

Who Is Enforcing the Stark Law of the United States?

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Eliminating healthcare fraud has long been a top priority of the United States government. The ramifications of healthcare fraud are far reaching: (1) it depletes billions of dollars from Medicare and Medicaid and other government-funded programs; (2) it adversely impacts the provision of objective quality healthcare; and (3) it bilks federal and state taxpayers out of billions in tax dollars. Improper patient referrals, a long-standing healthcare fraud scheme, place personal profit above patient care and burden the nation with enormous financial costs. As a result, the government has formed legions of task forces, whose sole purpose is to reduce and prosecute healthcare fraud. Emphasizing the government's reinvigorated focus on this goal, Lewis Morris, the former Chief Counsel of the Department of Health and Human Services (HHS) Office of Inspector General (OIG), has declared repeatedly that healthcare fraud "is a serious problem that demands an aggressive response."¹

Despite this powerful and unequivocal rhetoric, the government has yet to enforce aggressively a significant statute that offers perhaps the easiest means of recouping countless dollars lost to healthcare fraud: Section 1877 of the Social Security Act,² more commonly referred to as the "Stark Law." Closer examination of enforcement litigation data reveals that the government's proclamations on enforcing the Stark Law are inconsistent with its enforcement track record.³ Despite the lack of robust enforcement efforts by the government, Stark Law compliance continues to be an area of concern to all healthcare providers, in no small measure due to the success of whistleblowers utilizing the reinforced federal False Claims Act to litigate alleged Stark Law violations. To date, the majority of public Stark Law actions initiated, filed, decided, and settled have been pursued by private whistleblowers—and not initiated by the government.⁴ These actions have clarified some complexities and nuances of the Stark Law, and likely heightened provider vigilance, thereby helping to deter healthcare fraud.⁵ The government's reluctance to enforce the Stark Law given the results achieved by whistleblowers also raises the question: why has the government lagged behind the efforts of private litigants?

Stark Law Overview

Legislative History

In 1989, Congress passed legislation, known as Stark I,⁶ which precluded physicians from referring patients to clinical laboratories with which a physician or immediate family member had a financial relationship.⁷ Stark I was passed to address concerns that physicians ordered additional, and often medically unnecessary, laboratory tests when they stood to benefit financially.

In 1993, as part of the Omnibus Reconciliation Act of 1993, Congress enacted Stark II, which greatly expanded the federal physician self-referral ban to apply to a total of ten categories of designated health services (DHS).⁸ Stark II was based on a premise similar to that of Stark I; namely, that DHS was highly susceptible to overutilization when the referring physician stood to benefit financially.

In enacting Stark II, Congress defined prohibited physician financial relationships more broadly to include both direct and indirect ownership as well as investment interests and compensation arrangements. Underscoring the statute's

importance, the Stark Law was enacted, in large part, as a strict liability statute, requiring the lowest possible standard of proof for establishing a violation. Thus, proof of specific intent to violate the Stark Law is not required to prove liability. In sum, the Stark Law was intended to serve as a bright-line rule for prohibited referrals, thus providing the government with the greatest chance of meeting its burden at trial.

Congress authorized the HHS Secretary to create additional regulatory exceptions to the Stark Law, to issue advisory opinions, and to issue regulations interpreting the Stark Law.⁹ Under the Secretary's authority, the Centers for Medicare & Medicaid Services (CMS) published three phases of regulations interpreting the Stark Law: Phase I was issued on January 4, 2001, and effective January 4, 2002;¹⁰ Phase II was issued on March 26, 2001, and effective on July 26, 2004;¹¹ and Phase III was issued on September 5, 2007, and, with certain exceptions, effective December 4, 2007.¹² Additional changes to the Stark Law also were implemented as part of the Fiscal Year 2009 Medicare Inpatient Prospective Payment System¹³ and the Affordable Care Act.¹⁴ CMS' interpretation of the Stark Law has evolved with each phase of regulations.

Prohibited Conduct

The Stark Law prohibits a physician from making referrals for certain DHS payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an enumerated exception applies.¹⁵ The Stark Law also prohibits the submission, or causing the submission, of claims for DHS that are furnished as a result of a prohibited referral.¹⁶ Compliance with the Stark Law is a prerequisite for payment of all Medicare claims. Accordingly, amounts paid on claims submitted to Medicare based on prohibited referrals are improper overpayments. The Stark Law's breadth reaches *any* financial relationship between a referring physician and an entity furnishing DHS—even if the relationship itself is wholly unrelated to the DHS payable by Medicare or Medicaid. The financial relationship, moreover, may be direct or indirect. The Stark Law essentially includes all possible financial relationships. Of course, not every Stark Law violation requires any type of enforcement action or should be the focus of litigation.

Violations of the Stark Law can result in significant civil penalties. These penalties include civil fines of up to \$100,000 for a circumvention scheme, a penalty for each claim submitted for services provided pursuant to a prohibited referral, the denial of payment for DHS rendered, and the refund of all payments made for DHS provided in violation of the Stark Law. Providers, moreover, may be excluded from federal healthcare programs for violating the Stark Law.

Government Enforcement of the Stark Law

CMS is primarily responsible for enforcing the Stark Law. CMS also is responsible for issuing guidance and advisory opinions. While advisory opinions provide CMS with an opportunity to further clarify the Stark Law, the agency has issued only nine advisory opinions between 1998 and 2012, and most of those related to the limited issue of physician-owned hospitals. Suffice

it to say, CMS has adopted a conservative approach to its enforcement obligations. Considering its current responsibilities, CMS arguably lacks the resources to enforce the Stark Law more aggressively, which could explain why it seems to have assumed a more reactive, rather than proactive, enforcement posture.

Most recently, Congress included a provision in the Affordable Care Act that specifically requires the Secretary to establish a self-disclosure protocol to allow providers to self-disclose actual or potential violations of the Stark Law.¹⁷ While requiring CMS to undertake a greater role in addressing disclosed violations, the self-disclosure protocol nonetheless allows CMS to remain in a mostly reactive posture.

Although it is the primary agency responsible for enforcing the Stark Law, CMS has not appeared to investigate vigorously or refer cases to other government agencies for enforcement. This approach has resulted in little government-initiated enforcement litigation. Instead, qui tam relators have been the primary drivers of Stark enforcement actions for better and, at times, for worse.

In addition to CMS, the OIG is authorized to seek civil monetary penalties and exclusion of providers from participation in federal healthcare programs for Stark Law violations. The OIG also investigates suspected fraud and routinely refers cases to the U.S. Department of Justice (DOJ) for criminal or civil actions. The DOJ, with the assistance of the Federal Bureau of Investigation, has authority to investigate and prosecute violations of the Stark Law if such violations are in conjunction with violations of the Anti-Kickback Statute or the False Claims Act. For practical reasons, however, it seems the DOJ often follows its client CMS' less-aggressive lead with respect to Stark Law enforcement.¹⁸



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The Federal False Claims Act Overview

The Federal False Claims Act (FCA)¹⁹ provides the government with a powerful tool for combating fraud, abuse, and waste of government funds. Since the FCA was amended in 1986, over \$34 billion has been recovered under the statute.²⁰ In the last two decades, the number of FCA actions filed has increased significantly. For instance, in 1988, only 43 FCA actions were filed. In 2011, however, approximately 638 actions were filed, of which 417 were healthcare-related.²¹ Indeed, nearly 75% of all FCA recoveries have come from healthcare cases, amounting to \$15.8 billion.²² Moreover, 18 of the top 20 FCA recoveries are from healthcare cases.²³ The federal government is recovering \$15 for every \$1 invested in FCA healthcare investigations and prosecutions.²⁴

The Fraud Enforcement and Recovery Act of 2009 (FERA) and the Affordable Care Act of 2010 both included provisions to strengthen the FCA. These amendments expanded the scope of liability under the FCA and provide relators and the government with enhanced investigative powers.

Despite this powerful tool, the government has not utilized the FCA extensively to enforce the Stark Law. Whistleblowers have brought the vast majority of public cases alleging Stark Law violations, with or without government intervention, pursuant to the FCA's qui tam provision,²⁵ which permits private individuals to file false claims actions on behalf of the federal government. The FCA provides a lucrative incentive to encourage private individuals to pursue false claims actions, namely, the ability to receive a share of any recovery. The potential recovery includes both the Stark Law penalties and the penalties for violating the FCA, which are especially prohibitive.²⁶ Astonishingly, of the approximately 100 published legal actions alleging, *inter alia*, violations of the Stark Law, only two cases appear to have been brought directly by the United States government without any apparent involvement of a whistleblower.²⁷

Whistleblower Enforcement of the Stark Law

The lack of government-initiated Stark Law litigation has resulted in a paucity of case law interpreting the statute. Most of the legal advances in Stark Law jurisprudence have been made predominantly as a result of public whistleblower actions under the FCA. In addition to helping advance the law interpreting the statute, whistleblower actions involving Stark Law violations have achieved recoveries on behalf of the government, which, in turn, has had a deterrent effect on healthcare fraud. Without these whistleblower actions, in many of which the government declined to intervene, the Stark Law, while admittedly complex, would remain even less defined.²⁸

Significant Decisions

Beginning as early as the mid-1990s, whistleblowers have been achieving legal victories that have helped pave the way to establishing Stark Law violations.²⁹ More recent decisions confirm that these legal advances are the result of whistleblower actions. In *United States v. Rogan*,³⁰ the court held that the former owner and chief executive officer of a medical center caused the medical center to submit false claims to Medicare and Medicaid for services to patients referred by

physicians with whom the medical center had prohibited financial relationships in violation of the Stark Law and the Anti-Kickback Statute. The court awarded the government \$64 million in damages and penalties. An equally significant victory was achieved in *United States ex rel. Kosenske v. Carlisle HMA Inc.*,³¹ a case in which the government declined to intervene, where the Third Circuit confirmed that false certification of compliance with the Stark Law is actionable under the FCA. It appears increasingly likely that whistleblowers and their counsel will pursue alleged Stark Law violations under the FCA even where the government declines to intervene.

Whistleblowers continued to achieve legal success in *United States ex rel. Singh v. Bradford Regional Medical Center*,³² where the relators alleged that the medical center submitted false claims to Medicare in violation of the Stark Law and Anti-Kickback Statute based on improper lease and compensation arrangements to physicians. The court denied the defendants' motion for summary judgment and held that the lease and compensation arrangements constituted either "direct or indirect" arrangements for which no exception applied.³³

Most recently, in *United States ex rel. Drakeford v. Tuomey Healthcare*,³⁴ the Fourth Circuit analyzed whether part-time employment agreements with physicians violated the Stark Law. The federal district court entered a \$44 million judgment against Tuomey Healthcare System based on the court's findings that certain part-time employment agreements violated the Stark Law. The Fourth Circuit vacated the district court's order, holding that it violated Tuomey's Seventh Amendment right to a jury trial. In reaching its decision, the Fourth Circuit analyzed whether Tuomey had compensated physicians based on the volume or value of anticipated referrals in violation of the Stark Law, although the appeals court ultimately remanded the case for a jury to decide this issue.

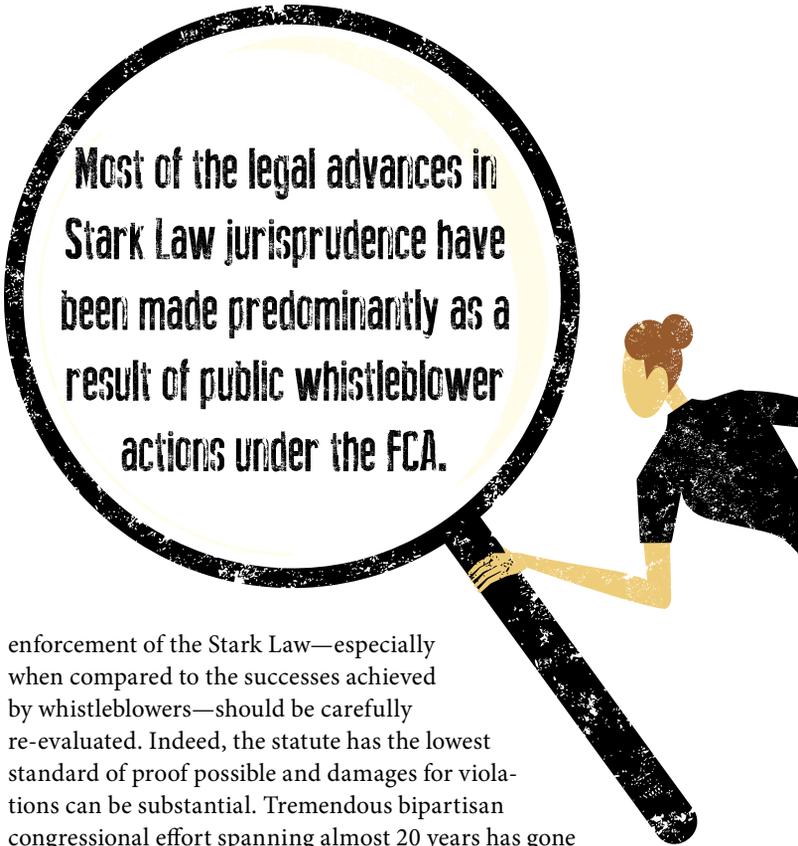
While the above decisions have advanced the legal precedent on which future Stark Law actions could be based, none of the violations at issue in these cases seemed particularly complex or involved so-called technical violations of the Stark Law, undermining a frequent contention that the government's reluctance to bring enforcement actions is based on the complexity of the statute or concerns about its overutilization.

Significant Stark-Related Settlements

Media attention to large whistleblower settlements also likely has encouraged providers to focus on Stark Law compliance, despite the dearth of aggressive enforcement initiatives in this area. In addition to the precedential decisions that have resulted from whistleblower actions utilizing the FCA, whistleblowers have negotiated significant settlements in cases alleging Stark Law violations. For instance, recently whistleblowers successfully settled an FCA claim based on the Stark Law with the Odyssey HealthCare for \$25 million and an FCA claim based on the Stark Law with Christiana Care Health System for \$3.3 million.

Conclusion

Despite the government's pronounced resolve to eliminate healthcare fraud, whistleblowers thus far have served as the primary enforcers of the Stark Law. The lack of government



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enforcement of the Stark Law—especially when compared to the successes achieved by whistleblowers—should be carefully re-evaluated. Indeed, the statute has the lowest standard of proof possible and damages for violations can be substantial. Tremendous bipartisan congressional effort spanning almost 20 years has gone into honing and expanding the Stark Law to ferret out multiple types of inappropriate physician self-referrals. While the Stark Law, in all of its permutations, remains a complex and intricate statute, the cases brought by whistleblowers largely have focused on clearly identifiable violations, and have recouped significant dollars lost to healthcare fraud and abuse. If the government were to investigate Stark Law violations more aggressively, and most importantly, vigorously litigate those cases, a 20-year-old law would achieve more significant recoveries to taxpayers, as well as provide a significant deterrent to non-compliant providers.

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Endnotes

- 1 See Statement by Lewis Morris on Improving Efforts to Combat Health Care Fraud before the House Ways and Means Subcommittee on Oversight, Mar. 11 2011, *available at* <http://www.dhhs.gov/asi/testify/2011/03/t20110302h.html>.
- 2 42 U.S.C. § 1395nn.
- 3 See, e.g., Statement by Tony West, Assistant Attorney General for the Justice Department's Civil Division, *available at* www.justice.gov/opa/pr/2010/March/10-civ-240.html ("The Justice Department is committed to investigating cases that threaten the integrity of the Medicare program. . . . The department will continue to protect patients by pursuing hospitals that have improper financial relationships with physicians."); Statement by Tony West, *available at* www.justice.gov/opa/pr/2009/August/09-civ-849.html ("Health care providers must act in the best interests of their patients. The Justice Department will protect patients by pursuing hospitals that have improper financial relationships with physicians."); Statement by former OIG Chief Counsel Lewis Morris, *available at* www.modernhealthcare.com/article/20091012/NEWS ("[u]nder the anti-kickback statute and Stark self-referral law, it takes two to tango When we're doing our analysis of the fraud problem, we have come to recognize we're only going to get our arms around this if we address both parties to the scheme.").
- 4 Review of approximately 100 public legal actions involving allegations of Stark Law violations reveals that all but two were either initiated or filed by private whistleblowers.
- 5 The healthcare system is and has always remained mostly dependent on self-compliance with the law. See www.oig.hhs.gov/compliance/self-disclosure-info/index.asp; www.cms.gov/physicianselfreferral; <http://www.dpw.state.pa.us/learnaboutdpw/fraudandabuse/medicalassistanceproviderselfauditprotocol/index.htm>; see generally www.oig.hhs.gov/compliance/compliance-guidance/index.asp; http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_Fraud_Physicians_FactSheet_905645.pdf (Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians).
- 6 See Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236-43 (1989).
- 7 See 42 U.S.C. § 1395nn(a)(1).
- 8 See Pub. L. No. 103-66, §§ 13562, 13624, 107 Stat. 312, 604, 636 (1993).
- 9 See 42 U.S.C. § 1395nn(b)(4); 42 U.S.C. § 1395nn(g)(4); 42 C.F.R. § 411.350.
- 10 66 Fed. Reg. 856.
- 11 69 Fed. Reg. 16054.
- 12 72 Fed. Reg. 51012.
- 13 73 Fed. Reg. 48683.
- 14 See Pub. L. No. 111-148, § 6406, 124 Stat. 772 (2010).
- 15 42 U.S.C. § 1395nn(a)(1)(A); 42 C.F.R. § 411.353. Partly in response to opposition from the medical community during the comment phase of each of the three sets of regulations, and partly to address a realistic approach for certain unknown "technical" violations, CMS has expanded greatly the enumerated exceptions to Stark Law. There are now 23 exceptions. See 42 C.F.R. § 411.357. If an entity can demonstrate that it falls squarely within an exception, the compensation arrangement does not violate Stark Law. Mistaken reliance on an exception may result in significant exposure to the entity, however, especially because a violation may occur regardless of intent.
- 16 *Id.*
- 17 See www.cms.gov/physicianselfreferral. The OIG previously oversaw voluntary self-disclosures of Stark Law violations through its Provider Self-Disclosure Protocol (SDP), which it launched on October 21, 1998. The primary purpose of the SDP was to provide a mechanism for healthcare providers to report voluntarily fraud and abuse affecting federal healthcare programs utilizing less government resources. Since its inception, OIG has issued five open letters providing guidance on the SDP. See www.oig.hhs.gov/compliance/self-disclosure-info/index.asp. In the most recent letter, issued in March 2009, the OIG essentially foreclosed its SDP as it related to the Stark Law by stating that it would no longer be available for Stark Law-only violations, and instead, it would only accept self-disclosures of Stark Law violations that included "colorable" violations of the federal Anti-Kickback Statute. The Affordable Care Act, however, requires the Secretary of HHS to ensure a process for providers to self-disclose Stark Law violations.
- 18 This statement is based on the author's 24 years of practical experience.
- 19 31 U.S.C. § 3729, *et seq.* The FCA prohibits the knowing submission of a false or fraudulent claim for payment to the United States. The FCA also prohibits anyone from causing someone else to submit a false claim.
- 20 See www.taf.org/statistics.htm.
- 21 See www.taf.org/DoJ-fraud-stats-FY2011.pdf.
- 22 See *id.*
- 23 www.taf.org/top20.htm
- 24 See www.taf.org/statistics.htm.
- 25 31 U.S.C. § 3730.
- 26 Penalties for violating the FCA include treble damages, attorneys' fees, and civil penalties of \$5,500 to \$11,000 for each false claim submitted to the government.
- 27 In 2011, there were 762 total new matters initiated or filed under the FCA. Of those 762 new matters, the government either has pursued or intervened in 638. See www.taf.org/DoJ-fraud-stats-FY2011.pdf.
- 28 Nonetheless, whistleblowers also have created bad precedent by pursuing weak to nonexistent Stark Law violations. See *United States ex rel. Repko v. Guthrie Clinic, P.C.*, no. 11-3682, 2012 WL 3104883 (3d Cir. Aug. 1, 2012).
- 29 See, e.g., *United States ex rel. Pogue v. American Health Corp.*, 914 F. Supp. 1507 (M.D. Tenn. 1996) (holding that self-referral violations are actionable under the FCA so long as the defendant acted with the intent of inducing payment from the government); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997) (holding that violations of the Stark Law may be found where the government's payment of Medicare claims was based on defendants' false certifications and remanded to district court for determination); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1023-44 (S.D. Tex. 1998) (holding that violations of Stark Law could independently form the basis of an FCA action).
- 30 459 F.Supp. 2d 692 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).
- 31 554 F.3d 88 (3d Cir. 2009).
- 32 752 F.Supp.2d 602 (W.D. Pa. 2010).
- 33 The government filed a rare Statement of Interest in a Stark Law action, on August 1, 2012, in *United States ex rel. Osheroff v. Tenet Healthcare Corp.* no. 09-cv-22253 (S.D. Fla.). Relying on *Singh*, the government argued that fair market value is an affirmative defense to be raised by the defendant, and that the failure to meet fair market value need not be pleaded by the plaintiff in the complaint.
- 34 No. 10-1819 (4th Cir. Mar. 30, 2012).

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