stark Law is false or fraudulent.

Because the Stark Law is a strict liability statute—containing an absolute prohibition on referrals for DHS if the physician has a financial relationship, *unless an exception applies*—courts have construed compliance with an exception as an affirmative defense that must be proven by defendants. As a result, courts typically permit discovery to proceed if the pleadings are otherwise sufficient.

Whether a defendant's motion to dismiss is based on Fed. R. Civ. P. 9(b), which requires a party to plead "with particularity the circumstances constituting fraud or mistake," or Fed. R. Civ. P. 12(b)(6) for failure to state a claim on which relief can be granted, courts generally look to the sufficiency of the complaint rather than to resolving factual disputes, the merits of a claim, or the applicability of defenses. Given the fact-intensive nature of alleged Stark Law violations, FCA cases predicated on such claims have generally survived motions to dismiss and proceeded to discovery. For example, allegations that compensation exceeds fair market value or is commercially unreasonable generally requires the parties to engage experts to present competing analyses of terms of employment, compensation, provider and community needs and a host of other factors, none of which can be adequately presented at the motion to dismiss stage. Ultimately, the lack of "bright line" rules surrounding many of the core requirements of Stark Law compliance introduces ambiguity that generally favors plaintiffs in the early phases of litigation.

This has contributed to a trend of FCA cases surviving a motion to dismiss even where the allegations are thinly plead. For example, in *United States ex rel. Bingham v. BayCare Health Systems* (M.D. Fla., No. 8:14-cv-73), the defendant hospital was unable to dispense with an FCA complaint based on a questionable Stark theory and very loose facts. While the hospital ultimately prevailed on summary judgment, it was forced to endure another year and a half of time-consuming and costly discovery and motion practice to defeat a relator who apparently had no evidence to support his claims. Many other organizations facing similarly weak allegations may choose the certainty of an early settlement over the potentially significant legal costs of discovery and the uncertainty of summary judgment.

## Potential for Relief From Stark Reforms

Any reforms that provide some degree of "bright line" guidance about satisfying key requirements in

Stark Law exceptions could prove helpful for FCA defendants. In particular, guidance around the concepts of fair market value, taking into account the volume or value of referrals, and commercial reasonableness could potentially shift the dynamics at the motion to dismiss phase of FCA cases. These three requirements are included in the vast majority of the compensation exceptions to the Stark Law and they are frequently implicated in FCA cases. Despite the centrality of these requirements to Stark Law compliance, there are no clear standards to define their parameters, which results in weak *qui tam* cases proceeding into active litigation and often results in unwarranted settlements.

To the extent the reforms result in bright line rules—for example, by describing attributes of arrangements that are "deemed" to be fair market value, not to take into account the volume or value of referrals, and/or commercially reasonable—FCA defendants may be able to leverage new arguments to knock out flimsy claims that allege general violations of the Stark Law with little substance to back them up. CMS could, for example, adopt the position that compensation is deemed to be fair market value within certain parameters, unless proven otherwise. Likewise, with the benefit of deeming provisions around "takes into account" and "commercial reasonableness," defendants could assert at the motion to dismiss stage that the compensation paid to physicians is compliant with the Stark Law if it has certain attributes. Just as CMS has previously done with its per-unit deeming rules and its set in advance deeming rules, it could effectively establish safe harbors under these standards. Ultimately, the introduction of bright line rules and certainty around these standards may help alleviate ambiguities that plaintiffs are frequently able to exploit in the early phases of FCA cases built on alleged Stark Law violations.

These developments may also align with the Department of Justice's (DOJ) recent guidance outlined in the so-called "Granston Memorandum," authored by Michael Granston, director of the Civil Division's Fraud Section. This memorandum provides guidance to DOJ prosecutors about when the United States should consider exercising its authority under 31 U.S.C. § 3730(c)(2)(A) to dismiss *qui tam* cases that "lack merit or are otherwise contrary to the interests of justice." While there does not appear to have been a significant uptick in the number of frivolous cases being dismissed by DOJ, significant changes to the Stark Law could provide additional bases for FCA defendants to advocate early in an investigation to encourage non-intervention and subsequent dismissal.

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