

The Intersection of the Stark Law and Medicaid Claims: Catching Providers in a Legal Quagmire

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Until recently, both the federal government and private healthcare practitioners have focused their litigation and compliance advice relating to the Stark Law¹ exclusively on Medicare. Two False Claims Act (FCA)² cases currently pending in the district courts represent a dramatic shift by the federal government and are forcing the private bar to re-evaluate the advice given to provider clients.

The federal government historically has enforced the Stark Law primarily through FCA cases.³ It has predicated these cases on the theory that the provider engaged in a prohibited financial relationship with a physician, improperly received referrals from that physician, improperly billed Medicare for such referrals, and improperly received Medicare reimbursement pursuant to those referrals. The Stark Law on its face applies only to Medicare. As such, healthcare attorneys often have advised their provider-clients that financial and compensation arrangements into which they enter with physicians who refer Medicare patients must comply with one of the many exceptions to the statute. They also often have advised their provider-clients that in the event any referrals violate the Stark Law, they likely will have to repay to Medicare any money collected as a result of those referrals, or in recent years, at least a lesser amount through the Self-Referral Disclosure Protocol established by the Centers for Medicare & Medicaid Services (CMS).⁴

Recently, the Department of Justice (DOJ) and relators have opened the door to a new area of enforcement: alleging FCA violations that result from the submission of claims based on prohibited referrals of Medicaid beneficiaries. This activity has led some attorneys to take a second look at the Medicare and Medicaid statutes, other case law, and guidance from CMS and its predecessor, the Health Care Financing Administration (collectively, CMS) to determine whether and when Medicaid referrals may become tainted by self-referrals and what liabilities a provider may incur in the Medicaid context. While currently there is little guidance on this issue, stakeholders should be aware of the possibility that FCA enforcement actions based on allegedly improper Medicaid referrals may continue, if not become commonplace, in the future. The potential for litigation activity based on Stark Law violations and Medicaid presents an interesting dilemma for providers, the resolution of which is impossible without regulatory and/or legislative action.

Statutory and Regulatory History

Section 1877 of the Social Security Act (Act)⁵ prohibits physicians from referring Medicare patients for certain designated health services (DHS) to any entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception to the prohibition applies. The statute also prohibits such an entity from presenting or causing to be presented a bill or claim for DHS



relating to a prohibited referral, and provides that Medicare shall not pay for such claims.⁶

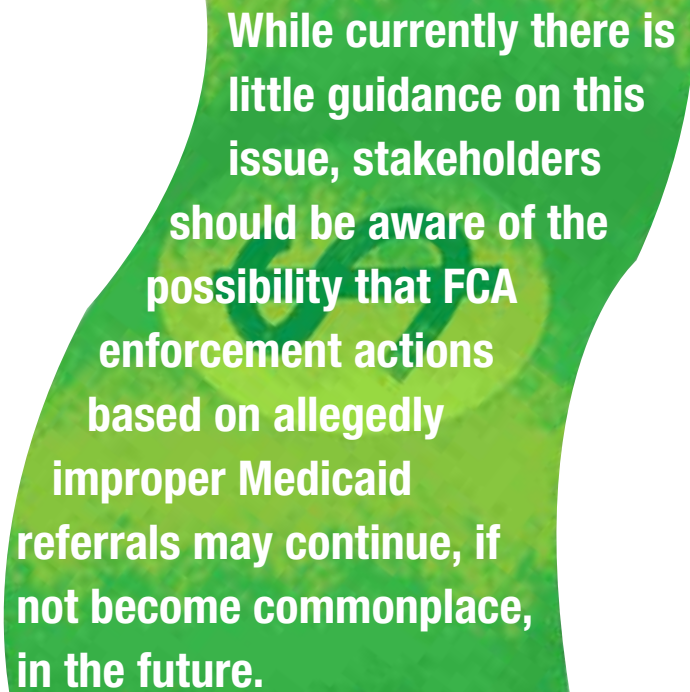
In 1993, Congress enacted the Omnibus Budget Reconciliation Act of 1993, which not only extended application of the statute's prohibitions beyond the context of clinical laboratories and to the context of ten specifically designated healthcare services, but also added Section 1903(s) to the Social Security Act (42 U.S.C. § 1396b).⁷ Section 1903 extended the impact of the Stark Law to the Medicaid program. Specifically, the provision restricts [federal financial participation (FFP)] for expenditures for medical assistance under the State plan consisting of designated health services, as defined under section 1877(h)(6) of the Act, that are furnished to an individual on the basis of a physician referral that would result in the denial of payment under the Medicare program if Medicare covered the service to the same extent and under the same conditions as under a State's Medicaid plan.⁸

The statute also expanded the Stark Law's reporting requirements under Section 1877(f) to apply to Medicaid providers as well as Medicare providers.⁹

To date, CMS has issued several sets of regulations to implement the Stark Law. Many refer to these regulations as Stark I and Stark II Phases I, II, and III.¹⁰ However, the agency only has released limited proposed regulations, which never have been finalized, to implement Section 1903(s) of the Act. This has left providers and other stakeholders with minimal guidance on how Stark's prohibition applies to the Medicaid program. CMS proposed clarifying some of this confusion in its 1998 Stark II Phase I proposed regulations by explicitly applying certain aspects of the Stark Law's prohibition on referrals to the Medicaid program. The agency then declined, however, to finalize the proposed regulations relating to Section 1903, indicating it would take the issue up again in its Phase II rulemaking. CMS did not raise the issue again in Phase II and, indeed, to date has not proposed any new alternative language.¹¹ As such, the states and Medicaid providers are left largely without guidance regarding the application of Section 1903(s).

Federal and state governments jointly finance Medicaid programs. The amount that the federal government pays to states is referred to as the federal financial participation (FFP). In the first set of proposed regulations for Stark II, CMS suggested that Congress likely enacted Section 1903(s) to curb financial relationships that would lead to improper utilization of Medicaid services.¹² The agency proposed, in accordance with the new statutory provision, that FFP would be denied for DHS furnished to an individual on the basis of a referral that would result in the denial under the Medicare program "to the extent the services were covered under both Medicare and Medicaid in a comparable way."¹³

In drafting the proposed regulations, CMS faced a number of challenges, including the fact that "because Medicaid has its own unique set of coverage requirements, a State can cover and reimburse [DHS] very differently from the way these services are covered and reimbursed under the Medicare program."¹⁴

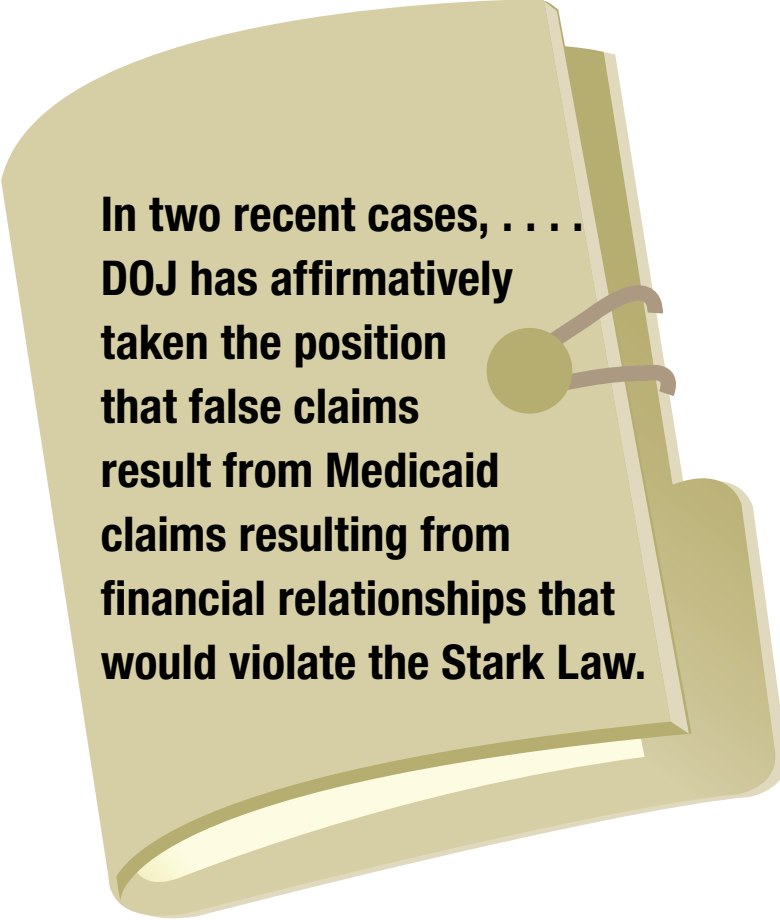


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CMS concluded that Congress was aware of these differences and that the language of the statute was intended to provide CMS "some flexibility" in applying the Stark Law's prohibitions in the Medicaid context.¹⁵

Therefore, CMS proposed to define each specific DHS category for Stark purposes in the same way for both programs when the definition of that service category is the same under both Medicare and Medicaid.¹⁶ On the other hand, when a state plan's definition of a DHS differs from Medicare's definition, the agency "would assume that the services under the State's plan take precedence, even if the definition would encompass services that are not covered by Medicare."¹⁷ Nevertheless, CMS would not include Medicaid services as designated health services when doing so would "appear[] to run counter to the underlying purpose of the legislation."¹⁸ Because the states administer Medicaid, however, CMS believed it was not "in the best position to determine when including particular services will have this effect" and, therefore, CMS specifically solicited comments "on how to implement our policy in a manner that will achieve the goals of the statute."¹⁹

Beyond the difficult issue of deciding which services are covered to the same extent and under the same conditions under Medicaid as under Medicare, CMS was able to propose some more concrete guidance in extending Stark to Medicaid, particularly in expanding certain definitions. For example, the proposed regulation proposed revising the definition of



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“referral” to include “a comparable service covered under the Medicaid State plan.”²⁰ It also would have added a new exception in the Medicaid regulations for services furnished to enrollees of Medicaid managed care plans.²¹

In addition, CMS explained that individuals who qualify as “physicians” under Medicare would be considered physicians for purposes of Section 1903(s) as well, even though Medicaid otherwise applies a much narrower definition of “physician,” limited to doctors of medicine and osteopathy.²² The agency reasoned that Section 1903 prohibits the Secretary from paying FFP to a state for services that result from a referral that would be improper under Medicare when certain coverage requirements are met.²³ Therefore, a referral by any “physician” listed in Section 1861(r) of the Act²⁴ could result in a referral that is prohibited under the Medicare program. Moreover, the agency added that Section 1903(s) would apply to all physicians, regardless of whether they actually participate in the Medicaid program.²⁵

With respect to Section 1903’s extension of reporting requirements, CMS proposed requiring providers to report the required information to the states rather than to CMS.²⁶ The agency adopted this position because it recognized that “it is the States that are at risk of losing FFP” and thus it is the states who “must determine whether a physician has a financial relationship with an entity that would prohibit referrals under Medicare.”²⁷ The proposed approach “will allow States to

protect themselves and to avoid any duplication of effort with [CMS].”²⁸

Consistent with this provision, CMS pointed out that Section 1903(s) is “strictly an FFP provision” that “imposes a requirement on the Secretary to review a Medicaid claim, as if it were under Medicare, and deny the FFP if a referral would result in the denial of payment under Medicare.”²⁹ Therefore, “these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services.”³⁰ Moreover, CMS noted, the statute does not prohibit states from paying for these services. Instead, it only provides that states cannot receive FFP for them.³¹ The states then “are free to establish their own sanctions for situations in which physicians refer to related entities.”³²

The proposed provisions discussed above would not have fully resolved the complex challenge of applying Section 1903, particularly as CMS left open for comment the question of how to determine when including certain Medicaid services would run counter to the purpose of Section 1903. The proposed regulations also did not seem to fully resolve the question of when Medicaid and Medicare would be deemed to “cover[] the service to the same extent and under the same conditions.” This latter question is made more difficult by the fact that in the final Phase I regulations issued in 2001, CMS revised its approach to bundled payments, such that individual DHS that are bundled and paid under a composite rate now are not treated as DHS unless the entire bundle is treated as DHS (e.g., inpatient or outpatient hospital services). The 1998 proposed rule had proposed treating the components as DHS even when bundled, regardless of whether the bundled category itself constituted DHS. In any event, for whatever reason, CMS decided when it issued its final Phase I regulations that it would not issue final regulations at that time to implement Section 1903. To date the agency has issued no further proposed or final regulations implementing Section 1903. As a result, not unreasonably, most practitioners within the health-care bar have considered the Stark Law, in practicality, to apply only to Medicare-reimbursable services.

Recent Case Law Challenges Providers’ Understanding of the Intersection Between the Stark Law and Medicaid

DOJ, on the other hand, has staked out a different position, by way of the FCA. In two recent cases, *United States ex rel. Baklid-Kunz v. Halifax Medical Center*³³ and *United States ex rel. Osheroff v. Tenet Healthcare Corp.*,³⁴ DOJ has affirmatively taken the position that false claims result from Medicaid claims resulting from financial relationships that would violate the Stark Law.

In *Halifax*, for example, DOJ alleges that Halifax Medical Center and Halifax Staffing, Inc. (collectively, Halifax) engaged in financial relationships³⁵ with a number of physicians that violated the Stark Law, and that the hospital submitted claims to both Medicare and Medicaid for DHS provided pursuant to referrals from those physicians.³⁶ As such, the government and

relator alleged that claims submitted as a result of those referrals violated the FCA.³⁷

The defendants argued on their motion to dismiss under FED. R. CIV. P. 12(b)(6) for failure to state a claim that neither the Stark Law nor the Medicaid statute prohibited Florida Medicaid from reimbursing them for their services and thus their Medicaid claims could not have been false in violation of the FCA.³⁸ DOJ argued, however, that by engaging in the prohibited relationship and submitting claims to the Florida Medicaid program, Halifax violated the FCA by causing the Florida Medicaid program to submit false claims to the federal government, in violation of the FCA.³⁹ Thus, the “false claims” alleged were not the claims submitted by the provider to Medicaid; they were the claims submitted by Medicaid to CMS for FFP.⁴⁰ Relying on the language in Section 1903 prohibiting FFP payment for Medicaid services that, if provided under Medicare, would have been non-reimbursable based on the Stark Law’s prohibitions, the court flatly rejected Halifax’s argument and held simply that the allegation that Halifax caused Florida Medicaid to submit false claims was sufficient to state a claim under the FCA.⁴¹

In *Tenet*, a case in which DOJ declined to intervene, *qui tam* relator Marc Osheroff (Relator) alleged that Tenet’s hospitals accepted patient referrals from physicians who leased space from the hospital chain and its subsidiaries (Defendants) at rates below fair market value.⁴² Therefore, Relator claimed that the Stark Law prohibited Tenet from submitting claims arising out of those referrals to Medicare and Medicaid for DHS, and thus both types of improper submissions constituted false claims under the FCA.⁴³ The court did not specifically address the issue of whether Defendants’ submission of allegedly tainted Medicaid referrals can serve as a basis for a FCA violation but noted that the United States, in a statement of interest brief filed in the case, asserted that the Defendants had certified compliance with the Stark Law and that compliance with that law is “a condition of the government’s payments under Medicare and Medicaid.”⁴⁴ The court also noted that the Defendants had conceded that Stark Law violations render claims submitted to the government for payment false under the FCA if the defendant knowingly certifies compliance and certification is a condition of payment.⁴⁵

Application/Future Enforcement

At least in the abstract, the position taken by DOJ in *Halifax* appears logical and would not stretch the FCA jurisprudence tremendously far. DOJ often has brought and litigated cases based on allegations that the defendant did not submit false claims but instead caused another person to submit false claims. The plain language of the statute supports such theories. The difficulty with DOJ’s position in *Halifax*, however, is that healthcare practitioners generally have not considered the Stark Law’s prohibitions to extend to Medicaid, at least not in practice. The Stark Law statute itself references only Medicare, and the regulations—of which much has been written, considered, analyzed, and agonized over—reference only Medicare as

well. The reimbursement prohibitions apply only to Medicare. Even the definitions of DHS are stated in terms of Medicare reimbursability. To the extent practitioners (not to mention their provider-clients) were aware of Section 1903, which on its face affects only state Medicaid plans, such awareness tended to be vague, and the general understanding was that Section 1903 simply would not apply until CMS issued regulations implementing it. Indeed, our informal review of numerous Stark Law presentations made by well-respected health law attorneys from both the private and government sectors over the past decade reflects a clear and limited focus on Medicare, not Medicaid.

Perhaps the judge in *Halifax* simply figured that at the motion to dismiss stage, it made no sense to distinguish between Medicare and Medicaid claims, given that the same conduct between the physicians and hospital was at issue. In a vacuum, if the hospital had been aware that submitting claims to Medicaid would cause Medicaid to submit false claims to CMS for FFP payment, then perhaps the hospital could be liable under the FCA for causing Medicaid to submit false claims. In the course of the litigation, no doubt, issues of knowledge on the part of the hospital, causation with respect to the state’s submission of its FFP claims, and whether in fact compliance with Section 1903 really was a condition of payment by CMS to Florida Medicaid, will be sorted out. And most likely, at least based on the tendency of providers to settle FCA cases rather than risk losing at trial and becoming subject to exclusion from federal healthcare programs, these issues ultimately will be resolved simply by settlement. So for those providers and practitioners who are not directly engaged in either the *Halifax* or *Tenet* litigation, these issues of knowledge, causation, and conditions of payment may seem interesting but academic.

But the import of these cases reaches far beyond their litigants. Providers are now on notice that at least DOJ, if not the other agencies within the federal government, believes that submitting claims to Medicaid can trigger FCA liability if the physician and DHS entity have engaged in a financial relationship that is prohibited under the Stark Law. This knowledge probably will not impact the way that most providers and physicians initially enter into financial relationships because most providers have a patient mix that includes Medicare and thus they already try to structure their arrangements to comply with the Stark Law.

The bigger challenge will arise more commonly when the provider discovers that an existing arrangement with a physician failed to comply with the Stark Law, particularly where the non-compliance was technical. Since CMS has issued its Self-Referral Disclosure Protocol (SRDP), numerous providers have availed themselves of that Protocol’s process for self-reporting and resolving violations for a fraction of the value of the affected Medicare claims submitted. But on its face and, as we understand it,



also in practice, the SRDP is available only for the resolution of Medicare overpayments resulting from claims resulting from Stark Law violations. It does not even acknowledge the possibility of resolving Medicaid-related claims. Moreover, the statutory provision allowing CMS to compromise violations for less than the full value of the claims is limited to Medicare claims.

Thus, the provider that discovers it has received reimbursement for Medicaid claims resulting from referrals from a physician with whom it engaged in prohibited financial relationships finds itself in a quagmire. It was entitled to submit and receive payment from the state for its claims, as acknowledged by CMS in its proposed regulation preamble, and thus those payments are not overpayments. On the other hand, the state will now seek payment from CMS for the FFP of those affected claims, and DOJ argues that those state-submitted claims are false and that the provider caused the state to submit them. The SRDP offers no assistance for the Medicaid claims, though with respect to the Medicare claims the provider may feel that Protocol provides the only reasonable path to resolution. The states have established no mechanisms analogous to the SRDP and if they were to resolve the provider's liability based on a reduced number (as CMS can through the SRDP), no provision would enable CMS to pay them either the full or reduced amount of FFP for those claims.

Providers' best option at this point is to look to Congress for a legislative solution or to CMS for a regulatory solution. The court system is unlikely and, perhaps, even unable to offer any meaningful assistance to this dilemma. **C**

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Endnotes

- 1 Social Security Act (SSA) § 1877; 42 U.S.C. §1395nn.
- 2 31 U.S.C. §§ 3729-33.
- 3 See, e.g., *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470 (5th Cir. 2012).
- 4 Section 6409 of the Patient Protection and Affordable Care Act required CMS to establish a self-referral disclosure protocol and authorized CMS to resolve Stark Law violations for less than the full value of the claims improperly submitted pursuant to improper referrals. See also www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRD_Protocol.pdf (last visited Mar. 30, 2013).
- 5 42 U.S.C. § 1395nn.
- 6 42 U.S.C. § 1395nn(a)(1)(A) and (g)(1).
- 7 The Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, (Aug. 10, 1993).
- 8 Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, Proposed Rule, 63 Fed Reg. 1659, 1672 (Jan. 9, 1998).
- 9 The Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, (Aug. 10, 1993).
- 10 When initially enacted, the Stark Law applied only to physician self-referrals involving clinical laboratory services (Stark I). Shortly thereafter Congress amended the law to apply to a variety of specifically designated healthcare services (Stark II). The first final regulations for Stark I were issued after enactment of Stark II, and the Stark II regulators were issued primarily in three significant groupings, commonly referenced as Phases I, II, and III.
- 11 Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, Final Rule, 66 Fed. Reg. 856 (Jan. 4, 2001); Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), Interim Final Rule with Comment Period, 69 Fed. Reg. 16064, 16065 (Mar. 26, 2004).
- 12 63 Fed. Reg. at 1673.
- 13 *Id.* at 1659.
- 14 *Id.* at 1673.
- 15 *Id.*
- 16 *Id.*
- 17 *Id.*
- 18 *Id.* at 1673-74.
- 19 *Id.* at 1674.
- 20 *Id.* at 1722-23.
- 21 *Id.* at 1697, 1727.

22 *Id.* at 1704.
 23 *Id.* at 1704.
 24 42 U.S.C. § 1395x.
 25 63 Fed. Reg. at 1704.
 26 *Id.* at 1705, 1727-28.
 27 *Id.*
 28 *Id.*
 29 *Id.* at 1704.
 30 *See id.*
 31 *See id.*
 32 *Id.*
 33 *United States ex rel. Baklid-Kunz v. Halifax Med. Ctr.*, Order, No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *1, *3 (M.D. Fla. Mar. 29, 2012).
 34 *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, Order Granting in Part and Denying in Part Motion to Dismiss First Amended Complaint, No. 09-22253-CIV, 2012 WL 2871264, at *1 (S.D. Fla. July 12, 2012).
 35 The decision does not specifically indicate the nature of the financial relationships, and in fact the defendants attacked the complaint for failing to adequately describe the relationships specificity as required by Fed. R. Civ. P. 9(b)'s requirement that fraud allegations be stated with particularity.
 36 *United States ex rel. Baklid-Kunz v. Halifax Med. Ctr.*, Order, 2012 WL 921147, at *1, *3.
 37 *Id.*
 38 *Id.*
 39 *Id.* at *4. The False Claims Act imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).
 40 *See United States ex rel. Baklid-Kunz v. Halifax Med. Ctr.*, Order, 2012 WL 921147, at *4.
 41 *Id.* at 4.
 42 *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, Order Granting in Part and Denying in Part Motion to Dismiss First Amended Complaint, 2012 WL 2871264, *1.

43 *Id.*
 44 *See id.* at *6; U.S. Statement of Interest in Response to the Court's June 29, 2012 Order, Case No. 09-22253-HUCK (June 22, 2012).
 45 *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, Order Granting in Part and Denying in Part Motion to Dismiss First Amended Complaint, 2012 WL 2871264, *6.

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