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Courts' Acceptance of FCA/Stark Law Theory in Medicaid Cases Expands Further

Member Briefing, November 2014

Children's Hospital Affinity Group, and Fraud and Abuse, In-House Counsel, and Teaching Hospitals and Academic Medical Centers Practice Groups

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In recent years, several courts have addressed the question of whether the Physician Self-Referral Law (Stark Law)[1] applies to providers in the Medicaid context. In holdings that five years ago may have seemed unthinkable to most health care practitioners, these courts have unanimously held that it does, through application of the False Claims Act (FCA).[2] While most of the earlier decisions arose in cases in which the defense argument had not been extensively briefed, the most recent decision was issued after significant briefing of the issue by the defendants, relator, and the United States. The Stark Law provisions that expressly govern providers apply only to Medicare, and prior to these recent decisions, Stark Law experts—including government representatives—generally took the approach, in advice and in public presentations, that the Stark Law in practice also applied only to Medicare. However, because of these recent cases, providers and their counselors now need to take note that the United States, through the U.S. Department of Justice (DOJ), has adopted a dramatically different position by using the FCA to enforce the Stark Law. This Member Briefing reviews the relevant history of the Stark Law and related Medicaid provisions and then turns to the legal arguments and analyses presented on motions to dismiss in two recent district court decisions under the FCA, *United States ex rel. Parikh v. Citizens Medical Ctr.* and *United States ex rel. Schubert v. All Children's Health Sys.*

Intersection Between Stark Law and Medicaid

The Stark Law, as initially enacted in 1989, focused solely on Medicare claims and was codified in the Medicare chapter (Chapter XVIII) of the Social Security Act (SSA or Act) at § 1877.[3] The plain language of this provision initially prohibited physicians from referring Medicare patients for clinical laboratory services to any entity with which the physician (or an immediate family member of the physician) had a financial relationship, unless an exception to the prohibition applied. The statute also prohibited such a clinical laboratory from presenting or causing to be presented a bill or claim for designated

[1] Social Security Act (SSA) § 1877; 42 U.S.C. § 1395nn.
[2] 31 U.S.C. § 3729 *et seq.*
[3] SSA § 1877; 42 U.S.C. § 1395nn.

health services (DHS) relating to a prohibited referral, and provided that Medicare shall not pay for such claims.

In 1993, Congress enacted the Omnibus Budget Reconciliation Act of 1993 (OBRA), which extended application of the statute's prohibitions beyond the context of clinical laboratories to ten specifically DHS.[4] In addition, OBRA added new language at Subsection (s) of Section 1903 of the SSA.[5] Section 1903, located in the Medicaid chapter of the SSA and entitled "Payment to States," details the various elements for the Centers for Medicare & Medicaid Services (CMS) to consider in determining the appropriate payment to each state Medicaid program. As such, the statute directly imposes requirements only on the state Medicaid programs. Subsection (s) specifically:

> 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 [SSA], 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.[6]

The OBRA provision also expanded the Stark Law's reporting requirements under SSA § 1877(f) to apply to Medicaid providers as well as Medicare providers.[7]

Notably, Section 1903 governs payments to state Medicaid programs by CMS (or at the time of enactment, CMS' predecessor, the Health Care Financing Administration (hereinafter, referred to collectively as CMS)). Section 1903 does not prohibit the submission of such claims to CMS by the state programs (unlike Section 1877, which prohibits DHS entities from submitting certain claims). Section 1903 also does not

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[4]The Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66 (Aug. 10, 1993).
[5] 42 U.S.C. § 1396b.
[6] 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).
[7] The Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13624 (Aug. 10, 1993).

prohibit any conduct by physicians or providers, although it does extend the reporting requirements set forth in Section 1877(f) to Medicaid.[8] As discussed below, those reporting requirements were put on hold by CMS, which even today has not developed any final regulations implementing this Medicaid provision. Section 1903 notably does *not* prohibit providers from submitting claims to Medicaid arising out of financial relationships prohibited under Section 1877. Congress could have added "and Medicaid" to the language in Section 1877 that prohibits the submission of claims to Medicare, or even changed the reference to Medicare to include all federal health care programs, as it did with the Federal Anti-Kickback Statute (AKS),[9] but it did not. Section 1903 also does not prohibit state Medicaid programs from submitting claims to CMS for the FFP of such items or services; it simply "restricts" FFP payments for those claims.

CMS Regulatory Actions

To date, CMS has issued several sets of regulations to implement the Stark Law, including the Stark I regulations and Stark II Phases I, II, and III regulations.[10] With respect to Section 1903, CMS only has released limited proposed regulations, which never have been finalized. As a result: (1) no regulations prohibit physicians with prohibited financial relationships with DHS entities from referring patients to those entities for Medicaid services; (2) no regulations prohibit the DHS entities from billing Medicaid for those services; and (3) no regulations require providers to disclose information about those relationships to state Medicaid programs (or even to CMS or

[8] The Stark Law requires Medicare providers to "provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements" "in such form, manner, and at such times as the Secretary shall specify." 42 U.S.C. §1395nn(f). Providers who fail to report such information as required are subject to a civil monetary penalty. 42 U.S.C. §1395(g)(5). The Medicaid payment provision incorporates these reporting provisions by reference, providing that "subsections (f) and (g)(5) of [§1395nn] shall apply to a provider of such a designated health service for which payment may be made under [Medicaid] in the same manner as such subsections apply to a provider of such a service for which payment may be made under [Medicare]." 42 U.S.C. §1396b(s).

[9] 42 U.S.C. § 1320a-7b(b).

[10] As discussed above, 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 DHS, after which the law became known as "Stark II." The first final regulations for Stark I were issued after enactment of Stark II, and the bulk of the Stark II regulations were issued in three significant groupings, commonly referenced as Phases I, II, and III.

the U.S. Department of Health and Human Services Office of Inspector General (OIG) unless specifically requested).

In its 1998 Stark II Phase I proposed rules, CMS initially proposed some concrete guidance regarding the extension of the Stark Law to Medicaid, particularly in expanding certain definitions. For example, the proposed regulation would have expanded the definition of “referral” to include not only Medicare, as written, but also “a comparable service covered under the Medicaid State plan.”[11] The proposed regulation also would have added a new exception in the Medicaid regulations for services furnished to enrollees of Medicaid managed care plans.[12] In addition, CMS proposed that individuals who qualify as “physicians” under Medicare would be considered physicians for purposes of Section 1903 as well, even though Medicaid otherwise applies a much narrower definition of “physician,” limited to doctors of medicine and osteopathy.[13] CMS added that Section 1903(s) would apply to referrals by all physicians, whether or not they participate in the Medicaid program.[14]

At the same time, CMS struggled to draft regulatory language that would implement Section 1903’s application of the FFP reimbursement restriction to claims for services for which Medicare would deny payment “if Medicare covered the service to the same extent and under the same conditions as under a State’s Medicaid plan.” In its preamble, CMS noted 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.”[15] CMS concluded that Congress was aware of these differences and that the statutory language was intended to provide CMS “some flexibility” in applying the Stark Law’s prohibitions in the Medicaid context.[16]

[11] 63 Fed. Reg. 1659, 1722-23 (Jan. 9, 1998).
[12] *Id.* at 1697, 1727.
[13] *Id.* at 1704.
[14] *Id.* 1704.
[15] *Id.* at 1673.
[16] *Id.*

Determined to exercise this flexibility, 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 was the same under both Medicare and Medicaid.[17] In contrast, when a state plan's definition of a DHS differed from Medicare's definition, CMS "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."[18] CMS would not include Medicaid services as DHS when doing so would "appear [ ] to run counter to the underlying purpose of the legislation."[19] Since the states administer the Medicaid programs, 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."[20]

With regard to Section 1903's extension of reporting requirements to Medicaid DHS providers, CMS proposed requiring providers to report the required information to the states rather than to CMS.[21] For its rationale, CMS explained that "it is the States that are at risk of losing FFP" and thus the states themselves "must determine whether a physician has a financial relationship with an entity that would prohibit referrals under Medicare."[22] The proposed approach "will allow States to protect themselves and to avoid any duplication of effort with [CMS]."[23] CMS, therefore, proposed a separate regulation, which would have been added to the Medicaid program integrity regulations as 42 C.F.R. §455.109, that would mandate states to require providers to disclose information regarding their financial relationships using the form to be prescribed by the state agencies and within the time periods specified by the state agencies.[24]

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[17] *Id.*
[18] *Id.*
[19] *Id.* at 1673-74.
[20] *Id.* at 1674.
[21] *Id.* at 1705, 1727-28.
[22] *Id* at 1727-28.
[23] *Id.*
[24] *Id.*

In this context, CMS noted that the Stark Law itself: (1) prohibits a physician from referring patients' services to a DHS entity with which the physician has a prohibited financial relationship for Medicare-reimbursable services; (2) prohibits the DHS entity from billing Medicare for items and services so referred; and (3) imposes sanctions on both the physician and the entity for violating any of those prohibitions. CMS then pointed out, however, that:

> [W]e do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services. The first part of section 1903(s) . . . imposes a requirement on the Secretary to review a Medicaid claim, as if it were under Medicare, and deny FFP if a referral would result in the denial of payment under Medicare. Section 1903(s) does not, for the most part, make the provisions in section 1877 that govern the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. *As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services.* A State may pay for these services, but cannot receive FFP for them. However, States are free to establish their own sanctions for situations in which physicians refer to related entities.[25]

Note that in CMS' analysis of what Section 1903(s) does and does not prohibit, CMS did not indicate that the state Medicaid programs are prohibited from submitting claims for the FFP portion of the claims at issue. On the contrary, CMS specifically states simply that the law "imposes a requirement on the Secretary to review a Medicaid claim" and deny it if required.

When CMS issued its Phase I interim final regulations in 2001, however, it did not include any provisions implementing Section 1903. CMS stated instead that "Phase II of this rulemaking will address section 1903(s) of the Act, which extends aspects of the

[25] *Id.* at 1704 (emphasis added).

referral prohibition to the Medicaid Program."[26] But when it issued Phase II in 2005, CMS again did not include any provisions implementing Section 1903:

> We had intended to address in this Phase II rulemaking section 1903(s) of the Act, which applies section 1877 of the Act to referrals for Medicaid covered services and which we interpreted in the proposed rule at § 435.1012 and § 455.109. However, in the interest of expediting publication of these rules, we are reserving the Medicaid issue for a future rulemaking with one exception. In this rulemaking, we are amending the prepaid plans exception at § 411.35[5](c) to cover Medicaid managed care plans.[27]

CMS explained later in the preamble that despite deciding to:

> defer[ ] final regulations for section 1903(s) of the Act, given the prevalence of managed care in the Medicaid program, we believe it would be useful and appropriate to expand the prepaid plans exception at § 411.355(c) to include referrals of enrollees in Medicaid managed care plans analogous to the Medicare plans previously included in the exception.[28]

To date, CMS has issued no further proposed or final regulations implementing Section 1903, nor has it offered any other guidance on that statute's applicability. 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, and they generally have advised their clients accordingly, at least until very recently. In light of CMS' own statement that physicians and DHS entities "are not precluded from referring

[26] 66 Fed. Reg. 856 (Jan. 4, 2001).
[27] 69 Fed. Reg. 16054, 16055 (Mar. 26, 2004).
[28] *Id.* at 16061.

Medicaid patients or from billing for designated health services,"[29] this seemed a well-grounded and reasonable approach.

Reporting Requirements

Section 1877(f) requires Medicare providers to report data to the Secretary of the U.S. Department of Health and Human Services (Secretary) regarding the items and services they provide and their financial relationships with physicians. The statute leaves to the Secretary the decision concerning the "form, manner, and . . . time" in which such data shall be required.

In interim final rules published in December 1991, CMS indicated that it would waive the reporting requirement for all providers except clinical laboratories for all but ten states; and within those ten states, CMS would waive the requirement for all providers except hospitals, End-Stage Renal Disease (ESRD) facilities, suppliers of ambulance services, diagnostic imaging providers, and physical therapy providers.[30] CMS then issued questionnaires requesting this data from the providers for whom it had not waived the requirement, to the extent they had submitted Medicare claims for more than 20 items or services in those categories in calendar year 1990.[31] CMS also required clinical laboratory entities to report similar information as part of a survey conducted in the fall of 1991.[32]

Having collected the required information through the questionnaire and survey, and having reported on it to Congress, CMS put on hold gathering any additional data in 1995 when it issued its final Phase I rule with comment period. CMS expressly stated at that time: "[P]roviders will not be held to the reporting requirements under section 1877(f) until we develop and issue the proper form and accompanying instructions

[29] 63 Fed. Reg. 1704.
[30] 60 Fed. Reg. 41914, 41922, 41972-74 (Aug. 14, 1995), *citing* 56 Fed. Reg. 61374 (Dec. 3, 1991). The waiver authority was contained in the then-current version of §1877(f); it has since been deleted.
[31] 60 Fed. Reg. at 41973.
[32] *Id.* at 41922.

booklet. Until that time, we will use audits and investigations as the primary tools to evaluate compliance with those provisions."[33]

In 1998, CMS proposed requiring providers to submit data annually to CMS and to the states.[34] As discussed above, CMS proposed, in connection with implementing Section 1903's reporting requirement, that the states be required to develop their own reporting requirements. CMS made clear, however, that: "At this time we are still developing a procedure for implementing the reporting requirements and plan to notify affected parties about the procedure at a later date. Until that time, physicians and entities are not required to report to us."[35]

The reporting requirements that CMS proposed in 1998 drew criticism for being overly burdensome, so in Phase II, CMS decided to require that providers retain the information but report it only upon request by CMS and OIG. In doing so, CMS noted in its Phase II preamble:

> We . . . decided that periodic reporting [as initially proposed] would not be particularly helpful to the agency. CMS and its contractors would be overwhelmed by the number of reports and financial relationships that would need to be analyzed. We decided that we would make better use of our available resources if we collected information on financial relationships in a more focused manner (such as during a fraud investigation of a particular provider or group of providers).[36]

And, consistent with CMS' prior decision to delay issuing regulations implementing Section 1903, the new language of the final regulation at 42 C.F.R. § 411.361 imposes reporting requirements only to "all entities furnishing services for which payment may be

[33] *Id.* at 41975.
[34] 63 Fed. Reg. at 1703-05.
[35] *Id.* at 1703.
[36] 69 Fed. Reg. 16054, 16125 (Mar. 26, 2004).

made under Medicare."[37] The proposed regulation that would have required the states to require providers to disclose the information, whether on a regular schedule or otherwise, never was finalized. As a result, although Congress extended reporting requirements to Medicaid providers through Section 1903, and CMS initially wanted to ensure that the state Medicaid agencies received this information directly so they could use it to inform their decisions regarding whether to submit the claims to CMS for FFP, by declining to finalize regulations that would apply to Medicaid providers and by making the information as it relates to Medicare available only upon request (after putting on hold providers' obligation to submit any information in 1992), CMS undercut any ability whatsoever on the states' part to determine which claims may not be eligible for FFP. And since the provider community and the health care bar generally took away the understanding that until CMS or a specific state took action to regulate what information needed to be reported, by whom, and when, the general understanding until recently has been that the Medicaid reporting provisions remained suspended, along with any other extension of the Stark Law to Medicaid.

Note also that nothing in the federal statute permits the state Medicaid agencies to deny payments to the DHS providers on the basis of the providers' financial relationships with physicians, even if that information were available to the Medicaid agencies. Nor did CMS at any time propose including such prohibitions in their regulations. States would need to enact their own laws to accomplish that (and presumably could do so even in the absence of any regulatory action by CMS).

To summarize, under the current Stark Law statutory and regulatory scheme as it applies to *Medicare*: (1) physicians with a prohibited financial relationship with a DHS entity may not refer to that entity for Medicare-eligible DHS; (2) that entity may not bill Medicare for services arising from such a referral; (3) Medicare may not pay for services out of such a referral; and (4) DHS entities need not report information regarding their financial relationships with physicians unless specifically requested by CMS or OIG. As the language applies to *Medicaid*, however: (1) physicians with a prohibited financial

[37] *Id.* at 16142; 42 C.F.R. § 411.361(a). Note that the same regulatory language was reissued in Phase III due to Paperwork Reduction Act concerns. *See* 72 Fed. Reg. 51012, 51053, and 51098 (Sept. 5, 2007).

relationship with a DHS entity may refer patients to that entity for Medicaid-eligible DHS; (2) the entity may bill Medicaid for services arising from that referral; (3) the state may pay the claims for services arising from such a referral (and arguably must pay such claims in the absence of a state law to the contrary); and (4) the state may submit the claim to CMS, but the Secretary shall review the claim and deny it based on the physician's financial relationship with the DHS entity, if Medicare "provided for coverage of such service to the same extent and under the same terms and conditions as" Medicaid. The only prohibition in the Medicaid context, under the statutory language, is against CMS paying the state Medicaid program for the resulting claims. And, while Congress enacted language in Section 1903(s) requiring providers to disclose financial relationships to CMS, CMS effectively (even if without authority) suspended that requirement by requiring the information only on an as-requested basis for Medicare (and even there only after finalizing the applicable regulations), by proposing that such information be provided to the states on terms to be specified by the states, and then by declining to finalize that approach.

Applying Medicaid to the Stark Law via the FCA

In recent FCA cases, however, DOJ has adopted the position that despite these regulatory false starts, despite the lack of guidance with regard to the reporting of financial relationships with Medicaid providers, despite the lack of CMS' enforcement of any reporting requirements, and despite Section 1877's prohibitions applying only to Medicare providers, DHS entities violate the FCA when they engage in financial relationships with physicians and then submit claims to state Medicaid programs without alerting the state programs to the existence of those financial relationships. An article published in *AHLA Connections* in May 2013, "*The Intersection of the Stark Law and Medicaid Claims: Catching Providers in a Legal Quagmire*," discussed two early decisions in which the courts found in favor of DOJ's position. In the context of motions to dismiss in two more-recent declined qui tam cases, two additional district courts considered whether a hospital's submission of Medicaid claims for patients referred by physicians with prohibited financial relationships with the hospital constituted FCA

violations. In both cases, which involved more-extensive briefing on the topic than did the prior cases, the district courts held that they could.

United States ex rel. Parikh v. Citizens Med. Ctr.

In the first case, *United States ex rel. Parikh v. Citizens Med. Ctr.*, three cardiologists who previously practiced at Citizens Medical Center (CMC), the county-owned hospital at issue, alleged that CMC and two key employees provided various physicians, including cardiologists, hospitalists, and emergency room (ER) physicians, with "additional compensation or other benefits in exchange for referring patients to the hospital."[38] The cardiologists alleged that these financial relationships with the physicians were prohibited under the Stark Law (as well as the AKS), and thus the claims that CMC submitted to both Medicare and Medicaid violated the FCA.

The hospital in *Parikh* argued in its motion to dismiss that the Stark Law-based FCA claims should be dismissed, among other reasons, because "the Stark Law . . . does not apply directly to providers like CMC for purposes of the Medicaid program." Citing language from CMS' preamble to its 1998 proposed rules, quoted above, CMC also asserted that "CMS (the agency responsible for implementing the Stark Law), has expressly stated that this provision does not apply to physicians and hospitals for purposes of Medicaid."[39]

DOJ filed a Statement of Interest brief arguing, inter alia, that contrary to the defendants' assertion, "the Stark statute applies to Medicaid claims."[40] Based on the intersection of SSA Sections 1877 and 1903 and the FCA's prohibitions against causing another person to submit a false claim, DOJ asserted:

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[38] 977 F. Supp. 2d 654, 661 (S.D. Tex. 2013).

[39] *United States ex rel. Parikh v. Citizens Med. Ctr.,* Defendant Citizens Medical Center's Motion to Dismiss Relators' Third Amended Qui Tam Complaint, Dkt. 53, Civil Action No. V-10-64, at pp. 34-35 (filed June 28, 2013).

[40] *Parikh*, United States' Statement of Interest in Response to Defendants' Motions to Dismiss, Dkt. 65, Civil Action No. V-10-64, at p. 8 (June 28, 2013).

> If a Medicaid provider knowingly or recklessly submits to a state Medicaid program claims for services that are prohibited by [Section 1903(s)] without disclosing the potential Stark issue, then that provider may be held liable under the FCA for causing the state Medicaid program to submit false claims for payment to the federal government.[41]

DOJ also cited four prior cases to support the proposition that other courts found "that the Stark Statute applies to Medicaid claims."[42]

CMC's arguments did not persuade the court. The court interpreted Section 1903's prohibition against states receiving federal reimbursement as expanding the Stark Law "to apply to Medicaid claims."[43] The court even went beyond DOJ's argument that a provider defendant could be alleged to have caused the state to submit a false claim and seemed to hold that the hospital theoretically could be liable even for submitting a false claim. In the court's view:

> the only difference between holding a defendant liable for Stark-predicated FCA violations based on Medicare claims and those based on Medicaid claims is that the former are submitted to the federal government directly, while the latter are submitted to the states, which in turn receive federal funding to help pay the claims. . . . [I]t does not matter, for purposes of the FCA, whether a claim is submitted to an intermediary or directly to the United States.[44]

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[41] *Id.* at pp. 8-9.

[42] The four included *United States ex rel. Baklid-Kunz v. Halifax Med. Ctr.*, 2012 WL 921147 (M.D. Fla. Mar. 29, 2012) and *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264 (S.D. Fla. July 12, 2012). DOJ also relied for support on a case in which a federal court in Florida considered and rejected dialysis providers' arguments that the Florida self-referral law was preempted by the federal Stark Law. *Fresenius Medi. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 937 (11th Cir. 2013). And finally, DOJ cited to a case in which DOJ alleged FCA liability based on AKS violations affecting both Medicare and Medicaid claims but Stark violations only as to Medicare. While the court's discussion of claims that could constitute damages included both Medicare and Medicaid claims, its analysis of the applicability of the Stark Law was limited specifically to Medicare, while its analysis of the AKS explicitly included both Medicare and Medicaid. *See United States v. Rogan*, 459 F. Supp. 2d 692, 712-14, 717 (N.D. Ill. 2006).

[43] 977 F. Supp. 2d 654, at 666.

[44] *Id.*

Under this approach, the initial claim allegedly was false because federal dollars constituted a portion of the state Medicaid program's payment, both under the FCA's definition of "claim" and prior case law. In reaching this conclusion, the court looked to the definition of "claim" under the FCA, including requests for payments submitted "to a contractor, grantee, or other recipient, if the money . . . is to be spent or used . . . to advance a Government program or interest."[45] The *Parikh* court also looked to language from a decision in *United States v. Rogan* where the court stated that "Medicaid claims submitted to a state are also 'claims' to the federal government under the FCA."[46] In addition to holding that the alleged submissions to the Medicaid program can be false under the FCA, though, the court echoed DOJ's proposed theory of liability, i.e., that the hospital "could still be liable for causing Texas to submit a claim in violation of Stark."[47]

United States ex rel. Schubert v. All Children's Health Sys.

The *Parikh* court's decision, in turn, was relied on by a federal court in the Middle District of Florida in a more recently decided case, in which the question of whether Medicaid claims could be false under the application of the Stark Law and Section 1903 received extensive briefing. In *United States ex rel. Schubert v. All Children's Health Sys.*, a former employee of Pediatric Physician Services Inc. (PPS), the physician management company affiliate of a health system and its pediatric hospital, alleged FCA violations arising from the overpayment of employed physicians by the system and its affiliates.[48] The relator, who while employed was responsible for "on-boarding" new physicians, specifically alleged that the hospital improperly overpaid members of the ER and pediatric hematology/oncology practices that it purchased, as well as overpaying pediatric general surgeons, a pediatric plastic surgeon, and pediatric cardiologists who

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[45] *Id.*, *citing* 31 U.S.C. § 3729(b)(2).
[46] 459 F. Supp. 2d at 717 (citation omitted).
[47] *Id.*
[48] *United States and State of Fla. ex rel. Schubert v. All Children's Health Sys., Inc.*, Third Amended *Qui Tam* Compl., Dkt. No. 45, Case 8:11-cv-01687-JDW-EAJ (April, 29, 2013).

were hired.[49] In addition, the relator alleged that a pediatric plastic surgeon's employment agreement created a "volume-based incentive for the *base* salary," while the employment agreements with pediatric neurosurgeons contained a volume-based bonus provision.[50]

Count I of the Third Amended Complaint (TAC) alleges FCA violations with a broad brush, at times blurring the line between whether the defendants are alleged to have submitted claims that were false or simply to have caused Florida Medicaid to submit false claims. The relator alleges that "all claims submitted by the Defendants to Medicaid for designated health services rendered as a result of referrals by the following physicians . . . are false claims as a result of the excessive compensation and remuneration paid to the physicians in violation of the Stark Statute."[51] Similarly, in Count III, the relator alleges that volume-based incentive bonuses offered to a group of neurosurgeons rendered false "all claims submitted by the Defendants to Medicaid for services rendered as a result of referrals by [those physicians]."[52] In the next paragraph following each allegation of submitting false claims, however, the relator asserts that "because of the [FFP] program, Defendants knew that submitting a claim to [Florida's Medicaid program] would, in turn, cause the State of Florida to submit a claim for reimbursement to the federal government"—an argument consistent with that taken by relators in a few other cases preceding *Parikh*.[53] Thus, the TAC is ambiguous as to whether the relator's FCA theory was that by submitting the Medicaid claims, the defendants were causing the Florida Medicaid program to subsequently submit false claims to the federal government (similar to the theory DOJ advocated in its Statement of Interest in *Parikh*), or that the defendants also were submitting claims that were false themselves (similar to the court's approach in *Parikh*).

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[49] *Id.* at 9-22.
[50] *Id.* at 17, 21 (emphasis in original).
[51] *United States and State of Fl. ex rel. Schubert v. All Children's Health Sys., Inc.,*, 2013 U.S. Dist. LEXIS 163075, at *27.
[52] *Id.* at *31.
[53] *Id.*; s*ee United States ex rel. Baklid-Kunz v. Halifax Med. Ctr*., 2012 WL 921147, at pp. 1, 3 (M.D. Fla. Mar. 29, 2012) and *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, at p. 1 (S.D. Fla July 12, 2012).

Rule 9(b) Argument

In their Motion to Dismiss, the defendants attacked, on a number of legal bases, the relator's premise that the Medicaid claims could have violated the Stark Law and thus the FCA. First, the defendants characterized the relator's theory as being "not . . . that Defendants submitted false claims directly to the federal government; instead she asserts that Defendants caused Florida to submit false claims to the United States for FFP payments."[54] Thus, the defendants argued under Fed. R. Civ. P. 9(b) that the relator was required but failed to "identify alleged false claims that *Florida* submitted to the federal government."[55]

DOJ took no position on the defendants' argument. The relator, however, argued that the specific claims data she provided exceeded what the U.S. Court of Appeals for the Eleventh Circuit required, particularly in a Stark case, and particularly given her position as "a corporate insider with personal knowledge as to the fraudulent conduct."[56]

The court rejected the defendants' argument on several bases. First, the court held that by identifying 30 allegedly false claims submitted to Florida by the defendants and alleging that Florida Medicaid passed these on to CMS, under Eleventh Circuit precedent, "Relator adequately alleges that Defendants *caused* the presentment of specific false claims to the United States with the particularity required under Rule 9(b)."[57] In addition to the identification of 30 specific claims, the court was persuaded of the sufficiency of the pleadings because the relator otherwise "alleged sufficient indicia of reliability" by alleging her involvement in conversations and processes within PPS involving the physician contracts at issue.[58] The court thus also indirectly adopted the defendants' characterization of the relator's theory of liability.

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[54] *Schubert*, Defendants' Motion to Dismiss Third Amended Complaint, Case No. 8:11-cv-1687-T-27-EAJ, Dkt. 58 (July 26, 2013), at 6.
[55] *Id.* at 7 (emphasis in original).
[56] *Schubert*, Relator's Memo. In Opp. T Defs' Motion to Dismiss Third Amended Complaint, Case No. 8:11-cv-1687-T-27-EAJ, Dkt.60 (Aug. 12, 2013), at 11.
[57] 2013 U.S. Dist. LEXIS 163075, at *30.
[58] *Id.* at *31.

Rule 12(b)(6) Arguments

The defendants also asserted several arguments against their alleged liability on Fed. R. Civ. P. 12(b)(6) grounds, asserting that all the counts were based on erroneous interpretations of the law and regulations. First, the defendants asserted that they did not falsely certify compliance with the Stark Law because that statute "regulates only the referral of Medicare patients (and does not regulate referral of Medicaid patients)."[59] Quoting from *Federal Register* language referenced above and cited by the *Parikh* defendants, they noted that in 1998, CMS even noted that the Stark Law's prohibitions do not apply to Medicaid and that providers are "not precluded from referring Medicaid patients or from billing for designated health services."[60]

The United States, in its Statement of Interest brief filed three weeks after and patterned closely on its *Parikh* brief, did not address head on the defendants' point that because the Stark Law, to which they were alleged to have certified compliance, does not itself apply to Medicaid claims, the only claims the defendants were alleged to have submitted, their certification of compliance with the statute, could not have been false. Instead, DOJ simply asserted that regardless of any non-binding language in the *Federal Register*, Section 1903 "extend[ed] the provisions of the Stark Statute to Medicaid claims."[61] Reiterating its argument from *Parikh*, DOJ stated:

> If a Medicaid provider knowingly or recklessly submits to a state Medicaid program claims for services that are prohibited by [Section 1903(s)] without disclosing the potential Stark issue, then that provider may be held liable under the FCA for causing the state Medicaid program to submit false claims for payment to the federal government.[62]

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[59] *Schubert*, Defs. MTD at 11.
[60] *Id.* at 12, citing 63 Fed. Reg. 1659, 1704 (Jan. 9, 1998).
[61] *Schubert,* U.S. Statement of Interest Brief, Case No. 8:11-cv-1687-T-27-EAJ, Dkt. 59 (July 26, 2013), at 2.
[62] *Id.* at 3.

The court adopted DOJ's reasoning, holding that "[t]he substantive prohibitions contained in the Stark Amendment are therefore applicable to claims submitted to Medicaid through § 1396b(s), and Relator has adequately alleged [FCA] violations."[63] For support of its position, the court cited the prior FCA cases that DOJ had cited in its briefs, as well as a non-FCA case, *Fresenius Med. Care Holdings, Inc. v. Tucker*,[64] in which a federal court in Florida considered and rejected dialysis providers' arguments that the Stark Law preempted the Florida self-referral law.

Second, the defendants argued that the state claims to CMS could not be false because, under CMS regulations, Florida Medicaid was entitled to FFP regardless of any Stark-related issue. The defendants relied on the language at 42 C.F.R. § 435.1002(a), which states that, "[e]xcept for the limitations and conditions specified in [other regulatory provisions], FFP is available in expenditures for Medicaid services for all beneficiaries whose coverage is required or allowed under this part [42 C.F.R. Part 435, concerning Medicaid]."[65] The defendants noted that the 1998 proposed regulations would have added a new provision to implement Section 1903 that "would have parroted the statutory language."[66] Because the existing regulation was not revised to implement the language of Section 1903, the defendants concluded, "Florida was entitled to the FFP payments under CMS's regulations."[67]

DOJ and the relator countered that the existing regulation and Section 1903 must be read in harmony and in fact are not inconsistent, and under such a harmonious reading, a state program is not eligible for reimbursement for claims prohibited under Section 1903.[68] They also argued that if the two provisions in fact conflicted, the statutory provision—Section 1903—would govern.[69] The court agreed with the relator and DOJ as to both points and rejected the defense argument.[70]

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[63] 2013 U.S. Dist. LEXIS 163075 at *14-15.
[64] 704 F.3d 935, 937 (11th Cir. 2013).
[65] *Schubert,* Defs. MTD at 14 (emphasis omitted).
[66] *Id.*, citing 63 Fed. Reg. at 1727.
[67] *Schubert,* Def. MTD at 14.
[68] *Schubert,* Rel. Opp. at 8; U.S. Statement of Interest at 6.
[69] *Schubert,* Rel. Opp.at 8; U.S. Statement of Interest at 6-7.
[70] 2013 U.S. Dist. LEXIS 163075, at *23.

Third, the defendants argued that Section 1903 was inapplicable to the circumstances of this case because Medicare and Florida Medicaid do not provide coverage under the same terms and conditions, as required by Section 1903 for the reimbursement prohibitions to apply.[71] The two programs provide coverage under different terms and conditions, they argued, because while only medically necessary services are reimbursable under both programs, the Medicare program defines "medical necessity" more broadly than the Florida Medicaid program, which restricts payment to those services for which there is no "equally effective and more conservative or less costly treatment" available within the state.[72]

The United States rejected the distinction between definitions of medical necessity as "irrelevant because the issue of medical necessity is immaterial in Stark cases."[73] The questions that should be asked when considering Section 1903, DOJ argued, are "whether Medicare covers the types of medical services at issue and whether the services at issue are properly characterized as 'designated health services' under both federal and state rules."[74] Note that DOJ did not actually answer either of those questions in its Statement of Interest, however.

The court agreed with DOJ and rejected the terms and conditions/ medical necessity argument in a perfunctory footnote, stating merely that the argument was "without merit based on the prior conclusion that the Stark Amendment is imputed to Medicaid through § 1396b(s)."[75] The court thus provided no guidance with regard to the meaning of the language requiring that the terms and conditions be similar.[76]

Fourth, the defendants argued that the relator's claims should be dismissed because she failed to allege materiality, i.e., that the United States would not have paid Florida

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[71] *Schubert* Defs. MTD at 15-17.
[72] *Id.* at 15 (citations omitted).
[73] *Schubert,* U.S. Statement of Interest at 7.
[74] *Id.* at 7-8.
[75] 2013 U.S. Dist. LEXIS 163075 at *22-23, note 10.
[76] Note that CMS struggled with this very issue when it tried to issue regulations. As described above, it seemed to interpret the statutory language to mean that payment mechanisms had to be similar, e.g., the service could not be part of a bundled payment in one program and separately reimbursable in the other. It is unclear how CMS' analysis reconciles with DOJ's language about the services being properly characterized as DHS under both sets of rules, and the court provides no guidance.

Medicaid the FFP for those claims if it had known the facts alleged by the relator.[77] In its Statement of Interest, DOJ asserted that the plain language of the statute providing that "no payment shall be made to a State" for such claims directly contradicts the defendants' argument.[78] DOJ also posited that:

> [t]he Defendants' suggestion that the United States never seeks to apply the Stark Statute to Medicaid claims overlooks *United States v. Rogan*, 459 F. Supp. 2d 692, 710-11 (N.D. Ill. 2006), *aff'd* 517 F.3d 449 (7th Cir. 2008), as [a] case in which the United States successfully did exactly that.[79]

The court rejected the defendants' arguments here, too, noting that the proper standard of materiality is whether the misrepresentation to the government has "the ability to influence the government's decision-making."[80] Since on its face Section 1903 prohibits payment for the types of claims at issue, the court held that the allegations were sufficient to allege materiality.[81]

Finally, the defendants argued that their Medicaid claims could not be "false" because the law and regulations that applied to the defendants' conduct were "exceptionally ambiguous," and FCA cases "cannot be predicated on the alleged violation of any ambiguous law or regulation that has not been subsequently clarified."[82] For its proposition that the regulatory framework is ambiguous, the defendants focused on CMS' failure to issue final regulations, combined with CMS' commentary in 1998 indicating that the law's rules and sanctions do not apply to physicians and providers in

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[77] *Schubert,* Defs. MTD at 17-18.
[78] *Schubert,* U.S. Statement of Interest at 8.
[79] As noted above, however, the *Rogan* case involved allegations of violations of both the AKS and the Stark Law. While the court's discussion of claims that could constitute damages included both Medicare and Medicaid claims, its analysis of the applicability of the Stark Law was limited to Medicare, while its analysis of the AKS explicitly included both Medicare and Medicaid. *See United States v. Rogan*, 459 F. Supp. 2d at 711-12.
[80] 2013 U.S. Dist. LEXIS 163075 at *23, quoting *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012).
[81] 2013 U.S. Dist. LEXIS 163075 at *24.
[82] *Schubert,* Defs. MTD at 18 (citations omitted).

the Medicaid context, so they "are not precluded from referring Medicaid patients or from billing for designated health services" under Medicaid.[83]

DOJ countered this argument on three bases. First, it stated simply that "there is nothing ambiguous about the fact that [Section 1903(s)] extends the application of the Stark Statute to Medicaid claims, and the case law on the subject has been clear and consistent."[84] Second, DOJ noted that when the statute itself is clear, any ambiguity in the regulations is irrelevant, and here, the relator was basing her FCA allegations "on alleged violation of two statutes—the Stark Statute and [Section 1903(s)]—that are clear on their face."[85] And third, DOJ asserted that under established case law, even if the provisions were ambiguous, such ambiguity is only "relevant to the extent that the Defendants acted based on a reasonable interpretation of the ambiguous requirement."[86] That, DOJ noted, would be a question for later in the litigation rather than the motion-to-dismiss stage.

The court concurred with the defendants' general proposition that claims cannot be knowingly false and thus trigger FCA liability where the defendant believes its submission of the claim to be consistent with "a reasonable interpretation of an ambiguous statute."[87] Nevertheless, the court noted that it otherwise already rejected the defendants' various arguments for ambiguity and that, in the court's view, "[t]here is substantial support for Relator's allegation that the Stark Amendment applies to Medicaid claims through § [1903(s)], and Relator adequately alleges that Defendants knowingly and falsely certified compliance with the Stark Amendment."[88] The court, therefore, declined to dismiss the relator's claims based on the ambiguity of the regulatory framework.

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[83] *Id.* at 19, *citing* 63 Fed. Reg. at 1704.
[84] *Schubert,* U.S. Statement of Interest at 8.
[85] *Id.* at 9.
[86] *Id.*, citing *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1357-58 (11th Cir. 2005).
[87] 2013 U.S. Dist. LEXIS 163075 at *25-26.
[88] *Id.* at *27.

Thus, despite the various arguments put forward by the defendants, the court adopted the relator's and DOJ's positions and refused to dismiss the relator's allegations that the Medicaid claims submitted by the defendants violated the FCA because their financial relationships with the referring physicians violated the Stark Law. It is possible, although the court does not expressly indicate this, that as a practical matter the court's receptiveness to the defendants' various arguments that the Stark Law was inapplicable was undercut by the relator's allegations in the TAC that in 2007 and again in 2009 the defendants' employees expressly referenced the importance of Stark Law compliance and made efforts to comply with it.[89]

Conclusion

Regardless of the reasoning, the district court's decision in *Schubert*, combined with the *Parikh* court's decision and prior decisions on which both courts relied, will increase the challenge future defendants will have in arguing successfully that their Medicaid claims cannot have been false under the Stark Law. Whether the decisions are correct, DOJ now has clearly adopted the position that Medicaid claims can be false under a combination of the FCA and the Stark Law, and the courts thus far have been receptive to that position. Providers should keep this in mind not only when preparing their investigation/litigation defense strategies, but also in their compliance programs.

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[89] *See Schubert,* TAC ¶ 19.
[90] *See "The Intersection of the Stark Law and Medicaid Claims: Catching Providers in a Legal Quagmire," AHLA Connections, May 2013.*

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